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Patient Privacy VS Autonomy of Patient's Family Members in Modern Genetic Diagnostics

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PATIENT PRIVACY VS. AUTONOMY OF PATIENT'S FAMILY MEMBERS IN MODERN GENETIC DIAGNOSTICS

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BARCELONA, 2021

ABSTRACT

A patient's medical record can contain information regarding the state of health of the patient's biological family, raising a question of whether patient privacy and patient's relatives' autonomy are compatible. This question has become particularly pressing in the last decades, with the incorporation of genetic technologies to medical practices. Conventionally, healthcare professionals are bound by their professional obligation to respect the confidentiality of patient's information and, unless there are extraordinary circumstances, cannot disclose health-related data to the patient's family. Such a limited access to information prevents blood relatives from receiving better medical care and making fully autonomous life choices. The open-access-family-history model, on the contrary, conceptualizes genetic privacy at the level of a group, providing safe and fair environment for all blood relatives to exercise their individual rights.

This research examines the historical approaches to regulating human rights in health care, focusing on the emergence of the right to privacy and the conditions that lead to a confrontation between a patient and his/her family. Additionally, the research presents a comparative analysis of the legislation on genetic information established in legal systems of Spain, Switzerland, the United Kingdom, and the United States. Both the historical approach and the comparative analysis reveal the issue of unbalanced protection of the rights resulting from the discrepancy between the paths science and the law have been following for a while. To fill this gap and to resolve this unnecessary conflict of rights, we propose a new definition of genetic information. This definition serves as the basis for the design of a two-tier system of electronic health records allowing each person unobstructed access to information about one's own health.

Based on our analyses and findings, we conclude that genetic privacy extends beyond the scope of individual right, and affects a wider range of individuals, that is, all biological relatives from a given genetic family. We recommend applying the open-access-family-history model to the relationships between patients, their families, and healthcare professionals treating them. This design is viable and better reflects the needs of all parties of concern. These theoretical suggestions can be gradually and smoothly implemented into healthcare systems, though we acknowledge that some details regarding its expanded application to other fields, such as clinical research, require further elaboration.

RESUMEN

El historial médico de un paciente puede contener información relativa al estado de salud de su familia biológica, lo cual plantea la cuestión de si la privacidad del paciente y la autonomía de sus familiares son compatibles. Esta cuestión se ha vuelto especialmente acuciante en las últimas décadas con la incorporación de las técnicas genéticas a las prácticas médicas. Lo habitual es que los profesionales sanitarios estén sujetos a la obligación profesional de respeto a la confidencialidad de la información del paciente. Salvo que existan circunstancias extraordinarias, no pueden revelar datos sobre la salud del paciente a su familia. Dicha limitación al acceso a la información impide que los parientes consanguíneos reciban una mejor atención médica y tomen decisiones vitales de forma completamente autónoma. En cambio, el modelo de historia clínica familiar de acceso abierto conceptualiza la privacidad genética a escala de grupo, ofreciendo un entorno seguro y justo a todos los parientes consanguíneos a fin de que puedan ejercer sus derechos individuales.

Esta investigación examina los enfoques históricos para la regulación de los derechos humanos en materia de atención sanitaria, poniendo el foco en la aparición del derecho a la privacidad y las condiciones que dan lugar a una confrontación entre el/la paciente y su familia. Adicionalmente, esta investigación presenta un análisis comparativo de la legislación en materia de información genética establecida en los ordenamientos jurídicos de España, Suiza, Reino Unido y Estados Unidos. Tanto el enfoque histórico como el análisis comparativo sacan a relucir el problema de una protección desequilibrada de los derechos, que resulta de la discrepancia entre los distintos caminos emprendidos por la ciencia y el derecho durante algún tiempo. A fin de salvar esta brecha y resolver este conflicto innecesario entre derechos, proponemos una nueva definición del término información genética. Esta definición sirve como base para el diseño de un sistema de dos niveles de los historiales médicos electrónicos, que permitiría a cualquier persona un acceso sin obstáculos a la información acerca de la propia salud.

Sobre la base de nuestros análisis y hallazgos, concluimos que la privacidad genética se extiende más allá del ámbito del derecho individual y afecta a un número mayor de individuos, a saber, todos los parientes biológicos de una familia genética determinada. Recomendamos aplicar el modelo de historia clínica familiar de acceso abierto a las relaciones entre pacientes, sus familias

y los profesionales sanitarios encargados de su tratamiento. Este diseño es viable y refleja mejor las necesidades de todas las partes implicadas. Estas recomendaciones teóricas pueden implementarse de forma gradual y armoniosa en los sistemas sanitarios, aunque reconocemos que algunos detalles relativos a su aplicación ampliada a otros campos, como la investigación clínica, requieren una mayor profundización.

RESUM

L'historial mèdic d'un pacient pot contenir informació relativa a l'estat de salut de la seva família biològica, la qual cosa planteja la qüestió de si la privacitat del pacient i l'autonomia dels seus familiars són compatibles. Aquesta qüestió s'ha tornat especialment urgent en les darreres dècades amb la incorporació de les tècniques genètiques a les pràctiques mèdiques. Habitualment, els professionals sanitaris estan subjectes a l'obligació professional de respecte a la confidencialitat de la informació del pacient. Llevat que existeixin circumstàncies extraordinàries, no poden revelar dades sobre la salut del pacient a la seva família. Aquesta limitació a l'accés a la informació impedeix que els parents consanguinis rebin una millor atenció mèdica i prenguin decisions vitals de forma totalment autònoma. En canvi, el model d'història clínica familiar d'accés obert conceptualitza la privacitat genètica a escala de grup i ofereix un entorn segur i just per a tots els parents consanguinis per tal que puguin exercir els seus drets individuals.

Aquesta investigació examina els enfocaments històrics per a la regulació dels drets humans en matèria d'atenció sanitària, posant el focus en l'aparició del dret a la privacitat i les condicions que donen lloc a una confrontació entre el/la pacient i la seva família. Addicionalment, aquesta investigació presenta una anàlisi comparativa de la legislació en matèria d'informació genètica establerta als ordenaments jurídics d'Espanya, Suïssa, Regne Unit i Estats Units. Tant l'enfocament històric com l'anàlisi comparativa posen sobre la taula el problema d'una protecció desequilibrada dels drets, que resulta de la discrepància entre els diferents camins que la ciència i el dret han emprès durant un temps. Per omplir aquest buit i resoldre aquest conflicte innecessari entre drets, proposem una nova definició del terme informació genètica. Aquesta definició serveix com a base per al disseny d'un sistema de dos nivells dels historials mèdics electrònics, que permetria a qualsevol persona un accés sense obstacles a la informació relativa a la pròpia salut.

Sobre la base de les nostres anàlisis i troballes, concloem que la privacitat genètica s'estén més enllà de l'àmbit del dret individual i afecta a un nombre major d'individus, és a dir, tots els parents biològics d'una família genètica determinada. Recomanem aplicar el model d'història clínica familiar d'accés obert a les relacions entre pacients, les seves famílies i els professionals sanitaris encarregats del seu tractament. Aquest disseny és viable i reflecteix millor les necessitats de totes les parts implicades. Aquestes recomanacions teòriques poden implementar-se de forma gradual i

harmoniosa en els sistemes sanitaris, malgrat que reconeixem que alguns detalls relatius a la seva aplicació ampliada a d'altres camps, com ara la investigació clínica, requereixen un major aprofundiment.

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INTRODUCTION

Health is an invaluable asset of every person, and one of the main guarantees and conditions for a fuller life. Therefore, improving the quality of life and life expectancy should be key priorities for society. A technological breakthrough in biomedicine has allowed us to come closer to this goal, offering more effective methods of disease prevention, diagnosis, treatment, and rehabilitation of patients. In this context, the integration of genetic technologies resulting from advancement of biological and medical sciences into medical practice plays a huge role. Today, the use of new treatments and tests based on genetic technologies has enabled healthcare professionals to identify diseases at an early stage and provide effective therapy, opening unprecedented opportunities in the fight against various diseases, bringing hope to address some of the greatest unmet needs in medicine that have gone unsolved task until recently. Genetic technologies are now allowing physicians and scientists to explore genetic information faster and more cost-effectively. What used to cost tens of thousands of euros is now available faster and for less than a thousand euros. For this reason, the use of genetic diagnostics permeated quickly to medical practice in different countries.

At the same time, despite the large number of benefits, any innovation is associated with certain ethical, social, economic, and legal problems. The main burden falls on the legal domain, which is responsible for adapting the existing standards and working out the missing ones, balancing regulation of innovation in such a way that, on the one hand, does not detract from the achievements of science, and on the other hand, does not allow infringement of the rights of the parties involved.

The implementation of genetic technologies has a great impact on the structure and content of relationships in the healthcare sector. This primarily concerns the relationship between physicians, patients, and the family of the latter. The history of the development of the concept of rights in health care, when the first attempts were made to guarantee certain rights to patients, goes centuries back even before recognition of medicine as a science. Today, the patient rights system is based on and inextricably linked with the concept of human rights, which has acquired its present form and content relatively recently. Historically, the right to privacy in general and the right to confidentiality of health-related information had a special place in the system of rights. However,

the use of genetic technology in medicine requires an immediate rethinking of the content and scope of these rights.

Genetic technologies produce or analyze genetic information, making it possible to investigate the family history of illnesses and health conditions and to explain the hereditary nature of their transmission. More and more diseases appear to have patterns of transmission among relatives. However, this information is usually beyond the access of the patient's family members and cannot be used for their benefit. This is due to several reasons, from practical and technical, such as the lack of a clear understanding and definition of genetic information, to fundamental ones, such as the conceptualization of privacy and the content of associated rights. This unilateral use of genetic technology not only limits its medical relevance but has also created a serious conflict of interest between the patient and the patient's family. Today's individualistic worldview has led to individuals considering themselves or being considered separate from society, including their own families, which is reflected in the legal status of the patient. By virtue of the fact that genetic privacy is considered an individual right, the protection of informational privacy of patients limits the autonomy of the patient's relatives, preventing the latter from accessing the information that directly relates to their health and is necessary for making vital decisions.

Despite some reservations, genetic information is generally treated like other medical information of interest only to a particular patient. In our opinion, this approach is fundamentally false. First, it contradicts medical practice itself, which has always considered family history to be one of the fundamental sources of extracting information about a patient for the diagnosis and treatment of a disease. Secondly, this approach also contradicts the essence of genetics, since it does not take into account the fact that blood relatives share a large percentage of genetic information that is passed down from generation to generation. Numerous legal cases have proven that modern legislation is left behind and is not able to effectively resolve this conflict of interest, ignited by the use of emerging genetic technologies. This is due to the fact that legislation is intended to regulate the circulation of medical information in the context of traditional medicine, when there was still no understanding of concepts such as genetics, genetic code, genetic information, heredity, etc., and how they relate to understanding the nature of diseases. Thus, the laws, for the most part, do not or do not sufficiently consider the characteristics of genetic information and the interests of others, that is, family members who share a significant portion of genetic information. This situation not

only exacerbates the conflict of interest between the patient and his/her family, but also puts the physician in a difficult position, making it impossible to follow ethical principles while performing professional duties.

On the one hand, there are the interests of the patient who has consulted a healthcare professional and expects that the very consultation as well as the content of his/her medical records will be kept secret. Often, people share their problems with family members, although sometimes, for various reasons, they prefer that relatives remain out of the loop. Even when patients are willing to warn other family members of a possible predisposition or illness, they are unlikely to have the necessary ability to convey complex medical information accurately. Moreover, they may be guided by their own judgments and ideas whether certain information should be disclosed to relatives depending on how they foresee such information to impact a particular family member. In this case, the patient's relatives are denied access to information about their own health, which is contained in the medical records of other relatives. As a result, this can affect both the level of treatment provided to them and the quality of decisions that relatives make regarding their health and future. Although legislation sometimes allows the physician to transcend the obligation of confidentiality in exceptional circumstances, such decisions do not balance the scales of this conflict between the interests of the patient and his/her family.

Thus, the main goal of this study is to find a way to resolve the existing conflict of interest, while ensuring the rights of each of the parties, as well as to develop practical recommendations to fill the gap in current regulation of genetic medicine and propose specific amendments to prevent the vulnerability of patients and their family members as technology progresses. Despite the fact that some scholars have previously made attempts to formulate the concept of genetic privacy, the topic has not been studied to a satisfactory level of academic elaboration, since there is still no full-fledged solution to this conflict of interest. Particular attention will be paid to the joint account model of genetic information, which is proposed by M. Parker and A. Lucassen. Their model differs significantly from the generally accepted view on genetic privacy, as it compares it to a bank account, to which a certain number of individuals have access. The joint account model is a revolutionary idea in the perception of informational privacy under modern circumstances of technological progress. We have taken some aspects of this theory as the basis for our solution, the so-called "open-access-family-history model".

To achieve our primary goal, we identify the following objectives in this research: to study the content and evolution of the right to privacy as part of the patient's legal status in selected jurisdictions; to describe the special nature of genetic information and identify the gaps in its legal protection; to reveal the essence of autonomy in the context of medical decision-making process and its limits; to define the content of potential new rights that should be guaranteed to patients and their relatives; to outline the boundaries of the professional responsibility of physicians and the mutual responsibility of relatives; and to substantiate the need to improve legislation affecting genetic technologies in medicine both at the international and national levels.

To resolve the conflict of interests in the context of modern genetic diagnostics, we will focus on the historical approaches to regulate privacy and autonomy and identify the prerequisites and the essence of the conflict from the point of view of the patient and the patient's family. This study is carried out based on a comparative analysis of emerging problems in regulation of genetic technologies regarding patient rights in legal systems of Spain, Switzerland, the United Kingdom, and the United States. These jurisdictions were chosen because they have some differences in legal systems, especially in the legal regulation of the healthcare sector, differences in insurance systems, but at the same time they have similar trends in the speed of development and use of genetic technologies, their role in the pharmaceutical and medical sectors.

The methodology employed in this study is a multidisciplinary approach, respecting the multifaceted nature of its main problem. This approach allows us to draw closer to the goal of overcoming the contradictions between the real organization and regulation of the healthcare system and the achievements of science. Our multidisciplinary approach deals with such conflict of interests from a legal, ethical, philosophical, and scientific points of view. In this research we rely on preceding works of scholars in the field of bioethics, data protection, criminal law, human rights, international law, theory and history of law, as well as of practicing lawyers, philosophers, and historians. We also turn to scientific articles and the results of scientific research in order to understand the roots of the main problem. Referring to the results of statistical studies and surveys conducted with the participation of healthcare professionals and patients, as well as relatives of the latter, allow us to assess the attitude to the problem directly from the point of view of the parties of the conflict being studied. The author's first-hand experience working in the pharmaceutical industry also provides insight into the magnitude of the problem even outside of healthcare.

Moreover, the research applies the methods of analogy and modeling. Therefore, we have divided the work into seven chapters, concentrating on different aspects of the main problem.

This approach requires us to delve deeper into history in order to trace the relationship between medical development and the formation of patient rights and draw conclusions about the current regulatory system. This is what the first chapter is about. Then, in the second chapter, the concept of privacy will be examined in light of the relationship with other values. Special attention will be paid to the components of the right to privacy, especially the right to confidentiality of medical information and the counter-obligations of the physician. The next chapter raises questions of privacy in the era of genetics and examines the nature of genetic information, its features and how it differs from other medical information. Analysis of the legislation reveals the absence of a unified definition of genetic information. Therefore, we propose our own definition that can be used for regulatory purposes.

In the fourth chapter, we will analyze the current conflict of interests, as well as the attempts by modern legislation to resolve it. In our opinion, the essence of this conflict lies much deeper, and it could have been avoided altogether by reconsidering the views on the concept of privacy. Therefore, in the fifth chapter a proposal will be forwarded to view privacy from the perspective of the group, namely the genetic group or genetic family, and not from the point of view of individual right and individual good. Thus, this part will examine privacy from the point of view of classification of economic goods. Having identified that privacy in general and genetic privacy in particular are very distinct from other individual goods and have a lot of similarities with public goods, a new concept of genetic privacy will be proposed, making clear the right to genetic privacy in its essence is very different from individual rights. Application of the concept of genetic privacy in health care would exclude any conflict of rights between family members regarding medical information. This chapter will also concentrate on balancing the right to genetic privacy with the individual autonomy of the patient and his/her family members. In this context, the right not to know and its limits will be studied as well.

Having established the existence of the right to genetic privacy, the sixth chapter will proceed with identifying the obligations associated with this kind of right, especially the obligation to inform at-risk relatives about the genetic health-related risks. We will pay special attention to intra-

familial obligations, analyzing moral and legal obligation among family members, including towards future generations. Further, in this chapter, we will envisage professional duty of healthcare professionals to inform the members of genetic family about their hereditary risks. Having analyzed the current solutions proposed by the law and legal practice, we will propose a new approach to provide family members with access to familial medical information as none of the existing approaches seem to guarantee their right to be informed. Thus, in the last chapter we will provide a disclosure system model, based on implementation of a unified electronic health records system. The advantages and possible objections of this model will be discussed in this part as well. This approach aims to solve the conflict of interests currently existing in the milieu of health care, facilitating the sharing of genetic information between the patients and their biological relatives, and also discerns the limits of physicians' liability.

1. OVERVIEW OF PATIENT RIGHTS

1.1. Historical perspective

1.1.1. Genesis of legal regulation of medical practice in Ancient East

One of the paramount achievements of modern health care is the creation and development of the concept of patient rights. Being aware and accepting the fact that the patient has well-defined rights play a huge role in the context of medical care, presenting a system of special opportunities for people who have the appropriate legal status and, therefore, have certain needs. Although this concept is already firmly established in modern societies, it is still relatively new. At the same time, some of the principles that later became fundamental to human rights have their roots in ancient times.

The first attempts to legislate the principles of professional responsibility in medicine and thereby anticipate ways to develop a system for patient protection were undertaken in Ancient East. The legislative process was associated with strengthening the power of their governors and was particularly active during the rise and heyday of the Ancient Eastern monarchies.[1] They assumed such noble duties as the protection of their people and maintenance of order and justice, the fulfillment of which was to be ensured by the socially important functions of the governors,[2] ultimately resulting in the drafting of codes. Thus, the first legal document mentioning the patient-physician relations was adopted in the XVIII Century B.C. by the King of Mesopotamia – Hammurabi. In this notable codification, known as the Code of Hammurabi, were systematized laws governing almost all domains of life and aimed to regulate human conduct. The code consisted of a total of 282 paragraphs, nine (§§ 215-223) of which were devoted to the services provided by physicians. Although the Code did not have special provisions on the legal status of the patient, it first formulated the principle of physician's liability, thereby guaranteeing people a certain standard of medical care.

[1] Zhidkov, O. A., & Krasheninnikova, N. A. (Eds.). (2004). *History of State and Law of Foreign Countries: Textbook for Universities: In 2 Parts. Part 1* (2nd ed.). Moscow: Norma [История государства и права зарубежных стран: Учебник для вузов: В 2 ч. Ч. 1 / Под общ. ред. д. ю. н., проф. О. А. Жидкова и д. ю. н., проф. Н. А. Крашенинниковой. – 2-е изд., стер. – М.: Норма, 2004.], p. 21.
[2] Cruveilhier, P. (1938). *Commentaire du Code d'Hammourabi*. Paris : Librairie Ernest Leroux, p. 5.

In the beginning, the physician's responsibility was absolute, excluding any mitigating circumstances by which a medical professional could explain away poor treatment outcome. Given the standard of medical practice at the time, operations threatened serious complications and forced physicians to resort to this type of treatment quite rarely, and even in those non-hazardous cases, when operations were nevertheless performed, there was a certain risk of an unfavorable outcome.[3] Depending on whether the treatment was successful, the patient died or was crippled by the physician, the Code established either the amount of fee paid or the type of punishment, respectively. The law specifically emphasized that the physician received payment for his work only if the patient was cured. Otherwise, he could not claim any reward.

Since Babylonian society was divided into classes and practiced slavery, the life and health of free people were assessed differently. The law of Ancient East openly promoted social inequality, primarily characterized by inequality of free people and by the depreciated position of slaves, who, regardless of the situation, were considered property in terms of law.[4] While the fees were differentiated according to the social classes, one of which the patient belonged to, the punishment depended only on whether the patient was free or enslaved. The Code provided penalties only for surgeons who performed operations. The physician who treated a free person was always punished for any adverse outcome by having his fingers severed, but if the patient was a slave and died as a result of treatment, the physician should then have taken the place of this slave, as a way to compensate the slave master.[5] Thus, the physician himself became the insurer of the services provided and was responsible in the case when he could not justify his credibility,[6] in a system which at least protected patients from charlatans and self-proclaimed healers. On the other hand, the fact that the Babylonian physicians carried out only those operations that they could, due to their level of complexity, means that they could also refuse to provide treatment to the patient, which hardly guaranteed the right of a patient to receive medical care.

Despite the fact that Ancient Egypt was rife with slavery and, therefore, had little to no ideas about the legal capacity and legal status of the individual, some attempts were still made to put medical affairs in order. Patients were exposed to public opinion, which meant that passersby who were

[3] *Ibid.*, p. 207.
[4] Zhidkov, O. A., & Krasheninnikova, N. A. (Eds.). (2004). *Op. cit.*, p. 21.
[5] The Code of Hammurabi, §§ 218-219, as cited in Cruveilhier, P. (1938). *Op. cit.*, p. 209.
[6] Sandor, A. A. (1951). Legal Duties of Physicians. *California Medicine*, *74*(5), 384–389, p. 385.

cured of the same disease gave advice to patients.[7] It was later decided that lists were to be made in temples, collecting the symptoms of diseases and methods of their treatment.[8] Physicians were required to comply with documents produced and approved by experienced colleagues, which, in essence, were a practical guide rather than a theoretical treatise, and to some extent were of regulatory in nature. To date, some Egyptian medical writings have been preserved, the most significant and well-known of which are the Ebers Papyrus, the Ramesseum Papyrus, and the Edwin Smith Papyrus.[9] If the physician complied with all contained prescriptions on how to treat certain symptoms, he did not bear any responsibility, regardless of the result.[10] However, if during treatment the physician did not follow these rigid requirements, thereby allowing the patient to die, then he was sentenced to death.[11] Any initiative not provided by scientific treatises was formally regarded a serious crime. Thus, the law was not in favor of experimentation with untested remedies and practices.

Ancient Egypt saw the change in the object of the obligations of a medical professional. The mode of responsibility depended on the nature of the actions of the physician without a guarantee of results, unlike in Babylonian legislation. However, in this case, this mode was more reminiscent of the absence of any responsibility and could hardly provide patients with an adequate level of care. This means that, as provisions on medical services and responsibility of physicians were less stringent than in Babylon, they were at the same time less progressive, which also affected the status of patients.

1.1.2. Antique ethics and law as sources of rights and obligations in medicine

The law of Ancient Greece, which initially resembled the legal systems of the countries of the Ancient East, gradually developed along with ancient society and, moving away from mysticism

[7] Py, B. (1993). *Recherches sur les justifications pénales de l'activité médicale* [Unpublished doctoral dissertation]. Université Nancy II, p. 13.
[8] Hu, E. (1880). *Étude historique et juridique sur la responsabilité du médecin, dans le droit romain, dans notre ancien droit, dans le droit actuel* [Doctoral dissertation, Faculté de droit de Paris]. Imprimerie et Lithographie de Cavaniol, pp. 1-2.
[9] Calvo Soriano, G. (2003). La medicina en el antiguo Egipto. *Paediatrica, 5*(1), 44–50, pp. 45-46.
[10] Glashev, A. A. (2004). *Medical Law: A Practical Guide for Lawyers and Medics*. Moscow: Wolters Kluwer [Глашев, А. А Медицинское право: Практическое руководство для юристов и медиков. — М.: Волтерс Клувер, 2004.], p. 2.
[11] Carrick, P. (1995). *Medical Ethics in Antiquity* (Philosophy and Medicine, vol. 18). Dordrecht: Springer Netherlands, p. 9.

and religion, appeared in its purest form as an authoritative and obligatory regulator of social life.[12] The established law was permeated by the principles of justice, but it emphasized social inequality because it was not accessible to slaves and foreigners. Although Ancient Greece had no special laws dedicated to the regulation of medical services and medicine was based on reason and logic, the statuses of free patients and physicians on one side and slaves on the other side still differed in practice due to the outcast position of the latter.

The profession of a physician was available to any person and did not require any special education or certification and training standards must have been very variable and inconsistent,[13] especially because this freedom of choice was not restricted anyhow. This profession was accessible not only to free people, but also to slaves, which did not affect the quality of services.[14] Even though the Greek physicians were immune from civil penalties if his patient died while under his care, this meant that he could treat his patient independently and to the best of his knowledge, according to his ability and judgment, but he could not murder his patient and expect to escape prosecution for homicide after charges were brought by relatives of the deceased.[15] It was recognized that the physician was morally obliged to the patient.

Science itself, as an entity, was born during this time and influenced the development of new ways of thinking. Philosophy was the source of all types of theoretical thinking, and all the main sciences, including medicine, were therefore inseparable from philosophy. The basic principles of Greek medicine were formulated by Hippocrates and his followers. Their views, instructions and prohibitions are set forth in *Corpus Hippocratum*, which consists of various individual books which originated approximately between 450 and 350 B.C. and represented the earliest medical writings. His famous oath, known as the Hippocratic Oath, became a turning point in the relationship between the physician and the patient, thereby remaining in the memory and on the lips of medical professionals for centuries. The Oath included both philosophical and practical

[12] Zhidkov, O. A., & Krasheninnikova, N. A. (Eds.). (2004). *Op. cit.*, p. 135.
[13] Cilliers, L. (2006). Medical Practice in Graeco-Roman Antiquity. *Curationis*, *29*(2), 34–40, pp. 5-6.
[14] Temkin, O. (1953). Greek Medicine as Science and Craft. *Isis: an international review devoted to the history of science and its cultural influences*, *44*(137), 213–225, p. 214.
[15] Carrick, P. (1995). *Op. cit.*, p. 9.

meaning, giving answers on practical issues, rather than simply being a declaration of abstract principles.

As for the relationship between the physician and the patient, according to Hippocrates, they must first of all be based on humanity and mercy. One characteristic of Hippocratic medicine was the idea of respect for a patient. The understanding that it was necessary to treat not just a disease, but a particular person with particular problems was fundamental and turned into the defining principle of medicine of that time. This individualistic approach presumed that the physician had to act always in the best interest of his patient, and his every action had to be directed to the benefit of the patient and in no way to the detriment. The principle *primum non nocere* has become one of the main precepts of medical ethics, all medical students have been learning it and still are. It has acquired a fundamental character in the provision of medical care throughout the world.

Any visit of a physician began with listening to the patient, and a physician's listening skills played a vital role because reaching a diagnosis depended largely on the patient's story about his/her health, since the underlying pathophysiology was completely unknown.[16] To make sure that the patient is outspoken and to get the most complete information out of the patient was only possible if the patient had complete trust in the physician. Relationships based on trust could only be built if the patient was assured that such intimate information about his/her body and health would not be available to others. In order to gain and, most importantly, maintain such confidence, the physician in turn needed to know how to encourage patient participation, by giving all necessary explanations, by following the principles of morality and by keeping secret everything seen and heard during the treatment. A kind of concept of medical confidentiality, and therefore respect for patient privacy, originated in the teachings of Hippocrates.[17] The prudent physician was distinguished by his ability to remain silent, which in turn was equated with the prowess of the soul.[18]

[16] Miles, S. H. (2009). Hippocrates and Informed Consent. *The Lancet*, *374*(9698), 1322–1323, p. 1322.
[17] "What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself holding such things shameful to be spoken about," as cited in Edelstein, L. (1943). *The Hippocratic Oath, Text, Translation and Interpretation*. Baltimore: The Johns Hopkins University Press, p. 3.
[18] Ivanyushkin, A. Ya., Ignatiev, V. N., Korotkih, R. V. et al. (Eds.). (1998). *Introduction to Bioethics: Study Guide*. Moscow: Progress-Tradition [Введение в биоэтику: Учебное пособие / А. Я. Иванюшкин, В. Н. Игнатьев, Р. В. Коротких и др. – М.: Прогресс-Традиция, 1998.], p. 98.

The balance of information between physician and patient was nevertheless disturbed by the strong paternalistic character of Hippocratic medicine. Since the Oath instructed the physician to perform every action for benefit of the patient, often such decisions were based solely on the discretion of the physician rather than the patient.[19] The physician himself could decide what to tell the patient and what to keep from him/her, so as not to cause excessive anxiety and deterioration.[20] In this case, it is hardly possible to say that the patient's participation in the treatment process was sufficient and that he/she really had the opportunity to express his/her own will. Such a model more closely resembled the modern concept of therapeutic privilege, which in modern day is an exception to the obligation to provide all information to the patient about his/her condition, treatment options and risks and is therefore a limitation of patient autonomy. In Ancient Greece, however, this was the norm rather than an exception. Taking into account the fact that the physician was the one who decided the scope of information disclosed to the patient, if patients gave any consent to treatment at all, it was based on limited knowledge.[21]

The principles set forth in the books of Hippocrates were neither absolute nor unified, and the Greek physicians did not apply it consistently, perhaps because they were the ideas of just one school of thought – Pythagorean.[22] However, this system of moral and ethical commandments and recommendations influenced the development of the moral and legal basis of medical services in Ancient Greece and Ancient Rome, where they were particularly popular and were used as a reference.[23]

In Rome, where laws have long been considered sacred, was developed the most complete, thoroughly elaborated and perfect legal system in all of the ancient world. Roman law at first glance might have seemed slave-built, but rather than slavery, the development of market relations predetermined the development of the Roman state and law. This drove the consolidation of, first

[19] Veatch, R. M. (1991). Theories of Medical Ethics: The Professional Model Compared with the Societal Model. In W. Land & J. B. Dossetor (Eds.), *Organ Replacement Therapy: Ethics, Justice, Commerce* (pp. 3-9). New York: Springer-Verlag, p. 4.
[20] Ivanyushkin, A. Ya., Ignatiev, V. N., Korotkih, R. V. et al. (Eds.). (1998). *Op. cit.*, pp. 99-100.
[21] Faden, R. R., & Beauchamp, T. L. (1986). *A History and Theory of Informed Consent*. Oxford: Oxford University Press, pp. 61-62.
[22] Higgins, G. L. (1989). The history of Confidentiality in Medicine: The Physician-Patient Relationship. *Canadian family physician, 35*, 921–926, p. 921.
[23] Rieder, P., Louis-Courvoisier, M., & Huber, P. (2016). The End of Medical Confidentiality? Patients, Physicians and the State in History. *Medical humanities, 42*(3), 149–154, p. 150.

of all, the interests of the individual, though not personal, but as a private property owner.[24] The attitude of the law to slaves was also influenced by the teachings of the Stoics, who considered in theory all people naturally equal, but such principles were still harder to put into practice, especially because the Stoics were not very enthusiastic in amelioration of social institutions as they believed they are incapable of change.[25] Since the provision of medical services also includes market elements, this feature of Roman law influenced the development of the norms that determine the legal status of a physician and a patient.

It is no coincidence, therefore, that Roman law tried to ensure that patients had access to high standard of care through development of regulations on liability of medical practitioners.[26] It protected physicians who adhered to modern prescriptions and recommendations on medical practice, freeing them from liability for any adverse result, but punishing them for incompetence. First of all, the Romans followed the rule that everyone should be responsible for all their actions, including damage caused to others.

As usual, in the beginning appeared criminal repressive measures against medical workers. The first law that enshrined the criminal liability of slave physicians and free physicians was *Lex Aquilia*. Other regulations, such as *Lex Cornelia*, *Lex Pompeia* and *Lex Julia*, listed professional crimes and the types of punishments that physicians could be subjected to, if malpractice was fully proven.[27] In order for a physician to be brought to justice, he had to be culpable or guilty of negligence, which could have manifested through improper actions or omissions due to lack of sufficient training, skills or care provided to the patient. In any case, the damage should have been caused as a result of the offense and the patient could have asked for criminal penalties for the physician, and at the same time, had the possibility of material compensation.[28] Also, Roman law provided for punishment for conducting an operation without the patient's consent, thereby

[24] Zhidkov, O. A., & Krasheninnikova, N. A. (Eds.). (2004). *Op. cit.*, p. 137.
[25] Ferngren, G. B. (2009). *Medicine and Health Care in Early Christianity*. Baltimore: The Johns Hopkins University Press, p. 97.
[26] Cilliers, L. (1993). Public Health in Roman Legislation. *Acta Classica*, *36*(1), 1–10, p. 3.
[27] Hu, E. (1880). *Op. cit.*, pp. 77-78.
[28] *Ibid*., p. 79.

protecting the patient's integrity.[29] By redefining the responsibility of the physician, the Romans improved the system of protecting the rights of the patient.

However, the problem of providing evidence of medical negligence at that time significantly limited the scope of legal proceedings related to the negligence of physicians. Indeed, many of the mistakes made during the treatment process were impossible to prove.[30] The goal to provide a certain standard of care could not be achieved only by means of professional liability and this was not enough to protect people from false physicians when, like in Ancient Greece, the medical profession was available to everyone and did not require training and licensing until the II Century A.D.[31]

1.1.3. Patient-physician relations in the Middle Ages

In the Middle Ages, the established and adopted Greco-Roman principles underwent some changes. After the collapse of the Roman Empire, which marked the end of an entire civilization, society suffered significant stagnation in development. Therefore, people living on the territory of modern Europe needed new ways to progress. The most important accelerators of the development of Western European civilization at that time were private property inherited from Antiquity, and Christianity.[32] For several centuries, the main source was legal customs, which were usually established only in oral form. Over time, collections of legal practices began to appear that governed, mainly, feudal relations. Even though laws of barbarian kingdoms were not dedicated to medicine, some codes, such as *Lex Visigothorum*, represented an exception and contained certain ideas about the regulation of medical practice, which were also reflected in the epistolary treaties.[33] Nevertheless, in the early Christian centuries, faith and morality played a major role in streamlining the relationship between a physician and a patient. The first laws that were consecrated to regulate medical activity appeared much later.

[29] Smith, H. W. (1941). Legal Responsibility for Medical Malpractice: I. The Legal Matrix of Medical Malpractice. *JAMA, 116*(10), 942–947, p. 944.
[30] Py, B. (1993). *Op. cit.*, p. 14.
[31] Cilliers, L. (1993). *Op. cit.*, p. 3.
[32] Zhidkov, O. A., & Krasheninnikova, N. A. (Eds.). (2004). *Op. cit.*, pp. 245-246.
[33] MacKinney, L. C. (1952). Medical Ethics and Etiquette in the Early Middle Ages: The Persistence of Hippocratic Ideals. *Bulletin of the History of Medicine, 26*(1), 1–31, p. 5.

The spread of Christianity had a deep and very diverse impact on various aspects of medical care, not only in terms of understanding patient care, but also entailed a change in the concept of health and disease. While early Christian society still kept the same views as in Ancient Greece and Rome regarding medicine and did not blame yet the demons and evil spirits for all diseases,[34] in the Dark Ages, the disease was no longer seen as a disturbance of natural balance of the human body. Within the framework of the Christian tradition, physical illnesses were interpreted as a consequence of sin and had a positive spiritual significance. The process of treatment and suffering, much like overcoming sin, gave the patient the opportunity to be morally elevated and be closer to God. With a corrected understanding of the essence of the disease, the interpretation of the needs of patients and, as a result, the organization of medical care changed.

Medical practice became overloaded with superstitions and faith and was seen as a gift to physicians from God. Despite the fact that it certainly impaired the role of medicine as a science and invoked reflection in the quality of medical care, one cannot say that this completely degraded medical science and its principles established during the Hippocratic times. Certain evidence suggests that the requirements for physicians regarding their professional secrecy were well-known at the decline of the Roman Empire, and then were adopted by the Christians, albeit in a modified form, in Medieval Europe.[35]

The new ideology introduced new values and proposed new norms and types of social relations. Based on such values as mercy, help and love for proximate, caring for the sick was the fulfillment of the main Christian duty. Since the manifestation of love for proximate is universal and does not depend on the social status of a certain person, theoretically, medical care for the sick, as a manifestation of such love and mercy, should have been equally provided to everyone.[36] Christian charity, in contrast to Greek philanthropy that was based to some extent on the principle of mutual benefit, acquired a new meaning and protected the interests of socially-vulnerable groups of people.[37] Thus, the position of the poor, the dispossessed, the widows and the sick had changed. On the one hand, the Christian value viewing all people to be equal led to provision of equal care to people, and, accordingly, the modern right to equal access to medical care. On the other hand,

[34] Ferngren, G. B. (2009). *Op. cit.*, p. 13.
[35] Higgins, G. L. (1989). *Op. cit.*, p. 922.
[36] Lain Entralgo, P. (1969). *El médico y el enfermo*. Madrid: Ediciones Guadarrama, pp. 70-71.
[37] Ferngren, G. B. (2009). *Op. cit.*, pp. 87-95.

this equality was rather fictitious in nature, given the differences between the rich and the poor that still existed, particularly to the sick and lepers who needed isolation. In any case, the Church served as an ideological base for creating conditions for the care of the sick and for developing a network of monastic hospitals, which was a prototype of the modern hospital system.

Despite its importance in the development of hospital work, the Church did not play an active role in the development of science, in particular medicine, considering it to be useless.[38] This was due to the lack of a balance between the material and the spiritual component, and the regard for the body as an ephemeral shell that does not have much importance compared to its content – the soul. Since physical illness was viewed as a manifestation of the ailment of the soul, healing meant primarily spiritual healing. Therefore, the main task of the physician in this process was to alleviate the suffering of the patient, and not to make a diagnosis and select appropriate treatment methods. Such lack of technique on the part of physicians could not guarantee a sufficient level of quality of medical care to patients, but it was substituted with mercy and compassion. This confrontation between religion and science stretched to the XIII Century, when the idea that not all diseases were sent from above and that the physician would not violate the will of God by treating the sick, was finally adopted.[39]

With the development of scholastic philosophy, attitudes toward knowledge in general and medicine in particular changed in such a way that medicine received the same high status as philosophy and began to be taught at universities over time.[40] With the transition of healthcare centers from monastic hospitals to cathedral schools, and then to universities, secular treatises on medical ethics began to appear. The first educational institution in Western Europe thought to have taught medicine was in Salerno, followed by the universities established in Bologna, Oxford, Montpellier, Paris, and Salamanca. Universities were conceived as autonomous and independent centers, but medicine and religion often continued to be intertwined.[41] Due to the intensified Latinization of Ancient Greek and Arab authors, mainly in Italy and Spain, universities opened the

[38] Prioreschi, P. A (1996). *History of Medicine: Medieval medicine* (Vol. V). Omaha, Nebraska: Horatius Press, p. 27.
[39] Arrizabalaga, J. (1994). Facing the Black Death: Perceptions and Reactions of University Medical Practitioners. In L. García Ballester, R. French, J. Arrizabalaga & Andrew Cunningham (Eds.), *Practical Medicine from Salerno to the Black Death* (pp. 237-288). Cambridge: Cambridge University Press, p. 249.
[40] Prioreschi, P. A (1996). *Op. cit.*, pp. 33-35.
[41] García Ballester, L. (2001). *La búsqueda de la salud: sanadores y enfermos en la España medieval*. Barcelona: Ediciones Península, pp. 106-107.

works of Avicenna, Galen, and others to medical students,[42] which they studied and interpreted. Although the Church did not prohibit autopsies, the study of medicine was primarily theoretical, which was explained by the cult of traditions and the blind observance of the authority of the authors of the studied literature.[43] The absence of progress in practical anatomy and the widespread conduct of surgery by barbers had a negative impact on surgery, thereby contributing to its separation from medicine in general and being partially stagnated until the Renaissance.

Patients, on the other hand, gained access to professional physicians, albeit not in the modern sense of the word, but those with a certain status in society and, most importantly, with a decent level of education obtained from an institution. Establishing examinations and licensing schemes for those who wanted to become a medical practitioner was one of the main measures to ensure patients received help from a qualified physician, rather than a charlatan. Thus, the first steps to regulate the organization of medical practice in this direction were observed in royal decrees, the first of which was adopted in the XI Century in Sicily, and its provisions were supplemented and expanded already by the XIII Century.[44] Similar regulations were also adopted in Paris, Montpellier, the Kingdom of Valencia in the XIII and XIV centuries, respectively, thereby publicly recognizing the growing influence of medical education and creating the basis for its control by public authority.[45] However, this can only be called the beginning of the formation of medicine as a profession, since the number of educated and licensed physicians in the Middle Ages did not meet the needs of the population, and the majority of the population sought medical help from lower-class surgeons, barbers and various healers.[46]

One of the main events that influenced the development of social and economic relations, including medicine, in the Middle Ages, was the plague epidemic. The Black Death, which began to engulf Europe in 1348 and in a couple of years claimed the lives of up to half its population,[47] demanded

[42] Porter, R. (1997). *The Greatest Benefit to Mankind: A Medical History of Humanity from Antiquity to the Present*. London: Harper Collins, pp. 106-109.
[43] Ackerknecht, E. H. (2016). *A Short History of Medicine* (4th ed.). Baltimore: The John Hopkins University Press, p. 71.
[44] French, R. (2003). *Medicine before Science: The Business of Medicine from the Middle Ages to the Enlightenment*. Cambridge: Cambridge University Press, p. 91.
[45] García Ballester, L., McVaugh, M. R., & Rubio Vela, A. (1989). Medical Licensing and Learning in Fourteenth-Century Valencia. *Transactions of the American Philosophical Society*, *79*(6), i-viii+1-128.
[46] Ackerknecht, E. H. (2016). *Op. cit.*, pp. 72-73.
[47] Arrizabalaga, J. (1994). *Op. cit.*, p. 237.

a response through organized measures that could not be found in the writings of ancient philosophers. Since medicine was powerless before the ailment, the only way out was to reduce the contact of healthy people with the infected. Physicians had no influence on public health measures, and they were required to cooperate with administrative authorities regarding the publication of the names of infected people.[48] Moreover, signs were put on the doors of their houses, which warned that someone in the house was sick or had died, which certainly put them in a discriminatory position and, at times, doomed to death.

In addition to restricting patient's rights to medical confidentiality, measures to coordinate public health included the removal of people infected with the plague to outside the city, and at the same time, imposing a ban on movement and the admission of strangers into the city.[49] For the first time, a quarantine was introduced in 1377 in Dubrovnik in Croatia, and the first permanent plague hospital (lazarette) was opened later in Venice in the XV Century. This restriction of the rights of the population as a whole, and patients in particular, is due to the extraordinary nature that any epidemic of transmitted diseases has, and the need to act in the interests of society as a whole and public health. By the end of the XIV Century, the epidemic had subsided, but had not disappeared – some outbreaks of the disease continued in European cities for centuries.

The beginning of the XV Century can be considered the birth of medical liability insurance. This originated from the practice in England to warn the city administration about those who were sick or in need of help.[50] Before treating patients with high-risk diseases, the surgeon had to report such a patient before the operation and, moreover, had to make a pledge of money to the city authorities in order to ensure that the level of their services complies with the requirements of civil-medical legislation. The pledge was not a penalty for improper medical practice, but a mechanism to protect the physician and his patient. This legal institution provided the patient with, if necessary, an examination by highly qualified professionals, and the physician was protected from the charge that the disease could be cured if a commission had been set up. In this practice, we can see a resemblance to how we seek a second expert opinion in modern health care.

[48] Rieder, P., Louis-Courvoisier, M., & Huber, P. (2016). *Op. cit.*, p. 151.
[49] Porter, R. (1997). *Op. cit.*, p. 126.
[50] Cosman, M. P. (1973). Medieval Medical Malpractice: The Dicta and the Dockets. *Bulletin of the New York Academy of Medicine*, *49*(1), 22–47, p. 33.

1.1.4. Patient rights through philosophical teachings in the Age of Enlightenment

In the Renaissance, medicine, on the one hand, was enriched with technical and clinical knowledge, but on the other hand, humanistic philosophy emerged at the time, and with it the concepts of individual and rational consciousness. Since then, the attitude towards the patient has changed, as a person experiencing suffering.[51] Supported by religious arguments and humanistic philosophy, the idea of universal equality developed more and more.[52] It is in this direction that medicine developed until the XVIII Century. Physicians acquired irreplaceable knowledge, the quality of services became paramount, and clinical observation replaced the home regime.

Of course, the development of the concept of patient rights was directly related to the emergence and development of the theory of human rights in general. Although by the end of the XVII Century there was still a legal imbalance between the people and the ruling authority, it was precisely in this time when human rights began to emerge, as they are understood nowadays. John Locke was a particularly influential figure. He described the "State of Nature" as a condition in which everyone has complete freedom and equality in the possession of his/her property and life, while trying to preserve the peace and security of other people and not harm their lives, health and property, which in turn must be guaranteed by the Government.[53] A logical extension of such autonomy can be considered the patient's right to medical confidentiality with the corresponding duty of the physician to keep secrets. It also led to the transition of the foundation of medical confidentiality from a professional ethical commitment and adherence of a particular physician, like in the study of Hippocrates, to the patient's right, which should not be violated only by the physician's subjective considerations about the patient's interests.[54]

Locke's ideas influenced the views of Jean-Jacques Rousseau, who built on them a more complex theory of social contract, as a consensus on the fundamental principles that serve as a necessary basis for the existence of a just society. At that time, public relations were not built on a contractual

[51] Manai-Wehrli, D. (1999). *Les droits du patient face à la médecine contemporaine*. Bâle : Helbing & Lichtenhahn, p. 101.
[52] Peel, M. (2005). Human Rights and Medical Ethics. *Journal of the Royal Society of Medicine*, *98*(4), 171–173, p. 171.
[53] Locke, J. (1988). *Two Treatises of Government* (P. Laslett, Ed.). Cambridge: Cambridge University Press. (Original work published 1689), p. 271.
[54] Higgins, G. L. (1989). *Op. cit.*, p. 924.

basis, but over time this played a significant role in organizing relations between hospitals, physicians, and patients for the optimal functioning of the healthcare system and the protection of the rights and interests of all parties, especially the patient. The apotheosis of the development of human rights in the XVIII Century came with the adoption of the American Declaration of Independence in 1776 and the Declaration of the Rights of Man and the Citizen in 1789.

Philosophy of Immanuel Kant had an enormous influence on the development of patient rights, even though he did not directly examine the issues of medicine as a science. While the term "autonomy" was not used in relation to human beings until the XVIII Century, Kant's concept brought moral philosophy to a new level. Morality, as the basis of autonomy, in his understanding was not subordination, but self-control, that is, the ability to act according to reasonable universal standards that would be meaningful for everyone and not just based on one's own needs. This freedom of self-determination was the natural ability of any "rational being who obeys no law except what he at the same time enacts himself".[55] To this moral autonomy, Kant also closely linked human dignity, which he considered inherent in all people from birth, much like autonomy, and which was not a sign distinguishing exclusively certain individuals. Hence came the judgment that every person was a goal in a relationship, and not a means, which would be incompatible with respect for a person's autonomy and dignity.[56] Such conclusions about human nature contributed to the understanding that every patient, in this case, whether sane or in a coma or with a mental disorder depriving him/her of legal capacity, should have the same right to protection of their rights and respect for dignity, since they have equal and absolute value based on moral autonomy.

As for the privacy of patients, the requirement of confidentiality did not become more specific and remained essentially close to the definition given by Hippocrates, despite the fact that this issue received sufficient attention in the literature.[57] For example, the book *"Medical Ethics"* by Thomas Percival,[58] which later served as the basis for the first Code of Medical Ethics of the American Medical Association adopted in 1847, contained provisions on medical secrecy, but did

[55] Kant, I. (1993). *Grounding for the Metaphysics of Morals with On a Supposed Right to Lie Because of Philanthropic Concerns* (3rd ed.) (J. W. Ellington, Trans.). Hackett Publishing Company. (Original work published 1785), p. 40.
[56] *Ibid.*, p. 36.
[57] Rieder, P., Louis-Courvoisier, M., & Huber, P. (2016). *Op. cit.*, p. 150.
[58] Percival, T. (1849). *Medical Ethics, or, a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons*. Oxford: J.H. Parker. (Original work published 1803), pp. 28, 47.

not determine the content of confidential medical information relying on the physician's judgment in a particular situation, nor the degree of privilege between the physician and the patient. These questions were raised earlier, in 1776, during the trial of Elizabeth Chudleigh, Duchess of Kingston, who had been accused of bigamy. When the surgeon of the party was involved as a witness, he refused to answer the question about the existence of the first marriage of the Duchess, referring to the professional honor and trust in the profession.[59] On the one hand, this information went beyond the professional relationship between the physician and his patient, even though this surgeon was present as a medical professional during the birth of the common child of the parties and mediated in their communications, when her husband asked for a divorce. On the other hand, from the point of view of the practitioner, it could look different. However, the court decided against such a privilege.

With the derivation of legal norms, the duty of physicians to keep confidential data about their patients has acquired a certain framework and structure. In 1810, the French Penal Code was adopted in France, which included the obligation to observe professional secrecy and imposed responsibility for violation in the form of a fine or imprisonment.[60] Then similar norms began to appear in the criminal codes of other European countries.[61] Thus, the burden of decision on confidentiality started to shift from a particular physician to the court, at the same time bringing the subjective medical practice to more structure through legislation and support by the justice system.[62]

To ensure the rights of the patient, the revision of nature of patient-physician relationship and the issue of the responsibility of physicians played a great role. In 1936, the *Mercier-Nicolas* case by the Court of Cassation of France established the contractual nature of the relationship between the patient and the attending physician.[63] Thus, some European countries developed a theory of a contract for medical care, which was based on the patient's trust and required physicians to take

[59] Bristol, E. C., & Great Britain. (1776). The trial of Elizabeth Duchess Dowager of Kingston for bigamy: Before the Right Honourable the House of Peers, in Westminster-Hall, in full Parliament, on Monday the 15th, Tuesday the 16th, Friday the 19th, Saturday the 20th, and Monday the 22d of April, 1776, on the last of which days the said Elizabeth Duchess Dowager of Kingston was found guilty. London: Printed for Charles Bathurst, p. 119.
[60] Code pénal : précédé de l'exposé des motifs par les orateurs du conseil d'état, sur chacune des lois qui composent ce code (12 février 1810), Art. 378.
[61] *E.g.*, Strafgesetzbuch für das Deutsche Reich (15 Mai 1871), § 300; Code Pénal Belgique (9 juin 1867), Art. 458.
[62] Rieder, P., Louis-Courvoisier, M., & Huber, P. (2016). *Op. cit.*, p. 150.
[63] Dr. Nicolas c/ Mercier [Civ. 20 mai 1936, GAJC, 12e éd., 2008], n. 162-163.

the best possible care of the patient, rather than achieve his/her complete cure.[64] This then secured the transition to a contractual model of the relationship between a physician and a patient, within the framework of which the moral values of an autonomous person were most protected. The idea that the contract is the worthiest of the human form of social relations was formed back in the Age of Enlightenment. The contractual relationship allows the physician and the patient to interact with each other in such a way that each party has certain obligations, and each achieves some benefits. The patient voluntarily establishes a relationship with a physician on those conditions that he/she considers acceptable to himself/herself. At the same time, he/she delegates certain powers to the medical professional so that he can adequately fulfill his professional obligations.

1.1.5. Consolidation of human rights in the post-World War II time

The next significant push in the development of human rights, including within the framework of public health, was caused by World War II. The Nuremberg process played an important role in the development of theory and practice in the field of responsibility of medical professionals and the protection of patients' rights. Twenty physicians and three medical administrators were accused of crimes against humanity for conducting experiments on people. People were tested for the effects of different air pressures for the needs of the Air Force, while hypothermia, artificial freezing and various diseases were artificially induced, bones and muscles were regenerated, the effects of poison and incendiary bombs were studied as well, and many more terrifying experiments were conducted.[65] Not all medical personnel who took part in such studies even had an appropriate level of qualification and experience, and most of the operations were performed by students. As a result, five of them were acquitted, seven were sentenced to be hanged, and the rest received various prison sentences.[66] Thus emerged an understanding that it was necessary to secure and guarantee rights of people, so that the state would be able to protect those who are in a

[64] Manai, D. (2009). Médecine et Droit : pour un pacte humaniste au-delà du conflit. En D. Bertrand, J.-F. Dumoulin, R. La Harpe & M. Ummel (Eds.), *Médecin et droit médical. Présentation et résolution de situation médico-légales* (3-éme éd., pp. 11-17). Chêne-Bourg : PAO Médecine & Hygiène, p. 14.

[65] Kudryavtsev, G. G. (1991). *Nuremberg Process. Crimes Against Humanity* (V. 5). Moscow: Legal literature [Кудрявцев, Г. Г. Нюрнбергский процесс. Преступления против человечности (Т. 5). М.: Юридическая литература, 1991], p. 5.

[66] Gorshenin, K. P., Rudenko, R. A., & Nikitchenko, I. T. (Eds.). (1954). *The Collection of Materials from the Nuremberg Trials of the Main German War Criminals in Two Volumes*. Moscow: Legal literature [Сборник материалов Нюрнбергского процесса над главными немецкими военными преступниками в двух томах подготовлен под редакцией К. П. Горшенина, Р. А. Руденко, И. Т. Никитченко. М.: Юридическая литература, 1954], p. 887.

less privileged position. After the decision of the Nuremberg Tribunal, there was a need to adopt regulations based on the principles that go back to Hippocratic deontology.

After World War II, the United Nations (UN) became the leading organization of the international community. At a meeting held in 1945 about its establishment, among other things, the question of creating a global health organization was discussed. The reason for this was the colossal changes that occurred after World War II, both in the political and in the socio-economic life of the countries involved. Therefore, in the UN Charter appeared mention of health,[67] and a declaration was adopted on the establishment of an international health organization. The year 1945 also saw the establishment of the United Nations Educational, Scientific and Cultural Organization (UNESCO). Its mission, as described in the Constitution of the organization, was "to contribute to peace and security by promoting collaboration among the nations through education, science and culture in order to further universal respect for […] the human rights and fundamental freedoms […]".[68] Therefore, there was an important link between its designation and the incitation of human rights in medicine.

The World Health Organization (WHO) was established in 1948 to ensure the implementation of human right to health, and a year earlier the World Medical Association (WMA) was created to guarantee the independence of physicians and high standards of their ethical activities. In the same year, during its second session, the WMA adopted the Geneva Declaration, which summarized the main professional duties of a physician, and which became the so-called "New Hippocratic Oath".[69] On the basis of this Declaration, the following year, the organization adopted the International Code of Medical Ethics to establish ethical principles for physicians from around the world in their relationships with patients and colleagues.[70]

With the adoption of the Universal Declaration of Human Rights (UDHR) in 1948, a system of international agreements on human rights began to be built. This fundamental document, on the basis of which the whole concept of protecting human rights is based, has embedded the human

[67] United Nations. (1945). Charter of the United Nations (1 UNTS XVI), Arts. 13, 55, 57, 62.
[68] United Nations Educational, Scientific and Cultural Organization. (1945). Constitution of the United Nations Educational, Scientific and Cultural Organization (UNESCO), Art. I, para. 1.
[69] World Medical Association. (1948). Declaration of Geneva [amended version of 2017].
[70] World Medical Association. (1949). International Code of Medical Ethics [amended version of 2006].

right to health and proper medical care.[71] Later, it was followed up by binding documents such as the European Convention on Human Rights (ECHR) and the International Covenant on Civil and Political Rights (ICCPR)[72].

In 1961, the European Social Charter was adopted, which proclaimed the right of every person to medical care, regardless of the availability of resources.[73] These documents marked the beginning of the emergence of a number of international legal documents on respecting the dignity of the person and developing and specifying the rights of patients. A series of acts were then adopted, such as the Recommendation 779 "On the rights of the sick and dying" by Parliamentary Assembly in 1976 and Charter of the Hospital Patient by the Hospital Committee of the European Economic Community in 1979, dedicated to the protection of vulnerable groups of the population and certain groups of patients, which determined the direction of forming the rights of patients.

Ever since the 1950s, the idea of providing the patient with information about upcoming medical intervention and obtaining consent for proceeding with such intervention has changed. Even though Prussia adopted regulations requiring consent from patients by the end of the XIX Century, this was more concerned with research.[74] With regard to diagnosis and treatment, medical ethics did not pay particular attention to the right of patients to consent to treatment. Basically, for centuries the patient did not receive sufficient information about his/her treatment and was subject to the will of the physician. Therefore, there could be no question of informed consent. Classical documents on medical ethics did not oblige the physician to rigorously disclose all information about the diagnosis and treatment to the patient and obtain patient approval for treatment. After the concept of obtaining consent was introduced by the German government to medical research, the court decision in the case of *Salgo v. Leland Stanford Jr. University Board of Trustees* introduced this element into medical practice in 1957 in the United States[75] and this introduction

[71] United Nations General Assembly. (1948). Universal declaration of human rights (217 [III] A), Art. 25.
[72] Reference to medical or scientific experimentation in Art. 7 of the United Nations General Assembly. (1966). International Covenant on Civil and Political Rights. *Treaty Series*, *999*, 171.
[73] Council of Europe. (1996). European Social Charter (ETS 163) [Revised], Art. 11.
[74] Vollmann, J., & Winau, R. (1996). Informed Consent in Human Experimentation Before the Nuremberg Code. *BMJ (Clinical research ed.)*, *313*(7070), 1445–1449, pp. 1445-1447.
[75] Salgo v. Leland Stanford Jr. University Board of Trustees, Stanford University [154 Cal. App. 2d 560, 317 P.2d 170] (Cal. 1957).

served as a starting point in the history of informed consent, which continued to be shaped and supplemented by other court decisions until the 1970s.[76]

Until the beginning of the 1970s, in Europe, every attempt to sue a physician for violating patient rights caused disapproval.[77] The courts sided with the latter, not encouraging patients to protect or be compensated for their violated rights. Moreover, the patient did not have free access to his/her file in order to receive any information about the course of treatment. The process of proving a medical error, which was criticized, as a violation of the rules of the art of healing, required a medical examination, the results of which rarely incriminated the defendant physician. The existing regulatory framework and legal mechanisms were not sufficient to adequately protect the interests of patients.

1.2. Current national and international regulations

1.2.1. Definition of a patient in modern legislation

The status of a patient in a patient-physician relationship, as well as the status of a person or a citizen in relation to the state, has changed over centuries under the influence of historical events, as well as through the development of philosophical and political thought. Throughout the evolution of medicine from magical medicine to modern medicine, attitudes toward disease and health have also changed dramatically. If health originally consisted in the patronage of the gods, the expulsion of evil demons and rescue from pain, this concept also now implies the attainment of "complete physical, mental and social well-being",[78] rather than being merely the absence of disruption of the body's proper functioning. This tendency has certainly affected patient empowerment and provoked a shift from paternalism in a relationship with a physician to a model of an informed patient who is actively involved in making decisions about personal care and the care process.

[76] Beauchamp, T. L. (2011). Informed Consent: Its History, Meaning, and Present Challenges. *Cambridge quarterly of healthcare ethics: the international journal of healthcare ethics committees*, *20*(4), 515–523, p. 515.
[77] Guillod, O. (2009). L'évolution du droit médical au cours des dernières décennies. En D. Bertrand, J.-F. Dumoulin, R. La Harpe & M. Ummel (Eds.), *Médecin et droit médical. Présentation et résolution de situation médico-légales* (3-éme éd., pp. 61-82). Chêne-Bourg : PAO Médecine & Hygiène, p. 78.
[78] International Health Conference. (2002). Constitution of the World Health Organization.,1946. *Bulletin of the World Health Organization*, *80*(12), 983–984, Preamble.

Today, the relationship between the patient and the physician still varies from country to country as a result of differences in the level of health care, cultural and social traditions. Whereas previously, patient rights were regulated mostly through provisions on physicians' responsibility and ethics, the principles of patient rights are now consolidated in international law, which also served as an impetus to the development of national legislation on this issue. The regulatory framework is not limited to specialized laws on the rights of patients, but includes legislation defining the duties of healthcare professionals, legal acts relating to specific issues or aspects, the direct application of the Constitution and of the general principles of civil, criminal, or administrative law.

Guaranteeing the rights of the patient not only respects personal freedoms and interests of the patient, but also ensures reciprocal obligations on the part of hospitals, medical professionals, and the state. This is an extremely important protective measure that takes into account the vulnerable position of the patient due to his/her particular psycho-physiological condition, dependence on the attending physician and limited access and training to and understanding of information about his/her own health. In addition, the approach to respecting and protecting the rights of patients is supported by a wide range of tools, such as the creation of organizations protecting rights, special supervisory authorities and officials, and the introduction of procedures. Nevertheless, all this legal structure is based on ethical principles and deontological codes, which have been regulating patient-physician relations since the very beginning and continue to be an important source of patient rights.

Now, when it comes to the patient, common sense refers to that of a person receiving healthcare services. It is on this definition that the legislators lean, but there is no single, universally-accepted concept of patient that would consistently define or reflect the constant criteria inherent in the patient. For the first time, the definition of a patient as any person "subject to a medical procedure" was proposed by the Committee of Ministers of the Council of Europe in 1985, by referring to another concept, a medical act, that was not delimited and which content was not clearly defined.[79] Later, the WHO Regional Office for Europe introduced another definition of the patient that

[79] Dubuis, A. (2017). *Les droits du patient en droit de l'Union européenne*. Bruxelles : Bruylant, §14.

included all health care users, both healthy and sick.[80] Such a definition is quite extensive, without linking this status with the obligatory presence of any pathologies, which logically follows from the WHO's definition of health. Thus, even though the word "patient" originates from the Latin word *patiens*, which means a person who suffers, the presence of physical or mental suffering is not the determining criterion of this status.

Some national laws also define the patient. Different laws emphasize various criteria that characterize belonging to this group. However, if to take into account the essence of the terms through which the disclosure of the definition of a patient occurs, such as "medical care" or "medical act", then they are not very different from one another. For example, in the U.S. laws, it is possible to find statements that relate the appurtenance to the group of patients that are receiving medical care, treatment, or services from licensed persons or institutions. Spanish law 41/2002 on patient autonomy (Ley básica 41/2002) focuses on the ultimate goal for which care is provided, meaning that a patient is "a person who needs medical care and professional care to maintain or restore his/her health".[81] Despite this, many national laws do not explicitly define what a patient is, or use other terms such as "the sick" (*malade*)[82] or "user of services", which do not always take into account the completeness of situations faced by people who are in contact with the healthcare system. Therefore, for purposes of consistency, and also in view of the constant development of medicine and the expansion of its essence and purposes, not limited to correcting physical ailments, the term "patient" will be used in a general sense, such as, for example, presented in the WHO Declaration.

1.2.2. Scope of patient rights and their classifications

Due to the rather consumer-acquired characteristics of a patient which directly connects this status to the receipt of certain health services, sometimes patient rights are opposed to human rights in patient care, calling the first a kind of codification of rights that are relevant only for the patient

[80] World Health Organization, WHO. (1994). Declaration on the Promotion of Patient's Rights in Europe: European Consultation on the Rights of Patients, Amsterdam 28 – 30 March 1994.
[81] Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Boletín Oficial del Estado, 15 de noviembre de 2002, núm. 274, pp. 40126 a 40132, Art. 3.
[82] *E.g.*, Loi n° 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé.

and not for all participants of patient care, especially medical professionals.[83] The concept of rights in the field of patient care is considered, therefore, to be a model that unites the rights of people who perform various roles in the field of health care regardless of their status, and pays special attention to the role of the state. However, as a phenomenon and legal construction, patient rights are also based on the idea of human rights, since the patient should be considered, first and foremost a person, and not a representative of a certain group of individuals who have any disease or illness or who receives any services for their health. Patient rights fall under the broad concept of fundamental rights and freedoms, and it is very important to maintain a link between patient rights and human rights so as not to lose the meaning of the first.

A clearer understanding of the rights of the patient can be achieved by classifying them according to the classification theories proposed in the framework of the conventional theory of fundamental rights. In other words, one can single out the most popular historical classification by generations of human rights, according to the epoch of their appearance and correlation with the ideals of the French Revolution, namely freedom, equality, and fraternity.[84]

There are three generations of rights, which makes it possible to create a system for the development of human rights in the context of the development of the state and society. The first generation is formed by civil and political rights, expressing an obligation of the state to refrain from interfering in certain areas of life. This category includes the rights to life, equality, and privacy – all of these rights apply to the status of the patient. The second generation of rights includes economic, social, and cultural rights that require government intervention in ensuring equal participation in the production and distribution of relevant values. An example of second-generation rights that directly interest any patient is the right to social security and health care. Finally, the third generation is so-called "collective rights", such as the right to peace and the right to a healthy and balanced environment. There is a constant controversy surrounding this category of rights, especially regarding its relevance in the classification of human rights. For now, we will focus on the first two categories, and we will return to the last category in the following chapters.

[83] Ezer, T., & Cohen, J. (2013). Human Rights in Patient Care: A Theoretical and Practical Framework. *Health and Human Rights*, *15*(2), 7–19, pp. 13-15.
[84] Vasak, K. (1977). Human Rights: A Thirty-Year Struggle: The Sustained Efforts to Give Force of the Universal Declaration of Human Rights. *UNESCO Courier*, *30*(11), 29–32, pp. 29, 32.

In order to compare the tools available to protect patient rights in different countries, it is most convenient to rely on three areas of classification, namely, basic individual rights such as autonomy, privacy and dignity and the right to access a medical file, then social rights such as the right to equal treatment and access to health care, and finally the consumer-based rights, such as the right to quality in health care, to choose a physician and to get a second opinion.[85] This classification also distinguishes procedural rights and informational rights, which are quite difficult to attribute to only one specific group, since they are inextricably linked or derived from rights of the main three categories.[86] Procedural rights include the right to complain, to compensation, to participate in making medical decisions, when informational rights comprise, among others, the right to receive information about one's own health, treatment options and rights.[87]

The majority of the rights of the patient can be divided into groups depending on what benefit is the object of protection or guarantee by securing a particular right. Thus, patient autonomy is guaranteed by respecting the right to informed consent, which, in turn, is ensured by the right to receive information about one's own health and by the procedural right to participate in making a medical decision and choosing a treatment. It also implies that the patient has the right to access his/her medical file, which is a fundamental prerogative. Confidentiality, in turn, is maintained by respecting the right to privacy and the right to keep medical data in secret. The right to a second opinion and the right to receive information about the provider of medical services, derived from the right to choose a physician, which is a consumer-based decision, provide the patient with the freedom of choice. Finally, patient safety and, indirectly, his/her life and health are ensured through the implementation of the right to receive safe and quality treatment in a timely manner.

Hierarchical classification would play a big role in resolving the possible conflicts of law. In contrast to the widely-used pyramidic model of human needs that is indicated and represented by the social psychologist Abraham Maslow,[88] patient rights are difficult to arrange in absolute order. Rather, it depends on the particular patient in a particular situation and a particular country.

[85] Townend, D., Clemens, T., Shaw, D., Brand, H., Nys, H., & Palm, W. (2016). *Patients' Rights in the European Union Mapping eXercise (Final Report)*. Luxembourg: Publications Office of the European Union, pp. 21-22.
[86] *Ibid.*
[87] *Ibid.*
[88] Maslow, A. H. (1954). *Motivation and Personality*. New York: Harper & Row, Publishers.

However, certain patterns can be seen in provision on human rights in the health sector. For example, the Universal Declaration on Bioethics and Human Rights organizes principles that contain different duties and responsibilities that correspond to the patient rights, depending on the expansion of the range of objects to which they are directed.[89] In the beginning, we have principles that are directed at the person himself/herself, namely his/her dignity, security, and autonomy. Then there are those that are directed at other people, such as informed consent, privacy, confidentiality, and equality. Finally, we have those that concern all of humanity, such as solidarity and social responsibility.[90] Based on this criterion, it is possible to order patient rights in some subordination too.

If we repose on the differentiation into conditional rights and absolute rights embodied in the Universal Declaration of Human Rights of 1948, the majority of patient rights will be assigned to the second category. According to the current practice of the decisions of the European Court of Human Rights (ECtHR), there is an approach to distinguish the intangible rights in all circumstances that form a solid core and include, but are not limited to, the right to life and the right not to be subjected to torture or inhuman or degrading treatment.[91] In its decisions, the ECtHR called these values fundamental to a democratic society, devoting special attention to the right to life.[92] On the other hand, in the laws of the European Union (EU), respect for human dignity is of particular importance, where it is an important principle and is characterized not only as a fundamental right that should be neither violated nor limited, but also as the basis for other rights that cannot be exercised in violation of the dignity of others.[93] Based on this, it is possible to conclude that if we were to still try classifying health-related rights in a hierarchical manner, dignity and all other derivative rights that indirectly relate to or ensure it will be at the top, since it has a more "inalienable" nature among others.

The list of rights common to all patients is exemplary, since international and national acts contain various formulations, narrower or more detailed, of similar rights, as well as special rights provided

[89] ten Have, H. A. M. J., & Stanton-Jean, M. (Eds.). (2009). *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, Principles and Application*. Paris: UNESCO, pp. 39-40.
[90] *Ibid.*
[91] Dubuis, A. (2017). *Op. cit.*, § 56.
[92] Pretty v. The United Kingdom [2002] ECHR 423 (App. No. 2346/02), para. 65.
[93] European Parliament, Council of the European Union, European Commission. (2007). Explanations Relating to the Charter of Fundamental Rights. *Official Journal of the European Union, C 303/17*, p. 17.

for certain categories of patients. Moreover, the very content of specific rights, especially consumer-based rights, varies depending on the level of development of a country, as well as the cultural and religious beliefs of a society.

1.2.3. International and regional documents regarding patient rights

At the international level, it is possible to single out several basic documents dedicated specifically to patient rights, which include both declarations adopted by non-governmental organizations and recommendations that are advisory in nature, as well as binding documents for signatories. The very first, Lisbon Declaration on the Rights of the Patient, adopted in 1981 by the WMA, does not establish legally binding obligations. It was revised in 1995 and 2005, and the current version was confirmed in 2015 at the 200th WMA Council Session. This document was addressed primarily to physicians and medical institutions, mandating them to protect and restore patient rights, even if they are violated by higher authorities, including the state and national legislation.[94] The Declaration includes rights to good quality medical services, freedom of choice, autonomy, information, medical confidentiality, dignity, education about health, religious assistance, and also pays attention to situations when the informed consent cannot be obtained from unconscious and incapacitated patients.

Another source of the soft law is the Declaration on the Promotion of Patient's Rights in Europe, endorsed during the WHO European Consultation meeting in March 1994 after understanding the need to formulate a new declaration on patient rights using the instruments of international patient rights, state and perspectives of medical practice.[95] There were discussions about a lot of strategies based on common approaches in order to facilitate and make efficient the promotion of patient rights, taking into account the legal frameworks of the countries, difference in economic conditions, as well as cultural and social values.[96] This document formed the foundation for the development of patient rights policy in the respective countries, which turned it into a specific scheme of action

[94] World Medical Association. (1981). Declaration of Lisbon on the Rights of the Patient [amended version of 2015], Preamble.
[95] Leino-Kilpi, H., Valimaki, M., Arndt, M., Dassen, T., Gasull, M., Lemonidou, C., Scott, P. A., Bansemir, G., Cabrera, E., Papaevangelou, H., & Mcparland, J. (2000). *Patient's Autonomy, Privacy and Informed Consent*. Netherlands: IOS Press, p. 8.
[96] World Health Organization, WHO. (1994). Declaration on the Promotion of Patient's Rights in Europe: European Consultation on the Rights of Patients, Amsterdam 28 – 30 March 1994.

and a general strategy for the observance of these rights. It encourages all member states to adopt regulations that clarify the rights and obligations of patients, healthcare workers and medical institutions. At the same time, this document symbolizes a new stage in the relationship between physicians and patients, explaining a number of principles guaranteeing the rights of patients in different situations for all countries.[97] It contains a more extensive and detailed list of rights compared to the WMA Declaration. Particular attention is paid to the need to provide complete information to the patient for exercising his/her right to autonomy, even if the patient is a minor, as well as to respect for privacy.

An important step taken to regulate this issue by national legislation was the adoption of the Convention on Human Rights and Biomedicine (Oviedo Convention) by the Council of Europe in 1997. The impetus for the development of this Convention was the inability of states to fully address the issues of bioethics and the need to reconcile their conflicting interests in this area.[98] The Convention is the first legally binding international text that aims to protect human dignity, rights, and freedom from misuse of biological and medical advances. Moreover, it is available to be signed and ratified for countries that are not members of the Council of Europe.[99] It comes into force upon signature. The Oviedo Convention was accompanied by two protocols, which cover more specific issues, and the signing and ratification of which are not obligatory for signing and ratifying the Convention, but not *vice versa*.

The purpose of this Convention is to create a system based on the fundamental principles of dignity and integrity, free consent, prohibition of the commercialization of the human body and especially the prevailing value of individual above any interests of society and science. Thus, the Oviedo Convention creates a socle or universal minimum standard, but does not unify the national legislation, allowing each party to provide more protection than provided by the Convention. Therefore, the majority of the provisions are addressed to the state parties, although some provisions can be directly used by individuals for authorization in front of the competent

[97] Manai-Wehrli, D. (1999). *Op. cit.*, pp. 55-56.
[98] *Ibid*., p. 60.
[99] Council of Europe. (1997). Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS 164), Art. 34.

authorities, as they recognize the right in a fairly precise way. This allows it to be used in relations between individuals or between private and public persons involved in the medical sector.

The Convention takes into account medical progress, emerging technologies in medical science and new types of research and treatment, the issue of genetic engineering and also prohibits all types of discrimination on the basis of genetics. However, it does not pay enough attention to clinical research, despite raising the question of conditions for those subjects who are not able to give their consent. With regard to medical treatment, the Oviedo Convention focuses on the need for consent to treatment, received beforehand, and the freedom to withdraw it, except for those who are not able to give such consent and whose treatment should then be carried out only if it can bring real and direct benefit to their health. The document recognizes the patient right to receive information about his/her health, the same way it respects his/her right not to know this information. It concerns the transplantation of organs and tissues, where it prohibits operations using organs and tissues that are recovered from people who are unable to give their consent.

The Convention has become a significant tool of law, confirmed by the fact that the ECtHR has a role in its implementation. According to the provisions of the document itself, the Court may give a consultative opinion on the interpretation of the Convention.[100] Sometimes, the Court mentions the provisions of the Oviedo Convention as well as the provisions of additional protocols in its decisions, in which it decides on complaints of violation of the ECHR provisions in the field of health.[101] In the case of *Vo v. France*, the ECtHR confirmed the provision of Article 2 of the Oviedo Convention on human primacy over science and devoted several paragraphs, summarizing the provisions of the Convention in relevant areas.[102] In its other decision, *Glass v. the United Kingdom*, the Court, through interpretation of Article 8 ECHR, took into account the provisions of the Oviedo Convention, despite the United Kingdom never having being a signatory due to its disagreement with several questions.[103] The Strasbourg Court gave a more important legal value

[100] Council of Europe. (1997). Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS 164), Art. 29.
[101] Mouvement Raëlien Suisse v. Switzerland, App. No 16354/06, 13 July 2012.
[102] Vo v. France [GC], App. No. 53924/00, 8 July 2004.
[103] Glass v. UK [2004] 39 EHRR 15 (App. No. 61827/00).

to this Convention, exceeding its sphere of influence, and thereby filling the gap in the harmonization of the laws of the member states, which could not fill the Convention.[104]

In addition to the European Union (EU) and the Council of Europe, other organizations have also focused on strengthening patient rights. In 2002, the Active Citizenship Network, which is a European network of public organizations, consumer organizations and patients, adopted the European Charter of Patients' Rights. It was the result of a mass movement throughout Europe, which encouraged patients to play a more active role in shaping the provision of medical services. According to the creators of this document, the rights of patients, their families and, above all, vulnerable groups of the population were threatened by the national health systems of the European Union.

The European Charter of Patients' Rights, unlike the Oviedo Convention, deals exclusively with the rights of the patient and does not touch on other topics of medical law and bioethics. Systematized in it are fourteen inalienable rights relevant to when receiving medical care, and are aimed to ensure a high level of protection of human health.[105] Compared to the Declaration on the Promotion of Patient's Rights in Europe (1994), the Charter contains new consumer-oriented rights, such as respect for the patient's time, compliance with quality standards, ensuring safety during medical intervention and providing access to innovative treatment methods that meet international standards, regardless of economic and financial considerations. This Charter draws attention to the importance of focusing on the individual needs of the patient and thereby ensuring everyone the right to a personalized approach to treatment.

Although this document is not legally binding, it plays a significant role in raising awareness about patient rights, intended for patients and healthcare providers themselves, as well as in increasing the participation of people in shaping health law and policy. Also, as a result of the development of this Charter, patient rights groups in many countries have successfully influenced national governments to adopt acts guaranteeing these rights.[106] Five years later, an initiative opinion on

[104] Negri, S., Taupitz, J., Salkić, A., & Zwick, A. (Eds.). (2013). *Advance Care Decision Making in Germany and Italy: A Comparative, European and International Law Perspective*. Berlin: Springer Science & Business Media, p. 72.
[105] Active Citizenship Network. (2002). The European Charter of Patients' Rights.
[106] Active Citizenship Network. (2007). *Monitoring Patients' Rights in Europe*. Retrieved June 8, 2019, from http://www.activecitizenship.net/patients-rights/projects/30-monitoring-patients-rights-in-europe.html/

the rights of patients was affirmed by the European Economic and Social Committee, in which it welcomed the European Charter of Patients' Rights.[107]

In 2005, after several years of multinational consultation, the Universal Declaration on Bioethics and Human Rights was approved by the UNESCO in order to further guide the countries to improve their legislations, policies, and other instruments in the field of bioethics.[108] Since bioethics is a domain of political debate and lawmaking,[109] the Declaration is addressed primarily to states. However, it sets itself the task of orienting the behavior of individuals and groups, as well as institutions and corporations, since the principles of bioethics are based on fundamental rights and freedoms and apply directly to individuals.[110] The document incorporates many principles generally accepted or supported by previous international acts, such as the principle of autonomy, consent, privacy, and confidentiality.

What is innovative about this Declaration is the attempt to balance individual and public moral values, while at the same time emphasizing the principle of autonomy and the principle of solidarity and cooperation, drawing attention to the responsibility for promoting the health and social development of the population. It raises the question of the need to protect future generations, including their genetic characteristics. Despite numerous advantages and intentions to combine bioethics and human rights,[111] the document received some criticism for insufficient "universalism" and inability to take into account economic and social inequality, as well as insufficient resources around the world, which diminishes its importance and attention to it in most countries.[112]

The General Data Protection Regulation (GDPR) plays a very important role in regulating the privacy of patients in the EU. It is a regional act that came into force in May 2018, replacing the Directive 95/46/EC that was applied over twenty-two years. The previous data protection

[107] European Economic and Social Committee. (2008). Opinion of the European Economic and Social Committee on "Patients' Rights". *Official Journal of the European Union, C 10/67*, p. 67.
[108] United Nations Educational, Scientific and Cultural Organization. (2005). Universal Declaration on Bioethics and Human Rights, Art. 2 (a).
[109] ten Have, H. A. M. J., & Stanton-Jean, M. (Eds.). (2009). *Op. cit.*, p .39.
[110] United Nations Educational, Scientific and Cultural Organization. (2005). Universal Declaration on Bioethics and Human Rights, Art. 1.2.
[111] Andorno, R. (2007). Global Bioethics at UNESCO: In Defence of the Universal Declaration on Bioethics and Human Rights. *Journal of Medical Ethics*, *33*(3), 150–154, p. 150.
[112] Macpherson, C. C. (2007). Global Bioethics: Did the Universal Declaration on Bioethics and Human Rights Miss the Boat? *Journal of Medical Ethics*, *33*(10), 588–590, p. 589.

legislation was drafted at a time when the Internet had not yet acquired such power and the term "big data" had not been coined. After long negotiations and, ultimately, approval of the text in 2016, countries received two years to study and implement this act into national systems. These rules did not revolutionize data processing but introduced stricter data protection rules. For the health sector, this document has become an opportunity to improve the system, policies, and processes to prevent any potential threat to the information of the medical institutions and patients.

Today, the definition of personal data is more extensive than in previous legislation. The GDPR explicitly includes genetic and biometric information in this category,[113] especially when the latter is processed with the help of special technical means that allow identifying an individual. As a general rule, the processing of such special data, which refers to the implementation of any actions, whether storage, analysis, or transfer to others, is prohibited. This is done because the processing of medical data poses significant risks to the rights and freedoms of the owner of these data. However, the rules fix the list of situations when such processing is possible in the field of health care and health management, putting first the criteria for obtaining explicit consent from the data subject (Article 9). All data storage principles now apply to medical records too.

At the same time, the patient gained more rights to receive information about what data on him/her are being processed, by whom and for what purposes. Moreover, in addition to the right to be informed, patients had additional rights, such as the right to access their own personal information, which implies the right to request copies of medical records. Also, the GDPR establishes the right to request corrections to data that are inaccurate or incomplete, the right to object to data processing in certain circumstances, to delete them and to limit processing, as well as the right not to be subject to automatic decision making.

The GDPR is a far-reaching regulation. All medical institutions and private physicians operating in the EU, as well as those outside it, have fallen under the scope of these rules. Foreign organizations must comply with their own privacy laws, but at the same time, they need to rethink their data protection policies if they interact with the EU in providing their services. Such a broad

[113] Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), Art. 4 (1).

scope is explained by the fact that information is now quickly transferred through channels that go beyond physical boundaries, and personal data of citizens of one country can be stored on servers located on other continents.

1.2.4. European national legislations

In terms of national legislation on the rights of the patient, Spain was one of the first countries to adopt regulations on this issue. First of all, the 1978 Spanish Constitution (Constitución Española, CE) focuses on human dignity, manifesting the rights to respect for life and physical and moral integrity, freedom and security, freedom of communication and information, privacy, and health.[114] This allowed to build a regulatory framework for the regulation of health care on the principles of autonomy, privacy, and informed consent, departing from the old paternalistic model.

The first attempts to designate the rights of the patient can be traced back to the General Health Law (Ley 14/1986). Article 10 lists the rights arising from the principles embodied in the Constitution, such as the protection of honor and dignity, confidentiality, and the receipt of information. Particular attention should be paid to the fact that this law takes into consideration the right to free choice of service provider.[115] The rules for implementation are contained in Real Decreto 1575/1993 on the free choice of a primary healthcare provider, and Real Decreto 8/1996 regulates the free choice of a physician in specialized health centers of the National Health Service.

In 1999, the ratification of the Oviedo Convention followed, which advanced further the legal definition of individual health rights. As a result, after three years, Ley básica 41/2002 was adopted – a special law on patient autonomy and informational rights and duties. This law does not explicitly establish, but mentions, as a basic principle, the patient's right to participate in the decision on treatment.[116] The patient is guaranteed the confidentiality of his/her health data (Article 7), ensuring the protection of the reciprocal duty to keep professional secrets (Article 16).

[114] Constitución Española. Boletín Oficial del Estado, 29 de diciembre de 1978, núm. 311, pp. 29313 a 29424, Arts. 15, 17.1, 18, 20, 43.
[115] Ley 14/1986, de 25 de abril, General de Sanidad. Boletín Oficial del Estado, 29 de abril de 1986, núm. 102, pp. 15207 a 15224, Arts. 10.13, 14
[116] Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Boletín Oficial del Estado, 15 de noviembre de 2002, núm. 274, pp. 40126 a 40132, Art. 2 (3).

Ley orgánica 3/2018, adopted in connection with the GDPR, which replaced Ley orgánica 15/1999, implements the provisions of the regional text, thereby amending parts of national legislation concerning personal data and their processing. For violation of professional secrets, the Spanish Penal Code (Código Penal de España, CPE) provides for punishments in the form of fines, imprisonment, or absolute disqualification.[117]

Ley básica 41/2002 imposes requirements on the amount of information that must be communicated to the patient in order to guarantee the right to informed consent (Article 8). According to Article 4, the information reported must include, at a minimum, the purpose and nature of each intervention, as well as its risks and consequences. However, the regulation makes an exception in the form of therapeutic privileges, allowing the physician to hide certain information at his discretion for the benefit of the patient (Article 5.4). In all other cases, consent must be obtained, as a rule, orally, with the exception of cases of serious intervention indicated in Article 8.2 that require written consent. All information about the state of health and therapeutic procedures performed during the course of treatment can be obtained from a medical file in a form convenient for the patient (Article 15.1). Moreover, the law guarantees the right to respect for autonomy by providing the patient with an opportunity to draw up preliminary instructions regarding his/her future treatment if he/she is not able to give informed consent (Article 11).

The Law on Cohesion and Quality of the National Health System (Ley 16/2003), which was adopted later, endorses in Article 4 (a) the right to choose a physician, which implies that the patient can get a second opinion in certain situations. In the same Article 4 (b), the law guarantees the receipt of medical care in the autonomous region where the patient resides, for the maximum prescribed time. In this regard, Real Decreto 605/2003 establishes the criteria, indicators, and minimum and general requirements for waiting periods for consultations, tests, and operations at the National Health System centers in order to guarantee uniformity and transparency of the information provided. Due to the fact that in Spain certain powers regarding health care are transferred to autonomous communities for the purpose of equitable distribution of powers, it is important to ensure patient rights in all territories. Therefore, attention is paid to the importance of

[117] Ley Orgánica 10/1995, de 23 de noviembre, del Código Penal. Boletín Oficial del Estado, 24 de noviembre de 1995, núm. 281, pp. 33987 a 34058, Art. 199.

cooperation between the Ministry of Health and the autonomous communities, in order to maintain quality and safety.[118]

Special legislation on patient rights exists in Switzerland too. However, due to the fact that the competence and responsibilities of health legislation falls to the cantons,[119] there are no laws at the federal level regulating the rights of the patient in everyday medical practice. The Swiss Constitution contains the general rules regarding the basic principles of protection of dignity, equality, life, mental and physical integrity, as well as privacy. Some provisions, especially regarding obtaining informed consent, are incorporated in the Swiss Civil Code (Code civil suisse, CCS). The Federal Act on the University Medical Profession also contains provisions on the rights of the patient, arising from the physician's very extensive duty to guarantee the rights of the patient, as well as the duty to respect professional secrecy.[120] In the absence of unity and centralization of provisions on the rights of the patient, it is only possible to identify a tendency on the basis of cantonal legislation, for example, in Geneva.

In 2006, the Canton of Geneva adopted the Health Act to promote and maintain the health of its residents, as well as respect for their dignity, freedom and equality in access to high-quality care.[121] This law outlined not only the rights of the patient, but also his/her obligations, which include cooperation with medical personnel by providing accurate health information, as well as compliance with the rules of the medical institution and respect for the physician (Article 40). In general, the list of rights guaranteed to the patient is similar to the rights listed in international documents and the national legislation of Spain.

Thus, in Switzerland the informed consent doctrine is relevant in tort and in contractual claims. If a treatment goes wrong and it is not possible to show that the patient agreed to this, the consequences for the physician can be dire, as any medical intervention that violates patient's bodily and/or mental integrity and, in principle, constitutes unlawful acts[122] which must be justified

[118] Ley 16/2003, de 28 de mayo, de cohesión y calidad del Sistema Nacional de Salud. Boletín Oficial del Estado, 29 de mayo de 2003, núm. 128, pp. 20567 a 20588, Arts. 60, 61.
[119] Constitution fédérale de la Confédération suisse du 18 avril 1999 (État le 7 mars 2021), Art. 3.
[120] Loi fédérale sur les professions médicales universitaires (Loi sur les professions médicales, LPMéd) du 23 juin 2006 (État le 1er février 2020), Art. 40 (c, f).
[121] Loi genevoise sur la santé (LS) du 7 avril 2006 (K 1 03), Art. 1.
[122] Code pénal Suisse du 21 décembre 1937 (État le 1er juillet 2021), Arts. 122ff.

by the consent of the patient according to Article 28 (2) CCS, and it is the physician[123] who must prove this justification and demonstrate that the patient's treatment decision was clear and informed.[124] Otherwise, the physician can be found liable even if the procedures were performed in compliance with rules of the medical art. The courts oblige physicians to communicate to their patients the diagnosis, therapy, prognosis, alternatives to proposed treatment, benefits, and risks as well as the financial aspects.[125] The scope and the timing (how early) the information is given depend on the nature and complexity of case and the treatment involved. Typically, it is one day before a simple procedure and at least three days before a major operation involving greater risks.[126] The right to receive information, stated in Article 45 of the Geneva Health Act, ensues from the provisions of Article 400 of the Swiss Civil Code on the mandate on which the relationship between physician and patient is based. Nevertheless, as in Spain, the right to hide or change information is reserved for the physician, for the benefit of the patient, in exceptional situations.

As such, there are no requirements for the form of expression of consent, and the written form is not a condition of validity and evidence of informed consent, except for certain situations provided by law. Various regulations governing specific issues of medical practice have been prescribed to obtain written consent for organ transplants,[127] participation in clinical studies,[128] and the conduct of pre-symptomatic genetic tests,[129] etc. As a result of autonomy and freedom of expression, consent may be withdrawn at any time prior to medical treatment, test, or surgery, regardless of the opinion of the physician.

An important component of the right to information is the ability to consult one's own medical file. The Geneva Health Act requires all medical professionals and institutions to file a medical dossier for each patient in order to ensure safety.[130] The medical file should include all information

[123] Code civil suisse du 10 décembre 1907 (État le 1er janvier 2021), Art. 8.
[124] TF 1P.71/2007 du 12 juillet 2007, c. 3.2.
[125] ATF 119 II 456 du 27 décembre 1993, c. 2.
[126] ATF 4P.265/2002 du 28 avril 2003, c. 5.2.
[127] Loi fédérale sur la transplantation d'organes, de tissus et de cellules (Loi sur la transplantation) du 8 octobre 2004 (État le 1er février 2021), Arts. 12 (b), 20.
[128] Loi fédérale relative à la recherche sur l'être humain (LRH) du 30 septembre 2011 (État le 26 mai 2021), Art. 16 (1).
[129] Loi fédérale sur l'analyse génétique humaine (LAGH) du 8 octobre 2004 (État le 1er janvier 2014), Art. 18 (3).
[130] Loi genevoise sur la santé (LS) du 7 avril 2006 (K 1 03), Art. 52.

relating to the patient, especially the history, research results, medical observation, and the proposed treatment options. This right, which derives from the provisions of the Swiss Constitution, Article 10 (2) on personal freedom and Article 13 (2) on the protection of privacy, is guaranteed by Article 8 of the Data Protection Act, being "the patient's absolute fundamental prerogative".[131] The patient can either consult his/her medical history or request a copy by means of a written request.[132] The right to access medical records is an absolute right, and its violation can result in disciplinary sanctions for the physician.

Based on values of patient autonomy, the importance of physician's professional secrecy is also emphasized in Swiss legislation.[133] Protection of patient right to the respect of his/her privacy, which includes medical information, falls under the scope of Article 28 CCS.[134] According to Article 28 (2) CCS, the disclosure of patient information is considered unlawful unless it is justified by his/her consent or by an overriding private or public interest or by law. In turn, the obligation of confidentiality is a typical obligation of a physician arising from his/her duty of loyalty envisaged by Article 398 (2) of the Swiss Code of Obligations (Code des obligations suisse, COS). The right of a patient to confidentiality of his/her information is so fundamental that it is even protected by penal law, providing for the possibility of imprisonment of up to three years or pecuniary penalty.[135]

1.2.5. Patient rights in common law countries

In the United Kingdom (UK), unlike in Spain and Switzerland, the patient rights have relatively recently acquired a systematic look and were outlined in a single document, where patients could familiarize themselves with the list and nature of such rights. Prior to the adoption of the Health Act of 2009, according to which the Secretary of State was to publish the NHS Constitution and the Handbook to the NHS Constitution in order to codify all types of patient rights,[136] the traditional patient rights were concentrated in the medical profession as such, as well as statutory

[131] Arrêt du TF 2P.202/2006 du 22 novembre 2006, c. 2.3.
[132] Ordonnance relative à la loi fédérale sur la protection des données (OLPD) du 14 juin 1993 (État le 16 octobre 2012), Art. 1
[133] Loi fédérale sur la protection des données (LPD) du 19 juin 1992 (État le 1er mars 2019), Art. 35.
[134] Büchler, A., & Gächter, T. (2011). *Medical Law in Switzerland.* Kluwer Law International, p. 97.
[135] Code pénal Suisse du 21 décembre 1937 (État le 1er juillet 2021), Arts. 320, 321.
[136] The Health Act 2009 (UK Public General Acts 2009 c. 21), Chapter 1.

requirements and judge-made law.[137] As for the consumer-based rights of patients, it is rather difficult to trace their development, especially prior to the establishment of the National Health Service (NHS), done so in England by the National Health Service Act of 1946, a year later in Scotland, followed by Northern Ireland and Wales.

The main goal of the NHS, as one of the results of the post-war social reform, was to provide all citizens with free and high-quality medical care. This is a publicly funded healthcare system which replaced a mixture of private, charitable, and local government provisions, where the ability to receive medical care directly depended on the patient's financial capacity. The principles of comprehensive, equal, and free-of-charge service underpin the functioning of the NHS along with other key principles that start the NHS Constitution for England. This document emphasizes the value of the patient and his/her dignity in healthcare system that seeks to provide care of the highest quality and professionalism. The principles and values listed at the beginning of the NHS Constitution are disclosed through the rights of patients and the responsibilities of medical workers, distributed according to their area of application, such as access to health care, equality, security, autonomy, informed choice, participation in the provision of treatment, and the complaint process. Particular attention is paid to the right to access to health care, namely its relation to the best distribution of medical resources. Therefore, the NHS Constitution uses the concept of an acceptable time period for assistance, and specific waiting periods for specific situations are listed in the Handbook to the NHS Constitution.[138]

The right to informed consent has undergone some changes in the UK law, yet the absence of patient's consent renders medical intervention an assault. A physician's general duty includes the obligation to inform the patient about inexorable risks. In England, for example, the right to be informed about a medical treatment or procedure is formulated in the NHS Constitution[139] and the Handbook to the NHS Constitution.[140] More detailed and practical information about the

[137] Townend, D., Clemens, T., Shaw, D., Brand, H., Nys, H., & Palm, W. (2016). *Op. cit.*, pp. 107-108.
[138] Department of Health and Social Care, Public Health England. (2015). *Handbook to the NHS Constitution for England*, p. 30. Retrieved October 13, 2019, from https://www.gov.uk/government/publications/supplements-to-the-nhs-constitution-for-england/the-handbook-to-the-nhs-constitution-for-england/
[139] Department of Health and Social Care. (2012). *NHS Constitution for England*, Section 3a. Retrieved October 13, 2019, from https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england/
[140] Department of Health and Social Care, Public Health England. (2015). *Handbook to the NHS Constitution for England*, pp. 54-55.

application of this right is explained on the NHS Choices website[141] and in the guidance of the General Medical Council (GMC)[142], where a clear distinction is made between the kind of information that is required to be shared with the patient, the decision-making process, and the expression and proof of consent. The physician is obliged to talk to the patient about various topics, especially about the diagnosis and prognosis, as well as uncertainties about them, the treatment options available, purpose and content of medical procedures, risks and benefits, and financial questions. As for the risks and complications, all serious adverse outcomes must be mentioned, even if they are very unlikely, as well as less serious adverse outcomes, if they are frequent.

As the list of matters that should be explained to the patient has not been defined adequately, the courts have accepted that, just in the case of treatment, the opinion of a respectable society of peers within the profession may be used to determine what should be disclosed, but if the patient asks a specific question, he/she is entitled to a truthful answer. This is due to the fact that the validity of the patient's informed consent was assessed by a legal test for the expected standard of care, which is based on the principle outlined in *Bolam v. Friern Hospital Management Committee*.[143] Pragmatically, the standard for consent was what a reasonable physician would want to reveal, as the Bolam test does not find negligence in a physician if his/her actions conform with what is accepted by a professional society. This practice, which was reconfirmed over 30 years ago,[144] did not entirely correspond to the modern principle of informed consent, since the amount of information received by the patient depended directly on the patient's awareness, and not on professional clinical judgment. Thus, the process of obtaining consent under English law was, until very recently, more about the fulfillment of physician's duty to provide the patient with information than respect for patient's autonomy.

This ruling was overturned in 2015 by the decision of the Supreme Court in *Montgomery v. Lanarkshire Health Board,*[145] which has redefined the standard for informed consent and disclosure, moving away from medical paternalism towards patient autonomy. This decision

[141] Retrieved October 13, 2019, from https://www.nhs.uk/conditions/consent-to-treatment/
[142] General Medical Council. (2020). *Decision making and consent*. Retrieved September 14, 2021, from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent/
[143] Bolam v. Friern Hospital Management Committee [1957] 2 All ER 118.
[144] Sidaway v. Board of Governors of the Bethlem Royal Hospital and others [1985] 871 AC.
[145] Montgomery v. Lanarkshire Health Board [2015] SC 11 [2015] 1 AC 1430.

rejected the application of the Bolan test to the informed consent and established a duty of care to warn about material risks, based on a patient-focused approach where special attention is paid to what risks are important for a particular patient, and not for the collective image of a reasonable patient.

Patients in the UK also have the right to privacy and confidentiality and may also expect the NHS to respect this right. However, due to the fact that the common law did not recognize privacy as a right, there is a distinction between privacy and confidentiality in medicine. This considerable difference is explained by the fact that the right to privacy was officially introduced by the Human Rights Act of 1998,[146] which has reinterpreted confidentiality in the light of the ECHR and ensured the development of common law in harmony with Articles 8 and 10 ECHR.[147] Thus, the duty to respect the confidentiality of the patient developed though the case law and is governed now by common law and various statutes.

For the first time, the common law duty to respect confidentiality was summarized in 1974 in the decision to *Hunter v. Mann*, confirming the obligation of the physician not to disclose information obtained in his/her professional capacity without the patient's consent.[148] Much later, in *Campbell v. Mirror Group Newspapers* the House of Lords recognized that medical information is "obviously private"[149] and its protection is directly related to ensuring autonomy and human dignity. These important court decisions underlie fundamental rights regarding the privacy and confidentiality with respect to patients' personal data, many of which are listed in the Constitution of the NHS and the Handbook. For example, the patient has the right to expect the NHS to ensure the safety and protection of confidential information, to know how and for what purposes this information is used, and also to demand the restriction of the use of this information only for care and treatment, etc.[150] This so-called "standard account" model of privacy rights[151] is also maintained in the GMC guide on confidentiality, where it advises physicians to receive in advance

[146] Townend, D., Clemens, T., Shaw, D., Brand, H., Nys, H., & Palm, W. (2016). *Op. cit.*, p. 111.
[147] Taylor, M. J., & Wilson, J. (2019). Reasonable Expectations of Privacy and Disclosure of Health Data. *Medical Law Review*, *27*(3), 432–460, p. 445.
[148] Boyle, C. (1975). Hunter v. Mann. *The Modern Law Review*, *38*(1), 69–72, p. 69.
[149] Campbell v. MGN Ltd [2004] UKHL 22 (6 May 2004).
[150] Department of Health and Social Care. (2012). *NHS Constitution for England*, Section 3a; Department of Health and Social Care, Public Health England. (2015). *Handbook to the NHS Constitution for England*, pp. 58-62.
[151] Taylor, M. J., & Wilson, J. (2019). *Op. cit.*, p. 433.

either implied or explicit consent from patients to disclose their personal information without breaching professional duties of confidence.[152] However, the nature of the implied consent seems to acquire vague borders in the realities of modern healthcare models.

One of the important rights, namely the right to access one's own medical information, had some obstacles in the development and recognition in the UK. Patients did not immediately receive this right, due to the fact that for a long time it was believed that the medical records belonged to the physician, and the patient had to be protected from information full of professional jargon and data.[153] Today, patients are presumed to have access to their health records and expected to correct inaccuracies.[154] Limited exceptions to this right are listed in the Handbook, the main type of which is when the information includes data about another person, or for the purpose of therapeutic privilege.[155] The way how medical records should be created and kept, how the patients can request their access, and the deadline for receiving a response are governed mostly by the Data Protection Act of 2018, which enacted the new requirements of the GDPR.

In the United States (U.S.), the current law governing health care, especially medical malpractice, has its roots in English common law, and in its fundamental principles, is very close to systems in continental Europe. Relations in the field of medical care are built on the basis of the same principles as respect for honor and dignity, privacy, choice, and autonomy. The U.S. laws seek to protect patient's bodily integrity and guarantees the patient to receive all information about the nature of recommended procedures. Material information includes the procedure's risks, its necessity, and alternative treatments based on expectation of a reasonable patient, unlike the Swiss approach of determining the amount of information based on needs of a specific patient. This "reasonable person" standard was established as a landmark for malpractice cases in 1972 in the *Canterbury v. Spence* case decision,[156] which also illustrated that the right to informed consent gained an important position among patient rights. This approach was reminiscent of the one that until recently existed in English law. Nonetheless, the informed consent in the U.S., as well as in

[152] General Medical Council. (2017). *Confidentiality: Good Practice in Handling Patient Information*. Retrieved October 13, 2019, from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality/
[153] Townend, D., Clemens, T., Shaw, D., Brand, H., Nys, H., & Palm, W. (2016). *Op. cit.*, p. 111.
[154] Department of Health and Social Care. (2012). *NHS Constitution for England*, Section 3a.
[155] Department of Health and Social Care, Public Health England. (2015). *Handbook to the NHS Constitution for England*, p. 57.
[156] Canterbury v. Spence, 464 F 2d 772, 786 (DC Cir 1972).

Switzerland, is rooted in constitutional rights to privacy and property, while under English law this right lacks such constitutional background.

Even though healthcare law is at the same time under federal authority and the authority of individual states, its framework has been established through court decisions and legal requirements across the country demanding that, in general, the same conditions are contained. One of the major federal laws, which affected both physicians and patients, is the Health Insurance Portability and Accountability Act (HIPAA) of 1996. It created certain policies and procedures for security of health information, described numerous offenses related to medical care, and imposed civil and criminal penalties. The HIPAA Privacy Rule, composed of national regulations, governs the use and disclosure of protected health information, including the patients' right to receive access to their own medical data. According to its provisions, individuals have the legal right to review and, upon request, receive copies of information in any medical records kept by healthcare providers and in health plans. The law sets out a list of data that a healthcare provider must maintain and which a patient can access,[157] at the same time indicating the types of data which is excluded from the access.[158] The patient can request, for example, financial statements, laboratory test results, medical images, recovery and disease control program files, and notes about patient's own clinical case. If the provisions of the laws of individual states are more favorable in this matter, they continue to apply regardless of the HIPAA provisions.

1.3. Interim conclusion

Based on a historical analysis, it can be concluded that the very first attempts to provide patients with any rights were limited to a guarantee of medical care of a certain level of quality, albeit not high, but in accordance with the time. This met the needs of the respective epochs when medicine was in its infancy and it was difficult to provide effective and, most importantly, the safest possible treatment. The first normative acts primarily ensured, in an indirect manner, the right to life and health, without directly securing or guaranteeing them. With the understanding that honor and dignity are inherent in a person and that respecting them is as important as the protection of life or health, the need to protect them in the field of medicine has risen. Initially, in the absence of legal

[157] 45 CFR § 164.501 (2002).
[158] *Ibid.*; 45 CFR § 164.524(a)(1)(i), (ii).

defense mechanisms, guaranteed only by the professional ethics of the physician and his professional respect, the right to medical confidentiality thus became one of the first rights guaranteed to the patient.

As such, the history of medical privacy spans three thousand years. Despite a certain superficiality of this guarantee, dependence on the subjective discretion of the physician, the absence of responsibility as such, the importance of keeping information about the patient secret has passed as a red thread over centuries at all major stages of the development of medicine. At the beginning of its development, it would be more appropriate to talk about medical privacy as something associated to physician's secrecy, rather than medical confidentiality. The appearance of the latter can be judged with the development of science and health care, when the circle of individuals who have access to the patient and his/her information has widened significantly, and the obligation to protect it has passed from physician to court. While this phenomenon developed quite slowly over the centuries, huge strides have been made in recent decades, not without the influence of the revolution in the field of information and communications technology as well as the development and introduction of new technologies in medicine, which gave access to more sensitive information about patients.

Medical secrets, as a type of professional secrecy, are an integral part of the right to privacy, a value guaranteed by constitutions, numerous laws, and regulations. Privacy, which is part of the foundation for the protection of human dignity, allows people to create a barrier against unwanted interference with life. Along with enhanced protection of patient autonomy and emphasizing the importance of informed consent, modern legal systems pay no less attention to protecting the privacy of people, including in the context of the provision of medical services. Such stir about medical information is directly related to the peculiarity and volume of this information, as well as the serious risks to which a patient can be exposed if it is disclosed.

2. RIGHT TO PRIVACY

2.1. Dignity and medical secret

2.1.1. Concept of human dignity

The history of the development of human rights in general and patient rights in particular has revealed their strong connection with the concept of dignity. The concept of dignity has become widespread and repeatedly stands out in fundamental human rights literature, declarations and conventions, legislations and jurisprudence, political and religious statements,[1] especially in the context of condemning variety of mixed types of activities said to be degrading human dignity.[2] In bioethics, the concept of dignity is very powerful, being the apple of discord between science on the one hand and ethics on the other by restricting or even prohibiting medical research or practice, such as cloning, genetic modifications, and reproductive technologies. In spite of this, no one legal document sufficiently explains what is meant by human dignity. Such a frequent, and sometimes even redundant use of this term is not followed by a clear interpretation, leaving its content to be a subject to controversial theories and disagreements. The vague nature of this idea originates in its complexity and long history.[3]

The etymological analysis of the word dignity reveals the evolution of the very concept from primarily social value to constitutional. Even though the term human dignity is relatively new and, as a standing phrase, has been used for only around two hundred years, the idea itself has much longer history.[4] Its emergence and early use date back before the Kantian model. Initially, the term *dignitas* was used by Ancient Greeks and Romans and implied a special position of a person in social subordination, putting some individuals above others. Grammatically, this term was used more as an adjective to describe one who is deserving,[5] than as a noun denoting quality or moral concept. People with high social status were considered worthy or decent and therefore earned

[1] Lusting, B. A. (2013). Dignity in the Discourses of Bioethics. *Soundings: An Interdisciplinary Journal*, *96*(3), 297–314, p. 297.
[2] Ashcroft, R. E. (2005). Making Sense of Dignity. *Journal of medical ethics*, *31*(11), 679–682, p. 679.
[3] Barak, A. (2015). *Human Dignity: The Constitutional Value and the Constitutional Right*. Cambridge: Cambridge University Press, pp. 3-4.
[4] Spiegelberg, H. (1971). Human Dignity: A Challenge to Contemporary Philosophy. *World Futures: The Journal of New Paradigm Research*, *9*(1-2), 39–64, p. 42.
[5] Valls, R. (2005). El concepto de dignidad humana. *Revista de Bioética y Derecho*, *5*. Retrieved October 21, 2019, from http://www.bioeticayderecho.ub.es/

respect. Elevated to the attribute of social status, dignity belonged only to representatives of high classes of society with appropriate behavior, merits, duties and responsibilities, and appeared being a synonym for honor to the extent that it embraced its elitist concept.[6] This basic characteristic of the idea of dignity made it possible to apply this term also to public officials, suggesting that a person was worthy to be appointed to this post.[7] According to this structure, the idea of dignity aimed to establish hierarchic differentiations based on social, political, military or administrative achievements.

Amid this anti-egalitarian spirit, one can find appeals to the *dignitas hominis* imputed to all people *per se*, due to the superior mind of human beings against the lower beasts and their standing in the cosmic order. It was the Stoics who first developed this understanding.[8] Thus, in Cicero's works, influenced by stoicism, this interpretation coexists with the aspiration of specific virtues. Even though some hints of movements towards natural rights can be found here, in the Universe as seen by Ancient Greeks and Romans, individuals were equal only in relation to the gods, as they share the power of reason, and in relation to animals, but not among each other. This is why this Cicero's emphasis did not exclude the aspiration of ranks and merits as components of dignity obtained and respected by justice.

The concept of human dignity in the ancient sense is difficult to define. In Cosmo-centric ancient philosophy, the value of people was considered directly proportional to their ability to dominate both their passions and the unreasonable part of the soul. Human dignity was seen as a virtue, expressing the improvement of personal qualities, or one's own moral effort. Since, in accordance with nature, such moral superiority was one of the necessary conditions for possessing human dignity, it can also be considered a necessity, but not the only criterion for determining the concept of dignity in those times.[9]

Early Christianity grasped the Stoic views and equalized all people in dignity by interpreting it as reflection of the dignity of God. However, the term human dignity has so far been used extremely

[6] Lusting, B. A. (2013). *Op. cit.*, p. 302.
[7] Valls, R. (2005). *Op. cit.*
[8] Bayertz, K. (1996). Human Dignity: Philosophical Origin and Scientific Erosion of an Idea. In K. Bayertz (Ed.), *Sanctity of Life and Human Dignity* (pp. 73-90). Kluwer Academic Publishers, p. 73.
[9] Lebech, M. (2004). What is Human Dignity? In M. Lebech (Ed.), *Maynooth Philosophical Papers* (pp. 59–69). Maynooth: Maynooth University Press, p. 66.

rarely. For example, Thomas Aquinas used it only once, as did Cicero.[10] Particular importance was then given to the relationship between man and God as an asymmetric recognition. According to Aquinas, having dignity depended on the nature of the human mind and free will. In other words, human dignity lies in the ability of a person as the sole possessor of the will to spiritually awaken and pursue the true knowledge of God. This did not include an arbitrary moment, but should have happened for a rational reason, since a rational and free person is the author of his/her actions. Therefore, dignity implied freedom of choice as a characteristic of human nature and responsibility for any decision made.

However, human dignity was to some extent understood destructible as people could lose their dignity if they deviate from the rational order due to sin, and then regain it in redemption. This sinfulness of humans resulting from their free will, on the one hand, and the ability of the human soul to resist sin through divine grace, on the other hand, were the main components of the idea of human dignity. In the theology of Middle Ages, human dignity was considered not as an independent category, but was seen as a reflection of the transcendental world and was deduced from man's special relation to God.

The philosophy of the Renaissance reconciled these old views in the light of separation from the theological beliefs.[11] The idea of dignity comes from a completely new concept of the person and his/her place in the world. Humanism brought forth the ideas about the unlimited possibilities for the development of human personality, whereas previously the person was never considered outside the relationship of natural and social cosmos or divine predestination. In the era of Enlightenment, when theological postulates lost their argumentative value after the Reformation and religious wars, the new worldview attempted to explain everything through Reason. It was during these times when the phrase "dignity of man", in English, and its equivalents in other languages began to be used as such.[12] Even though it had already appeared in the works of humanists of the Renaissance, the concept of dignity began to be freed from its class meanings and social evaluations and continued to be regarded by philosophers as an external rather than internal value, or as a price set on a person by society. Against this background, Kant developed his notion

[10] *Ibid*.
[11] Bayertz, K. (1996). *Op. cit.*, pp. 73-74.
[12] Spiegelberg, H. (1971). *Op. cit.*, p. 42.

of dignity as foundation of the moral relationship of humanity, bringing to its logical conclusion the ideas of Renaissance humanism. Finally, the term dignity is entrenched in use as a substantive, and not just as an adjective.[13]

Currently, there are four tendencies in understanding the theoretical concept of dignity with regard to bioethics.[14] The first group includes those who are skeptical about discussing this concept, or even consider it useless.[15] Nevertheless, the critics try to tidy up the use of the word "dignity" and bring it down to other moral or evaluative characteristics without calling the word itself meaningless as this incredulity is directed more to dignity-based theories than to dignity as such.[16] This idea they share with another group that bases its arguments to some extent on Kant's morality, reducing the definition of dignity to autonomy. The difference is that the representatives of the second group still believe in the "illuminating" way to use the concept of dignity to some extent.[17] The third group reveals this concept through such notions as abilities, functions, and social interactions. Finally, the fourth group, which represents the mainstream in European bioethics, views dignity as a metaphysical property that all people possess.[18]

In turn, leaving aside skeptical views and considering the third group as halfway between the other two models, all these four groups of different views can be divided into two main ones: the first is based on autonomy, and the second – on metaphysics, which seem contradictory and mutually exclusive.[19] Inconsistency in the choice between these two concepts can lead to confusion regarding very important modern bioethical issues.[20]

A significant contribution to the development of the first concept was made by Kant, according to whom dignity is quantitatively inexpressible and intrinsic to any human being and is grounded in

[13] Valls, R. (2005). *Op. cit.*
[14] Ashcroft, R. E. (2005). *Op. cit.*, p. 679.
[15] *E.g.*, Macklin, R. (2003). Dignity Is a Useless Concept. *BMJ (Clinical research ed.)*, *327*(7429), 1419–1420; Pinker, S. (2008). The Stupidity of Dignity. Conservative Bioethics Latest, Most Dangerous Ploy. *The New Republic*, *238*(9), 28–31.
[16] Ashcroft, R. E. (2005). *Op. cit.*, p. 679.
[17] *Ibid*.
[18] *Ibid*.
[19] García Manrique, R. (2009). La dignidad y sus menciones en la Declaración. En M. Casado (Coord.), *Sobre la dignidad y los principios. Análisis de la Declaración Universal sobre la Bioética y Derechos Humanos de la UNESCO* (pp. 41-64). Navarra: Civitas-Thomson Reuters, p. 48.
[20] *Ibid.*, p. 50; Valls, R. (2005). *Op. cit.*

the ability of human beings to have a rational morality, implying that all people are morally self-determined and able to establish and follow their moral laws. However, this concept faces some challenges in the light of regulatory application. The first problem is related to a different understanding of autonomy. On the one hand, since not everyone possesses same level of self-awareness, it appears that those with substantially limited or even absent autonomy cannot bear human dignity and human rights in part or in whole.[21] On the other hand, Kant rejected the definition of human dignity in concrete biological, social or psychological moral actions and the real ability to perform them, but instead saw it as a transcendent quality to morally develop.[22] This concept pays greater attention to the definition of morality, as well as to the contemplation of dignity as a universal human ability to act morally, which, of course, cannot be possessed by all people equally, which makes this concept not suitable enough for practical application in human rights legislation.[23]

The second problem here lies in liberal theories of equality,[24] which imply respect for autonomy, regardless of any concept of a good life and what gives value to life.[25] Without an external criterion, it is impossible to assess whether a particular person made the right or wrong decision; accordingly, it is impossible to understand whether he/she has such an ability to make decisions, that is, autonomy.[26] The understanding of dignity as a basis against the instrumentalization of an individual led to the reduction of this concept to autonomy, which is a clear simplification, especially for legislative purposes and in the field of bioethics, but this does not indicate the flaw of the concept.

The concept of "autonomous dignity" is opposed by the concept of "heteronomous dignity", which prescribes worth based on the place occupied by people in the general order of the world.[27] However, the most common version of this concept, presented by the Catholic doctrine, also cannot serve as the basis for legal documents such as constitutions and UNESCO Universal

[21] García Manrique, R. (2009). *Op. cit.*, p. 50.
[22] Rothhaar, M. (2010). Human Dignity and Human Rights in Bioethics: The Kantian Approach. *Medicine, health care, and philosophy*, *13*(3), 251–257, p. 254.
[23] García Manrique, R. (2009). *Op. cit.*, pp. 51-53.
[24] *Ibid.*
[25] Dworkin, R. (1978). Liberalism. In S. Hampshire (Ed.), *Public and private morality* (pp. 113-143). Cambridge: Cambridge University Press, p. 127.
[26] García Manrique, R. (2009). *Op. cit.*, p. 53.
[27] Valls, R. (2005). *Op. cit.*

Declaration on Bioethics and Human Rights, due to its irrational nature.[28] Nevertheless, this idea is also supported by other secular concepts of Aristotelian roots and teleological nature, as they argue that the current and potential way of human existence is part of the general order, and not established by the person himself/herself.[29] This means that, in linking the concept of human dignity with the concept of moral autonomy, it is nevertheless necessary to take into account the external criteria of good for assessing the significance and value of this autonomy.[30] Dignity is associated not only with the value of each individual person, but also with the attitude of others towards it, which means that in addition to the individual dimension, it has a public one. Thus, autonomy is a very important, but not the only criterion in determining dignity.[31]

Dignity is an important personal and social value that has the potential to address many of today's complex ethical dilemmas. As the approach to understanding the concept of dignity in different countries may still differ, which inevitably affects national lawmaking and the implementation of international conventions, it is very important to have a consensus about the contextual meaning used in international declarations and guidelines in order to make sure that the laws align.[32] Although this concept still seems vague and arbitrary, it is important to consider all existing concepts not as contradictory and mutually exclusive, but as interconnected and penetrating.

2.1.2. Privacy as a facet of dignity of human being

Along with the concept of dignity, scholars pay a lot of attention to the right to privacy, which represents one of the most pressing legal issues today. Reflections on privacy are as old as humanity itself, since privacy is a natural part of human life. Over time, its significance in the world changed, as did the concept of what should be considered private. Under modern circumstances, it has become not only a basic desire, but also an indicator of the development of society and a sign of a democratic state. Many legal systems provide privacy protection, but there is still no consensus on the core of the concept of privacy and what specifically requires protection.

[28] García Manrique, R. (2009). *Op. cit.*, pp. 53-54.
[29] *Ibid.*
[30] *Ibid.*
[31] Wolbert, W. (1998). The Kantian Formula of Human Dignity and its Implications for Bioethics. *Human Reproduction & Genetic Ethics*, *4*(1), 18–23.
[32] Horn, R., & Kerasidou, A. (2016). The Concept of Dignity and Its Use in End-of-Life Debates in England and France. *Cambridge quarterly of healthcare ethics: the international journal of healthcare ethics committees*, *25*(3), 404–413, p. 411.

Thus, often used in the sense of solitude, concealment from external control and exposition, or individual's sphere of vital interests, functions and emotions isolated from public spheres, privacy is a rather complex value, piled with conflicting meanings, which requires careful study.

Despite such a long history, the first legal analysis of the right to privacy was presented only by the end of the XIX Century, when, by reference to the judge Cooley who proclaimed the right to privacy as a "right to be left alone", the U.S. lawyers Samuel Warren and Louis Brandeis formulated a doctrine of this right based on common law precedents back in 1890.[33] Referring to the function of the law to respond to political, social, and economic changes in society, they demanded the right to privacy to be recognized as a separate right that protects emotional suffering rather than property, as opposed to the threat posed by technological development and gossip.[34] The "right to be left alone", the principle of which was the inviolability of the person, was mainly to provide protection against unwanted disclosure of private facts.[35] It ultimately influenced the development of American law and judicial practice, led to attempts to define the concept of private life, and also served as the impetus for the formation of the right to privacy in Europe. Thus, it was then that the modern concept of the right to privacy began to take shape, and since then it began to develop and became widely known and recognized as a fundamental human right.

Today, the analysis of legal literature and cultural differences allows to distinguish two fundamental – and at first glance quite incompatible – points of view on the conceptualization of privacy,[36] including its legal nature and significance for the individual, society, and the state. According to this, one concept connects privacy to dignity, and the second – to freedom, leaving aside all other concepts, which do not relate to the issue of privacy,[37] to fall outside the scope of this classification or represent a certain kind of addition. It is the contrast of these two models, the first of which has become widespread in Europe, when the second founded American views about private violations, that underlies the differences in understanding and regulation of the right to

[33] Warren, S. D., & Brandeis, L. D. (1890). The Right to Privacy. *Harvard Law Review*, *4*(5), 193–220, pp. 195-197.
[34] *Ibid.*
[35] Bratman, B. E. (2002). Brandeis and Warren's The Right to Privacy and the Birth of the Right to Privacy. *Tennessee Law Review*, *69*, 623–651, p. 644.
[36] Whitman, J. Q. (2004). The Two Western Cultures of Privacy: Dignity Versus Liberty. *Yale Law Journal*, *113*, 1151–1221, pp. 1153-1160.
[37] Post, R. C. (2000). Three Concepts of Privacy. *Georgetown Law Journal*, *89*, 2087–2098, pp. 2087-2090.

privacy.[38] Moreover, the result of such differences was a set of rights associated with and arising from the right to privacy.

It appears that in European legal systems, fundamental privacy rights include right to one's image, name, reputation, and to informational self-determination, etc.[39] For this reason, privacy can be seen as control over personal information[40] or a claim to restrict others from accessing it.[41] A common characteristic of these rights is the ability to manage one's own likeness, presented to the public; in other words, they are closely related to personal identity. This personal identity is interpreted through the concept of personal life[42] and falls under Article 8 ECHR, which protects and ensures respect for an individual's personal space. In turn, by protecting personal life, personal autonomy can be observed and the general principle of respect for autonomy can be expressed through a more specific provision on respect for the privacy of others.[43] If the features of the public sphere are openness and publicity and it belongs to all members of society, then the key characteristic of privacy is individuality, where a person can develop trusting relationships and project himself/herself to a variety of possible futures.

Such planning of own life requires a concept of self as empowered to determine future actions according to intentions.[44] The ability to make decisions independently involves an awareness of moral right to create own destiny. It is possible to function autonomously only when one is aware that they are in charge of their own life.[45] If the surrounding reality does not belong to that person, then it becomes impossible for this person to make a choice and bear responsibility for it. Therefore, if autonomy is a critical criterion for dignity, depriving an individual of this opportunity leads to encroaching on his/her dignity.

[38] Whitman, J. Q. (2004). *Op. cit.*, pp. 1160-1161.
[39] *Ibid.*
[40] Fried, C. (1968). Privacy. *The Yale Law Journal*, *77*(3), 475–493, p. 482.
[41] Westin, A. F. (2003). Social and Political Dimensions of Privacy. *Journal of Social Issues*, *59*(2), 431–434, p. 431.
[42] Goodwin v. United Kingdom [2002] ECHR (App. No. 28957/95), para. 90.
[43] Ebbesen, M., Andersen, S., & Pedersen, B. (2013). Further Development of Beauchamp and Childress' Theory Based on Empirical Ethics. *Journal of Clinical Research & Bioethics*, *3*, 1–7, p. 2.
[44] Kupfer, J. (1987). Privacy, Autonomy, and Self-Concept. *American Philosophical Quarterly*, *24*(1), 81–89, pp. 81-83.
[45] *Ibid*.

On the other hand, invasion of privacy can constitute "an intrinsic offense against individual dignity",[46] when it causes harm to a person regardless of any potential negative consequences.[47] In this sense, some authors oppose the offense against individual dignity to the offense against individual autonomy, explaining it by referring to the personal nature of autonomy and social nature of dignity.[48] However, in this case it is rather a matter of two contrasting aspects of dignity, rather than two opposite concepts. In this way, the connection between privacy and dignity is also seen through the social aspect of the concept of dignity, suggesting that privacy is a social form of respect. Yet, this does not equate the concept of privacy with the concept of dignity, but suggests it is an integral component, along with moral autonomy. Privacy acts as the social boundary necessary to conceive self-worth and self-esteem, as it affirms and assures a person to pursue his/her own choices. Thus, privacy is a special kind of social practice that unites people with common norms of behavior that determine the forms of their social interactions, but differ in different societies and cultures, as well as social structures.[49] Such understanding of privacy, as a shield protecting against public indignity, is more specific to continental legal systems, since in Europe the respect of dignity has always been given central importance than in the United States, where liberty, especially from the state, is considered a more important value.[50]

In the U.S., the most important right in the context of privacy is the right to freedom from intrusion by the state, especially in the context of one's own home,[51] where it should be possible to take off a social mask without trying to meet someone's expectations. Although the right to privacy is not explicitly provided in the U.S. Constitution, it can be found in liberty interests protected by the Fourteenth Amendment.[52] The purpose of privacy is to ensure freedom that would be unattainable in denial that people behave differently in public and in private.[53] The understanding of privacy as freedom is almost opposite to the concept of privacy as dignity, since it envisages certain freedom from social norms, as well as implying that people are quite autonomous, and not limited by

[46] Rosen, J. (2000). *The Unwanted Gaze: The Destruction of Privacy in America*. New York: Random House Inc., p. 19.
[47] Post, R. C. (2000). *Op. cit.*, p. 2092.
[48] *Ibid.*; Rosen, J. (2000). *Op. cit.*, pp. 12-17.
[49] Post, R. C. (2000). *Op. cit.*, p. 2093.
[50] Whitman, J. Q. (2004). *Op. cit.*, p. 1161.
[51] *Ibid.*
[52] U.S. Const. amend. XIV, § 1.
[53] Rosen, J. (2000). *Op. cit.*, p. 12.

imposed socialization.[54] This contrast is explained by the fact that privacy as an attribute of dignity protects the social aspects of a person, while privacy associated with freedom protects purely individual aspects of the personality, that is, autonomy.[55] However, this argument builds on the narrow and flawed concept of human dignity seen as respect, and for this reason needs to be challenged.

This concept does not consider that human dignity is possible without autonomy, and if privacy as freedom is aimed at protecting autonomy, then it thereby correlates with dignity. Of course, privacy can express and ensure freedom, but assuming that freedom is inherent in people by their nature, as well as dignity, limiting freedom by invading personal space also humiliates human dignity. Instead of contrasting the abovementioned concepts, it is worthy to try and discern aspects of privacy within the same concept. If we consider privacy as a structure, as previously proposed, or as an environment that ensures a person the respect for his/her dignity, then we could distinguish between the two aspects related to two main aspects of dignity – "inner privacy" as a guarantee of autonomy, and "outer privacy" as a guarantee of a social element of dignity. The right to privacy cannot be considered in isolation from socialization, as that would undermine its significance, since it is through critical analysis of the imposed norms that the frontiers of personal space are outlined. This conclusion can also be deduced from the premise that the general principle of privacy should be based on the more general principle of respect for personhood,[56] when person, in turn, is a concept developed to reflect the social nature of human. Moreover, the concept of privacy in the form of freedom implies rather legal freedom, or freedom from the state,[57] but such freedom is even more imposed and limited than social norms in order to bind the right to privacy to it.

In the present day, the concept of privacy as freedom is becoming more widespread, even in Europe, which can be seen even in the classification of rights in the Charter of Fundamental Rights of the European Union[58], which classifies the right to privacy and the protection of personal data as

[54] Post, R. C. (2000). *Op. cit.*, pp. 2094-2096.
[55] *Ibid.*
[56] Benn, S. (2007). Privacy, Freedom and Respect for Persons. In F. D. Schoeman (Ed.), *Philosophical Dimensions of Privacy: An Anthology* (pp. 223-244). Cambridge: Cambridge University Press, p. 228.
[57] Post, R. C. (2000). *Op. cit.*, p. 2096.
[58] European Union. (2010). Charter of Fundamental Rights of the European Union. *Official Journal of the European Union C83* (Vol. 53, p. 380), Chapters I, II.

freedom rather than dignity. Nevertheless, despite the fact that the privacy law is not the product of logic and is rather the result of immediate needs of a particular society, it must be borne in mind that the main value underlying the concept of human rights is human dignity. This contrast between the so-called continental and U.S. concepts has already worn itself out, since human dignity is no longer determined by social status, and its definition is intended for more basic and universal use, which even the right to freedom results from. Through this, we can see that the concept of privacy on either side of the Atlantic are less contradictory than their interpretations are. In any case, the right to privacy is not the same as the right to respect for dignity. The right to privacy in its general sense is rather a global term for components of life with dignity, or a kind of ability to preserve human dignity.

2.1.3. Scope of privacy and private life in doctrine and legislation

This deep-rooted commitment to dividing the privacy into the aforementioned concepts, along with very broad definition and language differences and nuances of translation defined the inconsistent use of the terms right to privacy, right to private life and right to intimacy, especially in non-English language literature and legislation. Thus, Article 8 ECHR refers to the right to respect for private life in the English version, which is translated identically in the French *(droit au respect de la vie privée)* and Spanish *(derecho al respeto de la vida privada)* versions of the Convention. Article 7 of the Charter of Fundamental Rights of the European Union uses the same translation in all three languages. A different situation occurs when comparing Article 17 ICCPR and Article 12 UDHR in their English, French and Spanish versions respectively. The English texts of these documents mentions the right to the protection against any interference with privacy, when French *(immixtions dans la vie privée)* and Spanish *(injerencias en la vida privada)* versions still refer to the protections of private life.

The ECtHR has explained that it is impossible to give an exhaustive definition to the private life,[59] which is not limited only to the "inner circle" of one's personal life, but also extends to their social interactions[60] and even professional activities.[61] The main purpose of such protection is to provide

[59] Peck v. UK [2003] EHRR 287 (App. No. 00044647/98), para. 57; Pretty v. The United Kingdom [2002] ECHR 423 (App. No. 2346/02), para. 61; Niemietz v. Germany [1992] ECHR 80 (App. No. 13710/88, A/251-B), para. 29.
[60] Botta v. Italy [1998] ECHR 12 (Application No. 21439/93), para. 32.
[61] Fernández Martínez v. Spain [GC] [2014] ECHR 615 (App. No. 56030/07), para. 110.

a guarantee that each person can evolve, develop his/her personality and build relationships with others without external interference.[62] However, even if such personal relationships with others can expand into public context, this does not make them public in nature.[63] According to the Convention organs, it would be unreasonable to define the right to privacy for the reason that it would impede the development of the concept of what personal interests include, and would significantly limit the protection of certain types of activities that would appear beyond any possible clear definition.[64] The ECtHR determined that the right to respect for private life covers a much wider range of relationships than the concept of the right to privacy, used in the meaning of the concept of being left alone.[65] In this interpretation, the right to respect for private life seems to comprise similar situations as the right to privacy in general sense, including issues concerning psychological, physical and moral integrity, [66] reproductive rights,[67] end of life,[68] forced medical care and mental illnesses,[69] sexual orientation and sexual life,[70] right to image and photographs,[71] defamation and protection of reputation,[72] access and control over own information,[73] including health information, [74] surveillance, [75] identity and autonomy, [76] religious and philosophical convictions,[77] etc.

[62] Niemietz v. Germany [1992] ECHR 80 (App. No. 13710/88, A/251-B), para. 29.
[62] Botta v. Italy [1998] ECHR 12 (Application No. 21439/93), para. 32.
[63] Council of Europe. (2018). *Guide on Article 8 of the European Convention on Human Rights – Right to respect for private and family life, home and correspondence*, pp. 20-21. Retrieved November 15, 2019, from https://www.echr.coe.int/Documents/Guide_Art_8_ENG.pdf/.
[64] *Ibid.*
[65] X v. Iceland [1976] ECHR 7 (App. No. 6825/74), para. 87.
[66] Glass v. UK [2004] 39 EHRR 15 (App. No. 61827/00), para. 74-83.
[67] Evans v. The United Kingdom [GC] ECHR 2007-I (App. No. 6339/05), para. 71.
[68] Pretty v. The United Kingdom [2002] ECHR 423 (App. No. 2346/02), para. 67; Haas v. Switzerland [2011] ECHR 2422 (App. No. 31322/07), para. 51-52.
[69] Shtukaturov v. Russia [2008] ECHR (App. No. 44009/05), para. 94-96.
[70] Burghartz v. Switzerland [1994] ECHR 2, 47 EHRR 38 (App. No. 16213/90), para. 24.
[71] Peck v. UK [2003] EHRR 287 (App. No. 00044647/98), para. 57-63.
[72] Polanco Torres and Movilla Polanco v. Spain [2011] ECHR 2415 (App. No. 34147/06), para. 40.
[73] Kopp v. Switzerland [1998] 27 EHHR 93 (App. No. 23224/94), para. 53.
[74] Roche v. The United Kingdom [2005] ECHR 956 (App. No. 32555/96), para. 167.
[75] Halford v. The United Kingdom [1997] 24 EHRR 523 (App. No. 20605/92), para. 44.
[76] Pretty v. The United Kingdom [2002] ECHR 423 (App. No. 2346/02), para. 61; Niemietz v. Germany [1992] ECHR 80 (App. No. 13710/88, A/251-B), para. 29.
[77] Folgerø and Others v. Norway [GC] ECHR 2007-III (App. No. 15472/02), para. 98.

The same point of view about the definition of privacy was supported by the UN Human Rights Committee.[78] In *Coeriel et al. v. The Netherlands*, the Committee reached the same conclusions about the scope of right to privacy under the ICCPR as did the ECtHR.[79] Taking this consensus into account, the right to private life and the right to privacy in different versions of translation of Article 17 ICCPR should mean the same thing in all three mentioned languages. However, analysis of national legislation reveals the use of other terms. For example, while the French versions of Swiss laws[80] confirm the same wording of this right as in the French versions of international documents, majority of Spanish laws[81] prefer another term *(derecho a la intimidad)*, except for the new Ley orgánica 3/2018 adopted to adapt the EU GDPR to Spanish legislation where the word privacy *(privacidad)* is used.

On the one hand, this terminological diversity can be explained by the fact that "privacy" is a loaned word coming from the English language, along with the concept of privacy and, according to dictionaries, is indeed translated as *intimidad* or *vida privada*. To a greater extent, the word privacy is used in the doctrine, rather than in legislation. This does not prevent the ECtHR from referring to Article 18 of the Spanish Constitution when ruling out the cases against Spain under Article 8 ECHR, equating these concepts.[82] On the other hand, the semantic content of these words is not the same, which represents a serious problem. This problem does not remain at the dictionary level but can lead to confusion regarding the scope of the right to privacy and its protection.

[78] United Nations Human Rights Committee. (1988). CCPR General Comment No. 16: Article 17 (Right to Privacy), The Right to Respect of Privacy, Family, Home and Correspondence, and Protection of Honor and Reputation. Retrieved November 5, 2019, from https://www.refworld.org/docid/453883f922.html/

[79] United Nations Human Rights Committee. (1994). Coeriel et al. v. The Netherlands, Communication No. 453/1991, UN Doc CCPR/C/52/D/453/1991, (1994) 2 IHRR 297, IHRL 2250, para. 10.2.

[80] Constitution fédérale de la Confédération suisse du 18 avril 1999 (État le 7 mars 2021), Art. 13; Code pénal Suisse du 21 décembre 1937 (État le 1er juillet 2021), Art. 173.

[81] Constitución Española. Boletín Oficial del Estado, 29 de diciembre de 1978, núm. 311, pp. 29313 a 29424, Art. 18; Ley 14/1986, de 25 de abril, General de Sanidad. Boletín Oficial del Estado, 29 de abril de 1986, núm. 102, pp. 15207 a 15224, Art. 10; Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Boletín Oficial del Estado, 15 de noviembre de 2002, núm. 274, pp. 40126 a 40132, Art. 7; Ley Orgánica 10/1995, de 23 de noviembre, del Código Penal. Boletín Oficial del Estado, 24 de noviembre de 1995, núm. 281, pp. 33987 a 34058, Arts. 197ff.

[82] *E.g.*, Polanco Torres and Movilla Polanco v. Spain [2011] ECHR 2415 (App. No. 34147/06); Moreno Gómez v. Spain [2005] 41 EHRR 40 (App. No. 4143/02).

The RAE dictionary[83] (DRAE) emphasizes the inner spiritual zone that belongs to a person or group, especially the family in the definition of intimacy *(intimidad)*. The adjective *íntimo* comes from the Latin word *intimus*, meaning secret or located in the depths. Now this etymological meaning seems to underlie the different uses of this word in Spanish language. According to the same source, privacy *(privacidad)* is understood as a sphere of private life, which is kept safe from interference, and is associated with the concept of private *(privado)*, which is in turn described as something personal and individual of a person, and has the quality of being non-governmental or non-public. DRAE reflects the characteristics of privacy as a dimension of the person, which is separated from public and is subject to legal protection. The classification of these terms followed from reducing privacy only to its original concept of the possibility to be left alone when intimacy being understood as the opposite of public[84] might be misleading.

The term intimacy is much narrower and most correlated with the person himself/herself, covering issues such as feelings, beliefs, health, whereas the term privacy or private life is formed by a much larger volume of activities and related information. Dividing the sphere of personal activity into three levels, one can distinguish the most general private area, then confidential and finally secret, or intimate area. All issues related to intimacy are included in the concept of private life, but not *vice versa*, and require even more protection than other private questions, since at times they are not known even to the closest circle of a person.

For instance, Lucrecio Rebollo Delgado recognizes conflict between the terms and argues that it would be more convenient to depart from Anglicism 'privacy' and to embrace the concept of private life.[85] According to his doctrine, the Spanish legal system employs the term intimacy *(intimidad)* when referring to privacy *stricto sensu* while the term privacy *(privacidad)* is used as a globalizing concept of the block of personality rights without substituting any of them.[86]

[83] Diccionario de la lengua española de la Real Academia Española. Retrieved November 17, 2019, from https://dle.rae.es/
[84] *E.g.*, Martínez-Montauti, J. (2009). Privacidad y confidencialidad. En M. Casado (coord.), *Sobre la dignidad y los principios. Análisis de la Declaración Universal sobre la Bioética y Derechos Humanos de la UNESCO* (pp. 267-276). Navarra: Civitas-Thomson Reuters, pp. 269-270.
[85] Rebollo Delgado, L. (1998). Derechos de la personalidad y datos personales. *Revista De Derecho Político*, *44*, 143–205, p. 167.
[86] *Ibid.*

The Spanish Constitution is an example of a more restrictive model than international conventions. Amid such terminological diversity, the Constitutional Court (Tribunal Constitucional, TC) developed several concepts of the right to intimacy, on the basis of which its content and relations with privacy and private life can be delineated. Instead of the private life, there are constitutional guarantees provided for some specific aspects of such individual freedom to live the way one wishes, and some aspects are completely deprived of constitutional protection.[87] Initially, the TC adhered to an objective approach to the right to intimacy, distinguishing personal intimacy and, within it, bodily intimacy.[88] The right to personal intimacy was linked to the existence of own environment, inaccessible to the knowledge and intervention of others, and necessary to maintain a minimum quality of human life.[89] In turn, the content of the intimate sphere was not determined based on the point of view of the person himself/herself, but rather based on what society understands as such, at a certain point in time.[90] The scope of intimacy depended on reasonable expectations.

This objective, or material concept is still used from time to time by the TC, but in recent decades, a new subjective, or formal, concept has also been introduced in some decisions.[91] Thus, an attempt was made to find out what norms should be referred to in determining what is covered by the concept of intimacy.[92] The competence to establish the physical or informational frames of the intimate sphere belongs directly to the right holder, [93] and the role of the legislator and judges is to create certain limits to it, when necessary, in order to maintain balance with the conflicting rights or needs of others.[94] In any case, both concepts show that this right includes neither the right to autonomy and the determination of a way of life, nor the right to private life and the freedom to live as conveniently as one wishes. The CE, in its Article 18.1 guarantees the right to decide what will be hidden and what is not from the eyes of others, be it the state or private individuals who do

[87] Villaverde Menéndez, I. (2013). La intimidad, ese "terrible derecho" en la era de la confusa publicidad virtual. *EJJL (Espacio Jurídico Journal of Law)*, *14*(3 Ed. Especial), 57–72, p. 61.
[88] Casas Baamonde, M. E., & Rodríguez-Piñero y Bravo-Ferrer, M. (Eds.). (2018). *Comentarios a la Constitución Española. XL Aniversario* (Vol. I). Madrid: Boletín Oficial del Estado, p. 519.
[89] STC 231/1988, de 2 de diciembre, FJ 3.
[90] Casas Baamonde, M. E., & Rodríguez-Piñero y Bravo-Ferrer, M. (Eds.). (2018). *Op. cit.*, p. 520.
[91] *Ibid*.
[92] Villaverde Menéndez, I. (2013). *Op. cit.*, pp. 62-63.
[93] STC 134/1999, de 15 de julio, FJ 5.
[94] Villaverde Menéndez, I. (2013). *Op. cit.*, p. 64.

not belong to the intimate circle.[95] At the same time, although this provision does not directly connect intimacy with autonomy and freedom, the information disclosed and taken out of their context will be subjected to social judgment, which may indirectly lead to damage to autonomy and freedom. Moreover, this information or the sphere of life will always be available to the public and will not become a secret again. In addition to the two previously discussed concepts of privacy – privacy as freedom and privacy as dignity – this concept of intimacy forms a kind of another, third concept.

The abundance of terms and theories once again proves the complexity and vastness of these fundamental concepts, and also leads to less functional protection of rights in some situations. The unification of theories and concepts, at least at the national or regional level, could provide more reliable protection of rights. With respect to the topic of this thesis, protection and access to medical information is not necessarily ensured by the right to privacy in local laws, but may fall under other rights, such as the constitutional right to protection of personal data in Spain (Article 18.3 CE). Nevertheless, we will adhere to the general concept of privacy, without dividing it into different ideas that reflect only one or another aspect of this right. Given all the differences identified, the term "right to privacy" in the broad sense will be used below.

In order to analyze the right to privacy within the healthcare sector, it is important to keep in mind the differentiation of privacy into the following dimensions – territorial, bodily and informational privacy.[96] Territorial privacy protects people, not territory, while bodily and informational privacy seeks to protect human dignity.[97] In the latter case, the violation of human dignity occurs through access to the information about a person, which, in fundamental way, should be considered his/her own,[98] as well as through ignoring his/her preferences regarding its disclosure or, on the contrary, retention. It is this dimension of privacy that is of particular interest in the context of patient rights.

[95] Villaverde Menéndez, I. (2013). *Op. cit.*, pp. 61-62.
[96] Department of Justice. (1972). *Privacy and Computers*. *A Report of the Task Force Established by the Department of Communications*, as cited in Hughes, R. L. D. (2015). Two concepts of privacy. *Computer Law & Security Review*, *31*(4), 1–11, p. 3.
[97] *Ibid*.
[98] *Ibid*.

2.1.4. Privacy in medicine and medical confidentiality

The key to successful treatment and recovery of the patient lies not only in the professionalism of the physician, but also in the preparedness of the patient to cooperate. The more information a physician can get about the patient's medical history, symptoms, lifestyle and even family, greater the chance he has to correctly diagnose and choose the right therapy for the patient. However, such a desire to make a contribution even to his/her own health depends on how safe the patient feels, namely how confident he/she is about his/her information not being distributed outside the physician's office. For this reason, a relationship of trust between a physician and a patient constitutes technically and morally essential element of efficient medical care. Privacy in the healthcare system is not a guarantee of comfort but serves as the basis for a fair medical decision, while keeping personal information confidential. Respect for privacy in medicine ensures patient autonomy when making medical decisions, providing informed consent to treatments and procedures, and also guarantees the right to informational self-determination, which involves, for example, the processing of biological samples and data.[99]

Despite the fact that these two notions – privacy and confidentiality – are quite different, they are often misunderstood and used interchangeably, regardless of their important role in medical ethics and practice. Even though most authors, usually in discussions about restricting access to patient information, prefer the term confidentiality rather than privacy, sometimes these terms are used haphazardly. For example, the HIPAA Privacy Rule almost always refers to the privacy of medical information rather than confidentiality.

The simplest interpretation of this difference will be that the concept of privacy is tied directly to the individual, and confidentiality is a category rather related to information – roughly, it is an expectation of control about the destiny of shared information.[100] It does not mean that privacy is directed to the protection of physical body of an individual, and confidentiality protects all information about him/her. Informational privacy includes data that allows a person to be identified and contacted, the nature of this data, situations and methods on how and where they are

[99] Martínez-Montauti, J. (2009). *Op. cit.*, p. 270-271.
[100] Francis, L. P. (2008). Privacy and Confidentiality: The Importance of Context. *The Monist, 91*(1), 52–67, pp. 52-53.

collected, and, finally, the permission or detail of access to this information. Confidentiality, on the contrary, implies certain data that has already been accessed, as well as further actions for their dissemination, storage, processing, as well as about the circle of people to whom they will be available, and ways to protect this information, including procedures and responsibilities.

Confidentiality can be defined as an obligation that must be fulfilled by a person who has gained access to personal information about another person and is required not to transfer this information further without the consent of the owner of the information. The original Latin meaning of the word *confidentia*, which means trust, explains the need to protect confidential information arising precisely from the fact that it was communicated on terms of trust. However, not everyone whom the person trusts bears this obligation. In the context of medical relations, confidentiality is understood as an implied agreement to not disclose information obtained while performing professional duties to anyone who is not engaged in the patient's treatment process. Although the obligation of confidentiality protects information obtained while providing services, it does not have an expiration date and binds the physician even after the termination of his professional relationship with the patient. This is both an ethical and legal obligation of members of healthcare personnel. Aside from references to confidentiality in codes of ethics, the source of professional secrecy lies in contractual law, privacy law, penal law, and legislation regarding the organization of medical practice. The most common sanction for the breach of confidentiality is penal responsibility, which is usually is very hard on a physician.

Not without reason, there are different terms to define violations of these two rights. Thus, violation of privacy is called invasion, and violation of confidentiality – breach. Here, it may seem that intrusion does much more harm than just a violation, so respecting the right to privacy is much more important than maintaining confidentiality.[101] On the other hand, correlation of importance of privacy and confidentiality depends on the context, as does what requires primary protection.

In most cases, the main focus is on protecting confidentiality within patient-physician relationship, since through confidentiality the right to privacy is ensured. Thus, if a genetic disease is detected as a result of testing, the main desire of a patient who fears, for example, discrimination due to a certain medical condition, is to make sure that this information would not be known outside the

[101] *Ibid.*

room. In case this information is leaked, its confidentiality will be violated, which will lead to unwanted access to it by other people. In this situation, the physician's duty of professional secrecy directly corresponds to the patient's right to confidentiality and indirectly ensures his/her right to privacy. At the same time, there can be situations where only confidentiality is breached, but the right to privacy is not violated. For example, if a physician accidentally brings home a patient's test results, and then returns them back to the hospital without anyone else having seen this information, the data protection measures would be violated, but not privacy.

In some other cases, this interconnection is reversed. Protection of privacy leads to ensuring confidentiality in case when there is no certainty about the reliability of the future storage of data that may potentially be collected, and the person resists having such information collected in the first place.[102] Taking the same patient as an example, if he/she suspects a genetic disease based on symptoms or familial medical anamnesis, the patient may not voluntarily take tests if he/she is embarrassed or scared that the physician may need to report the results to his/her relatives and/or employer. In this case, in deciding not to undergo analysis and preventing the collection of information about himself/herself, the patient ensures that the confidentiality of this information is not breached in the future. Thus, these rights are interrelated, and it is impossible to single out which one is more important, and which one is less.

According to the ECHR, the confidentiality of medical data, as well as their collection, conditions, purposes and duration of storage and disclosure are subject to Article 8 of the Convention.[103] Thus, we can assume that the right to privacy is more general and covers a wider range of concerns than the right to confidentiality. In the field of medicine, breach of confidentiality of information leads to invasion of privacy, which in turn manifests in harmful consequences for the patient in the form of discrimination, expulsion, and even denial of access to the healthcare system, etc.[104] With regard to terminology, what matters is that the following four terms make sense – the right to

[102] Francis, L. P. (2008). *Op. cit.*, p. 60.
[103] Council of Europe. (2018). *Guide on Article 8 of the European Convention on Human Rights – Right to respect for private and family life, home and correspondence*, pp. 41-42. Retrieved November 25, 2019, from https://www.echr.coe.int/Documents/Guide_Art_8_ENG.pdf/
[104] Martínez-Montauti, J. (2009). *Op. cit.*, p. 274.

confidentiality, right to privacy, patient privacy and, finally, confidentiality of information, but not the confidentiality of patient, as it is an attribute of information and not of patient.

2.1.5. Patient's health information and medical records

A common element connecting the concept of confidentiality and privacy is information – a fundamental element and one of the main objects of protection within privacy. As far as classifying information goes, there are few different categories of information according to the level of protection granted by privacy laws. The term "personal information" is the most general, including absolutely any data about a particular person. The use of such information allows to directly or indirectly identify a person on the basis of certain characteristics. Since this term implies absolutely any data, it should be interpreted as broadly as possible. However, not all personal information receives the same level of protection, for the reason that not all personal data fall under the private life of a person. For example, information about the state of health is personal and at the same time refers to private life, while the taxpayer identification number, although referring to personal information, goes beyond the category of private life. Accordingly, aside from general personal data, it is necessary to take into account special categories of personal data, or sensitive personal data, which are of greater importance compared to other information, and for this reason they are subject to a higher level of protection. Sensitive personal information, in addition to personal data about ethnic origin, political and religious beliefs, as well as biometric data and other types of information, includes health information and genetic information.[105]

Protecting health information, as a type of personal data, is very important for ensuring the right to privacy. It represents a collection of various facts related to the state of health, through which the patient can be identified. It is difficult to draw a line to distinguish which health data belong to the intimate sphere, and which belong to the general private sphere, as this is a fairly subjective matter, and the patient decides which sphere of life this data belong to. Some people freely share their health problems, while others hide it even from the closest family members and friends. Anyway, modern legislations classify such identifying health information as specially and

[105] *E.g.*, Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, Art. 4; Loi fédérale sur la protection des données (LPD) du 19 juin 1992 (État le 1er mars 2019), Art. 3.

thoroughly protected, and usually grant the highest level of protection possible when processing it. The main provisions regarding the content of medical information, its storage and protection, as well as maintaining medical records and providing the patient with access to his/her records are similar in all jurisdictions considered in this thesis.

Health information includes whatsoever information, received before or during the treatment, allowing medical personnel to obtain knowledge about the physical and mental condition of the patient, as well as to expand this knowledge in order to restore, maintain or improve his/her state of health.[106] These include, but are not limited to, medical history, health reports, radiographs, test results and procedures, a list of medications, patient-reported assessments, services received, treatments offered and provided, etc.[107] Nevertheless, based on the fact that the legal documents separate the concepts of health information and genetic information, this leads to the conclusion that the latter is not absorbed by the concept of health information, but only intersects when it comes to a history of genetic disease or the results of genetic analysis.

In order to provide better health care, as well as to ensure patient safety and transparency, medical institutions are required to store health data in medical files. Medical records serve as the basis for planning patient care and ensuring continuity, as well as documenting the progress of treatment and changes in the patient's condition.[108] Moreover, they are documented evidence of the interactions between the physician in charge and the treating staff, which plays an important role, in the event of having to prove a violation of patient rights and in case of filing malpractice or incompetence cases against the physician.

Requirements for maintaining medical records, including maximum retention periods, safety requirements, rules for making changes and correcting errors, are stipulated in national laws or regulations. The medical files can be maintained both in traditional physical (paper) form and in electronic form.[109] In addition to immediate information about health, medical records contain

[106] Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Boletín Oficial del Estado, 15 de noviembre de 2002, núm. 274, pp. 40126 a 40132, Art. 3.
[107] Loi genevoise sur la santé (LS) du 7 avril 2006 (K 1 03), Art. 53.
[108] Annas, G. J. (1992). *The Rights of Patients: The Basic ACLU Guide to Patient Rights*. Totowa, NJ: Humana Press, p. 160.
[109] Loi genevoise sur la santé (LS) du 7 avril 2006 (K 1 03), Art. 54.

many other identifiers that link health data with its direct owner, such as name, address, telephone number, date of birth, social security number, photos, next of kin. Healthcare professionals derive this information from different sources, such as directly from the patient, from previous files, and finally from medical knowledge. At the same time, medical files sometimes contain information that relates to the physician's private sphere.[110] Such comments should not interfere with the patient's access to his/her own medical files in accordance with the principle of self-determination and the right to privacy, except in the field of psychiatry,[111] where the subjective comments nevertheless constitute one of some exceptions to this right. Thus, with the exception of personal records of the physician, data relating to the interests of third parties, information necessary for legal proceedings and some other categories of data provided for by the laws of specific countries, the patient can access all the information that the medical institution stores about him/her.

The right to access medical records is strictly personal and not inherited, belonging exclusively to the patient. Therefore, even the delegation of this right to legal representatives of patients incapable of discernment and guardians or parents of patients who are minors is carefully regulated in such cases in order to ensure that the confidentiality of this information is adequately protected. Despite all limitations, in some cases access to medical files may be granted to third parties, such as the patient's relatives, should their interests prevail. In this case, it may be a matter of satisfying the personal and independent right of a patient's relative to receive information about their health. The disclosure of the patient's medical information should not be allowed in such circumstances, but only information that relates to the third party of concern can be revealed. To ensure patient privacy, such information can be communicated by a physician, who will be limited only by disclosing the necessary data. However, such claims do not guarantee access to the information of interest, because they always involve a certain margin of appreciation. In all other cases not stipulated or required by law, non-observance of professional secret, which covers all patient information contained in his/her medical file and known by physicians and nurses, leads to serious consequences for medical personnel.

[110] Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Boletín Oficial del Estado, 15 de noviembre de 2002, núm. 274, pp. 40126 a 40132, Art. 18 (3).
[111] 45 CFR § 164.524(a)(1)(i) (2001); 45 CFR § 164.501 (2002).

2.2. Fundamental but not absolute right

2.2.1. Professional liability for breach of confidentiality

As discussed previously, the duty of confidentiality is based on many legal sources, but penal law remains the main source. The consolidation of provisions on professional secrecy in the penal codes of most modern countries points to the importance of this obligation and contributes to its reinforcement. Although there are no special provisions in the U.S. and the UK regarding criminal liability for the breach of professional secret, courts may still set criminal prosecutions.[112] Typically, these violations can cost the physicians a fine or imprisonment, as well as a rather lengthy and unfavorable criminal process. In such cases, only the consent of the patient, the prevailing public or private interest or the direct requirements of the law can be considered as justifying motives.

The breach of physician's duty of confidentiality as a crime and its elements can be examined based on Spanish and Swiss national criminal laws, which provide generally similar regulations. Thus, the Spanish Penal Code contains a provision about medical secrets in Article 199, especially in its second part, which clearly concerns professionals. Despite the fact that this article does not contain a list of professions, based on the definition of a professional as a person who publicly performs work, and whose services are required for reasons of necessity and are regulated by laws due to the public interest,[113] medical workers belong to this category. A more or less exhaustive list of professions tied by professional secret can be found in Article 321 of the Swiss Penal Code (Code pénal suisse, CPS). There, in addition to lawyers and priests, are listed physicians, dentists, chiropractors, pharmacists, midwives, psychologists, as well as their assistants. The mention of the latter is very important, since all those who work with a person bound by a duty of confidentiality fall into this category, regardless of whether they perform direct therapeutic functions, like nurses, or a single task at the request of a physician, like physiotherapists and

[112] Department of Justice. (2005, June 1). *Scope of Criminal Enforcement Under 42 U.S.C. § 1320d–6. Memorandum Opinion for The General Counsel Department of Health and Human Services and the Senior Counsel to the Deputy Attorney General*. Retrieved December 1, 2019, from https://www.justice.gov/sites/default/files/olc/opinions/attachments/2014/11/17/hipaa_final.htm/; United States v. Luthra [No. 15-cr-30032-MGM] (D. Mass. 2017).

[113] Bajo Fernandez, M. (1980). El secreto profesional en el Proyecto de Código Penal. *Anuario de Derecho Penal y Ciencias Penales*, *33*(3), 595–610, p. 606.

laboratory assistants. In this regard, this article also applies to medical secretaries, receptionists, pharmacy vendors, etc. Moreover, the same sentences of imprisonment of up to three years or a fine apply to medical students who disclose confidential information that they received access to during their studies.[114]

Both of these articles mention secrets, that is, information available to a limited circle of people, the access to which is closed to the general public. The patient should have a legitimate interest in keeping such information secret, in the same way that a medical professional should be prepared to ensure its confidentiality before gaining access to it. On the one hand, it is necessary to distinguish the notions of medical files and health data, since the physician during professional activity receives primarily information that is medical in nature, and no other personal data that can be stored in a medical record but can be accessed from other sources and in other circumstances. On the other hand, the professional secret is not limited only to health data, but nevertheless covers other personal data of both the patient and his/her relatives, the situation in the family and at work, as well as other problems and issues, including fact of a patient seeking medical help and about the patient-physician relationship.[115] As for the volume of information disclosed, this should not be a determining factor, since in order for the crime to be considered complete, it is enough to make available data for those who do not have the right to access them.

A typical punishable action is reflected in the verb "disclose" (*divulgar/révéler* in CPE and CPS respectively),[116] which means the communication of information to third parties in absolutely any form and with the help of any means. The category of third parties includes, among others, the legal representative of a patient without capacity for discernment, the heirs of a deceased patient, state authorities, other healthcare professionals who do not participate in the treatment process of the patient. This does not apply to physician's assistants, since the information is necessary in order to provide effective medical care, nor to any other disclosure required for the performance of professional duties. When the patient is treated by a medical team, it is believed that there is

[114] Code pénal Suisse du 21 décembre 1937 (État le 1er juillet 2021), Art. 321 (1).
[115] Hirsig-Vouilloz, M. (2017). *La responsabilité du médecin : aspects de droit civil, pénal et administratif*. Berne : Stämpfli, pp. 192-193.
[116] Ley Orgánica 10/1995, de 23 de noviembre, del Código Penal. Boletín Oficial del Estado, 24 de noviembre de 1995, núm. 281, pp. 33987 a 34058, Art. 199 (2); Code pénal Suisse du 21 décembre 1937 (État le 1er juillet 2021), Art. 321 (1).

tacit consent for the exchange of information within the team, otherwise it would be impossible to carry out any treatment. However, in situations such as seeking a second opinion, the patient must give prior consent to transfer the information to the physician providing the second opinion. The disclosure of confidential information to another individual with duty of professional secrecy, who is nevertheless an unauthorized person, will also be considered a violation of criminal law.[117]

As previously noted, the professional duty of confidentiality does not expire. It does not matter whether the information was disclosed during or after engaging in professional activity, just as it does not matter that the healthcare professional ceased working or the student finished studies and graduated.[118] The criminal prosecution for breach of confidentiality in accordance with the aforementioned articles occurs only for the intentional and conscious action of a healthcare worker. Negligence is not punishable in this case, and in practice, it is hard to prove. The basis for criminal pursuit is the claim of the patient, his/her legal representative in case the patient is incapable of discernment, or successors in case of death of the patient. Finally, part three of Article 201 CPE establishes that if the patient or legal representative forgives the physician, it excludes criminal prosecution or imposed punishment.

In addition to the criminal process, a patient whose right to confidentiality has been violated by medical personnel may bring a civil action. Classical conception of private law distinguishes two types of liability – contractual and tort, or extracontractual liability. Contractual liability is applicable to a physician who failed to fulfill a particular duty imposed by a contract binding him and a patient. Liability in tort is retained when there is no contract between a physician and a patient but there is a violation of general duty imposed by law. Depending on the structure of the healthcare system, may prevail contractual or extracontractual liability.

In Switzerland, medical liability proceedings are often based on rules of contractual liability. The basis for contractual liability is the failure to fulfill the obligations stipulated by the contract between the physician and the patient. Thus, the contract of mandate[119] envisages the obligation of discretion, which implies the obligation of the physician not to disclose any information

[117] Hirsig-Vouilloz, M. (2017). *Op. cit.*, p. 195.
[118] Code pénal Suisse du 21 décembre 1937 (État le 1er juillet 2021), Art. 321 (1).
[119] Loi fédérale complétant le Code civil suisse (Livre cinquième : Droit des obligations) du 30 mars 1911 (État le 1er juillet 2021), Art. 398 (2).

received from the patient, as well as to ensure that there is no unauthorized access to it by other persons both during and after the fulfillment of the contract. In order for contractual liability to emerge, four conditions must be met. The physician must violate a contract, be at fault (which is presumed), the patient must have suffered a damage, and there must be a natural and adequate causal relationship between the breach of contract and the damage suffered.[120] The contractual liability of the physician also includes responsibility for the actions of assistants who acted according to physician's instructions.[121]

In rare situations where a contract for medical services is absent, physician's liability is tortious.[122] Overall, tort liability has similar structure to contractual liability and the general clause of Article 41 COS dictates that the same four conditions as contractual liability apply for tort liability. The difference is that the physician must commit a wrongful act by violating an absolute right instead of breaching a contract. In addition, the patient is required to prove the fault of the physician as it is not presumed as in the case of contractual liability. Contractual liability is of greater interest to a living patient, while extracontractual liability is more important in the event of patient's death or when the interests of third parties are affected.

In Spain, the majority of lawsuits related to medical activities involve extracontractual liability, even in cases where there are previous contractual relations between the parties.[123] This position is supported by the theory of unity of civil fault, as well as by the fact that in both cases, whether bringing the physician to contractual or tort liability, the patient needs to prove the same set of evidences, that is damage, causality with the activities of the accused physician and, in particular, his fault.[124] To these cases applies Article 1902 of the Spanish Civil Code (Código Civil de España, CCE), which deals with the regulation of obligations arising out of fault or negligence. Also, civil liability can be imposed together with criminal liability if a civil lawsuit has been brought in

[120] *Ibid.*, Art. 97 (1).
[121] *Ibid.*, Art. 101.
[122] Muller, C. (2008). La responsabilité civile du médecin. In F. Bohnet (Ed.), *Quelques actions en responsabilité* (pp. 99-143). Neuchâtel : Université de Neuchâtel, p. 104.
[123] Santos Morón, M. J. (2018). La responsabilidad médica (en particular en la medicina "voluntaria"): Una relectura desde el punto de vista contractual. *InDret: Revista para el Análisis del Derecho, 1*, p. 4.
[124] *Ibid.*

criminal proceedings, and it is supposed to cover damages caused by private physicians and private medical clinics.

The situation where lawsuits against healthcare professionals, even if they relate to the private sector, are more often based on extracontractual liability rules, is exemplary not only of Spanish law, but also of English law. One reason why contractual claims have minimal importance in England is because health care is largely provided through the NHS, where treatment under contract is not possible. Therefore, regarding the relationship between the physician and the patient within the NHS system, physicians are not contractually bound to maintain the confidentiality of the patient data in question. However, patients have the option to pay for private care, in which case, contract law applies. In a contract for any professional service, the implied term concerns that reasonable professional care and skill is used to perform the service, and that the burden of proof in the event of a breach of this requirement still rests with the patient. Accordingly, there is no realistic difference between conditions of tort and contractual liabilities,[125] same as under Spanish civil law. Private patients have a choice between tort liability and contract. Usually, the liability under contract law is not more attractive than tortious liability.[126]

Unlike Switzerland, medical liability in English law is mostly tort-based and, for this reason, closer to the Spanish system. Tort of negligence is the core legal element of medical malpractice. Three conditions – a physician's duty of care towards his/her patient, breach of this duty and resulting damage to the patient – dictate physician's liability.[127] However, the main source of protection of medical confidentiality is an equitable doctrine,[128] which obliges the physician to respect the confidentiality of patient's information and allows the patient to demand legal remedies when his/her confidence has been breached. This happened as a result of the fact that historically, English law did not associate the protection of the confidentiality of personal information with the protection of privacy. Although the equitable cause of action has traditionally been related to the leakage of trade secrets, essential requirements for bringing such a claim set out in the decision

[125] Koch, B. A. (Ed.). (2011). *Medical Liability in Europe. A Comparison of Selected Jurisdictions*. Berlin: De Gruyter, p. 187.
[126] Hondius, E. (Ed.). (2014). *The Development of Medical Liability*. Cambridge: Cambridge University Press, p. 35.
[127] Koch, B. A. (Ed.). (2011). *Op. cit.*, pp. 172-173.
[128] Michalowski, S. (2003). *Medical Confidentiality and Crime.* London: Routledge, p. 129.

ruled for the case *Coco v. A.N. Clark (Engineers) Ltd*,[129] also apply to claims against healthcare professionals who have breached professional secrets. First of all, the information must be of a personal or intimate nature, which is generally true for medical information.[130] Second, the information must be communicated under circumstances imposing the obligation of confidentiality, and patient-physician relationship falls under this requirement.[131] Finally, such information should be used without authorization and to the detriment of the patient.

In the U.S. system, medical malpractice is a specific subset of tort law that deals with professional negligence.[132] Since 2006, after the decision in relation to *Acosta v. Byrum*,[133] breach of medical confidentiality as a result of behavior contradicting the HIPAA Privacy Rule started to be recognized in a greater number of court decisions.[134] The patient alleging a physician's liability must prove four elements, namely the existence of legal duty to provide care or treatment to the patient, breach of this duty by failing to meet the standard of care, adverse outcome and causal relationship between such breach of duty and damages.[135] Compensatory damages resulting from actions for unlawful disclosure may include recovery of emotional stress, expenses for medical or psychiatric treatment of emotional injuries caused by disclosure and lost wages or job loss.[136] However, in the U.S., the relationship between a physician and a patient is often based on a contract, and the problem with claims under contract law is that compensation will be limited only to the extent resulting from the breach of contract, and will exclude compensatory damages.[137] The grounds for civil liability of medical professionals resemble one another well, due to the similar level of development of medicine and society.

However, there are several differences that are quite fundamental. The institution of civil liability law plays a more important social role for American patients in the absence of an appropriate level of available social insurances. That is why the compensatory function of civil liability is of

[129] Coco v. AN Clark (Engineers) Ltd [1968] F.S.R. 415.
[130] Herring, J. (2014). *Medical Law and Ethics*. Oxford: Oxford University Press, pp. 224-225.
[131] Attorney-General v. Guardian Newspapers Ltd. (No. 2) [1988] 2 W.L.R. 805 (statement of Lord Keith).
[132] Beau Baez, H. (2010). *Tort Law in the USA*. Kluwer law international, p. 57.
[133] Acosta v. Byrum [638 S.E.2d 246] (N.C. App. 2006).
[134] Jackson, J. Z. (2015). The Costs of Medical Privacy Breach. *MD Advisor*, *8*(3), 4–12, pp. 6-7.
[135] Perrin, J. (2006). L'influence du droit américain sur la responsabilité du médecin en droit privé suisse. En N. Dongois & M. Killias (Eds.), *Américanisation des droits suisse et continentaux* (pp. 27-50). Genève : Schulthess, p. 29.
[136] Jackson, J. Z. (2015). *Op. cit.*, p. 7.
[137] Michalowski, S. (2003). *Op. cit.*, pp. 223-224.

particular interest for the inability to receive compensation from other sources. Another difference is that American civil law is aimed not only to repair, but also to punish for actions or conduct. The U.S. widely uses the institution of punitive damages, which assumes to some extent the function of criminal law, as it aims both to punish the defendant and to prevent others from committing such an act in the future. Unlike compensatory damages, the purpose of punitive damages is not to compensate the patient, although the patient may receive all or part of the compensation for damages. Another difference is that due to the participation of the jury in the civil process, the assessment of damage is quite subjective, or rather depends on the emotional perception of the jury. Therefore, the amounts determined as moral compensation may exceed several times the amount reasonable for Europe. And finally, the last difference, which also concerns the financial side of the issue, is the lawyer's direct interest in the outcome of the case, as legal representatives receive payment in a percentage in case of favorable decision rather than a fixed amount regardless of any outcome. Such a system of contingency fees provides motivation for a lawyer to win a case, as well as to achieve a more significant amount of compensation. In sum, these differences are determining factors for filing more civil lawsuits against healthcare workers, with the interest based on much more significant monetary compensation than often in European practice. However, the emotional burden for the patient and the physician does not depend on financial interest, so patients are increasingly choosing criminal lawsuits against healthcare professionals.

In addition to criminal and civil law, national and regional legislations on data protection play a significant role in establishing responsibility for breaching the confidentiality of medical information. For example, the GDPR contains special provisions on administrative fines imposable on data controllers, which under certain circumstances can reach up to 20 million euros or 4% of the annual turnover.[138] Finally, as for public health institutions and their medical staff, they can be held accountable with administrative liability in accordance with special national laws.[139]

[138] Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), Art. 83.

[139] *E.g.*, Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Boletín Oficial del Estado, 15 de noviembre de 2002, núm. 274, pp. 40126 a 40132; Loi sur la responsabilité de l'État et des communes (LREC) du 24 février 1989 (A 2 40).

Despite being a fairly developed system of legal norms intended for ensuring the right to confidentiality and serious sanctions in case of its violation, this right of the patient as well as physician's counter obligation of professional secrecy are not absolute. In some situations, the law provides exceptions to the general rule, establishing either obligation or authorization for physicians to inform third parties. These vary across jurisdictions, but in general the breach of confidentiality, regardless of patient's desire, is demanded by public or private interest to minimize or prevent harm to health or safety of an individual or a group of individuals.

2.2.2. Professional secret and third parties

Aside from the circumstances specified in laws when a physician may or must disclose confidential data, in certain cases not necessarily predetermined by law, third parties, other than the patient himself/herself and the medical personnel directly providing medical assistance to the patient, have their own interest in the patient's medical data. In most of these cases, common foundation, or authorization for a physician to free himself from professional duty of confidentiality, is to obtain the patient's consent to disclose his/her information. This can be to, among others, insurance companies, patient's employer, even another physician, as well as family members of the patient.

Sometimes such consent is implied, for example, in the case of transferring data to other physicians in the process of treatment. Typically, patients understand and agree that information should be passed on to healthcare providers to ensure optimal patient care or possibilities to ensure training opportunities. Therefore, the disclosure of personal information occurs between members of the medical team often without additional consent. This argument is also reflected in the WHO Declaration on the Promotion of Patient's Rights in Europe.[140] Normally, patients do not object to the circulation of their information among all other staff involved in the treatment, but sometimes there may be disagreements about who may be involved in the treatment process and, accordingly, regarding this person's access to the patient's medical records.[141]

[140] World Health Organization, WHO. (1994). Declaration on the Promotion of Patient's Rights in Europe: European Consultation on the Rights of Patients, Amsterdam 28 – 30 March 1994, Art. 4.2.
[141] Hartlev, M. (2007). Striking the Right Balance: Patient's Rights and Opposing Interests with Regard to Health Information. *European Journal of Health Law*, *14*(2), 165–176, p. 171.

Disclosure should always be limited only to information necessary to solve a specific problem of an administrative or therapeutic nature and should not include the transfer of absolutely all information from the patient's medical records or other personal information known to the physician. However, upon admission to the hospital, the patient's personal data, including the medical history, become available for about 150 people of various professions, starting from the main attending physician to the ambulance driver.[142] Even though they do not have the same information about the patient and do not get access to the same data, there are still no clear rules that would regulate the specific amount of information available to each of these professionals.[143] All these employees are undoubtedly bound by an ethical or legal obligation to keep patient data confidential, but depending on profession, level of education, gender and age differences, everyone has their own ideas about the importance of confidentiality,[144] as well as depending on the country in which they practice.[145] Regardless of whether it is implicit or explicit consent, in reality the patient is not fully aware of what he/she is agreeing to and has no choice to disagree because of the risk of complicating the medical process and harming his/her own health.

The concept of implicit consent is used as well while making urgent decisions regarding the patient in intensive care, in situations when people are often in a state of sedation or suffering from painful processes that disturb their consciousness. Any decision made on behalf of a person who does not have at a certain moment the ability to disclose information should be made proportionally and in the best interests.

Otherwise, it is necessary to obtain explicit consent of the patient before revealing his/her health data. Explicit consent involves the provision of active consent, either in writing or orally. For this, the patient must have the ability to agree, that is, understand, retain, and analyze information, and express his/her decision. It is important that the patient is explained who will be able to see the

[142] Martínez-Montauti, J. (2009). *Op. cit.*, p. 271.
[143] *Ibid.*
[144] *E.g.,* Beltran-Aroca, C. M., Labella, F., Font-Ugalde, P., & Girela-Lopez, E. (2019). Assessment of Doctors' Knowledge and Attitudes Towards Confidentiality in Hospital Care. *Science and engineering ethics*, *25*(5), 1531–1548.
[145] Slowther, A., & Kleinman, I. (2008). Confidentiality. In P. Singer & A. Viens (Eds.), *The Cambridge Textbook of Bioethics* (pp. 43-48). Cambridge: Cambridge University Press, p. 46.

information, what will be disclosed, for what purpose, and whether there are any significant and predictable consequences of such disclosure.

For example, insurance companies usually require a detailed and understandable invoice, as well as additional information necessary for calculating the remuneration. One of the requirements for such invoices may be a diagnosis and a description of the procedures that the patient goes through. In addition, more specific medical information may be required. The physician must obtain patient consent before transmitting the information to the insurance company. This means that if there is no consent, the patient will not be able to receive an insurance benefit. Therefore, a significant number of people who seek psychiatric help refuse to use insurance.

Another example is the measures to protect the health of workers established by labor protection legislation, when the employer may require a medical report about an employee on his/her ability to perform work duties. Even though the employer can receive neither information about the possible diagnosis and medical history, nor other data regarding the health of the employee, certain conclusions can be drawn based on a medical opinion expressed in the report, as long as it is for employment or insurance purposes. Due to the nature of the information being about the health of the employee, the employer must nevertheless be subject to data processing legislation. The human resources department is responsible for making decisions on the need for a medical report, as well as for obtaining the employee's consent for accessing the report, and to ensure the safety of these data.

The attending physician is also required to obtain the consent of a patient with capacity for discernment, on which of the family members can or should be notified about his/her condition, if any. A medical professional who discloses the patient's health status at his/her request or with his/her permission cannot be punished for this. However, in order for the consent to be valid, it is very important to determine how much information the patient wants to communicate to relatives. Members of the medical staff can share this health information in person, by phone, or in writing. Often, the patient does not mind notifying his/her family and may even specifically ask the physician to do so, but at times, for various reasons, the patient may object to this.

Nevertheless, the statistics paint a different picture. For example, even after the adoption of Ley básica 41/2002 in Spain, which explicitly requires in the first part of Article 5 that physicians obtain the consent of the patient before informing his/her family, most medical professionals were sharing information about the patient's health status with patient's relatives, but only half had obtained the patient's prior consent to do so.[146] Moreover, in the vast majority of cases, it was about informing the relatives of an adult patient, and not a minor.[147] Thus, such statistics elucidate that, in the end, more than a third of physicians disclose information to others without prior consent, which indicates a fairly frequent violation of the law.

As for children, usually the right to access the medical information of a child between the age of fourteen to sixteen years old, depending on national law, belongs to the parents of the child. After reaching this age, the right belongs to the child and parents, with the consent of the child. If the physician is sure that the child is able to understand the situation and make decisions, his/her opinion should be taken into account in his/her interests even before reaching a specific age. Children may want to hide confidential information from their parents, but their right to keep it from parents is only allowed if it is in the best interests of a mature teenager. Usually, the physician is still obliged to convince the child to let his/her parents know about the condition. In life-threatening situations, or by discretion of a physician, the consent of the child is neglected. This alleged lack of confidentiality is a serious problem within health care for adolescents, and even affects their willingness to seek medical help.[148]

2.2.3. Authorized and obligatory revelations

Managing medical secrets always requires the physician to compromise the interests of both the patient and society. There are no complications in situations where the interests of the patient go hand in hand with the interests of other interested parties. Although the primary concern of the medical professional is to ensure the patient's privacy interests, in some cases there may be a conflict of interests between various stakeholders. What is most important is to find out if the

[146] Pérez-Cárceles, M. D., Pereñiguez, J. E., Osuna, E., & Luna, A. (2005). Balancing Confidentiality and the Information Provided to Families of Patients in Primary Care. *Journal of medical ethics*, *31*(9), 531–535, p. 532.
[147] *Ibid.*
[148] *E.g.*, Pérez-Cárceles, M. D., Pereñiguez, J. E., Osuna, E., Pérez-Flores, D., & Luna, A. (2006). Primary Care Confidentiality for Spanish Adolescents: Fact or Fiction? *Journal of medical ethics*, *32*(6), 329–334.

public or third party's interest outweighs that of the patient, when the patient does not want or cannot, for various reasons, including unconsciousness or even death, give his/her consent. This usually refers to conclusions about the threat to the safety of others or the patient himself/herself and corresponds to another duty of the medical professional – the duty to warn. This professional obligation was introduced by the decision to the case of *Tarasoff v. Regents of University of California*, where the parents of a young woman killed by a psychiatric patient sued the psychiatrist and his employer for negligently failing to communicate to them the patient's expressed threat to kill their daughter.[149]

In limited cases, the legislator has already balanced all interests for the physician and identified certain situations when medical professionals not only can, but also are obliged to notify the relevant authorities, regardless of their professional duty of confidentiality. In other cases, it is the medical professional's task to decide whose benefit is more important. And this is rather a matter of a moral and ethical nature and not a legal one as the law is not able to provide any solution for each situation. However, no code of ethics contains single-purpose answers for such situations. Therefore, the only way to fulfill one obligation is to violate another.

These kinds of ethical conflicts can be approached from the point of view of the principles of biomedical ethics by using them in real practice. We can take as a basis the dominant approach to the evaluation of ethical dilemmas in health care, namely the principles introduced by Tom L. Beauchamp and James F. Childress – principles of autonomy, beneficence, non-maleficence, and justice. [150] The duty of confidentiality complies with the principle of autonomy, as it ensures the patient's right to make decisions regarding his/her own information, which also correlates with the right to privacy. The duty to warn follows from the principle of non-maleficence, which mandates physicians not to harm. At the same time, it can relate to the principle of beneficence when it concerns actively preventing harm. Even though these two latter principles have technical differences, in practice, the principles of non-maleficence and beneficence often coincide.[151]

[149] Tarasoff v. Regents of University of California [17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14] (Cal. 1976).
[150] Beauchamp, T. L., & Childress, J. F. (2001). *Principles of Biomedical Ethics* (5th ed.). Oxford: Oxford University Press.
[151] Petronio, S. (Ed.). (2017). *Balancing the Secrets of Private Disclosures* (1st ed.). New York: Routledge, pp. 72-73.

In order to solve an ethical problem, they propose a procedure of moral reflection, or "deliberation".[152] This balancing model consists of analyzing the full set of possible lines of action, allowing to compare the advantages and disadvantages of each of them, or weighing all the risks of following and violating each of the abovementioned principles, and finally choosing the course of action that maximizes the values which are at stake. This model is designed just to resolve those situations that do not fit into the general structure of norms and require an individual approach.[153] Despite the fact that this process is inevitably subject to the influence of intuition and subjectivity, it does not exclude the reflection, justification, and adoption of reasonable decisions. However, it is clear that when using this model, the results of the deliberation and, accordingly, the solution to the same problem will differ depending on who was in charge of making the decision.[154] In the same way, it is impossible to determine with certainty, which of the medical professionals making decisions regarding the same patient, but choosing different strategies, is right.[155]

In order to objectify the decision-making process and the decision itself of such situations of weighing interests as much as possible, depending on the country, the law provides for the opportunity to apply to the supreme body or supervisory body, which in this case is the ethics commission. The permission of such a commission should release the physician from the obligation of confidentiality and serve as justifying motive. For example, in Switzerland, such an authority is established in accordance with the requirements of the Swiss Penal Code (Article 321 part 2), and the structure and process of application are regulated at the cantonal level. In some cantons, functions are assigned to the collective body, in some to the chief physician or administrative authority. In the canton of Geneva, these functions are performed by the Professional Secret Commission *(Commission du secret professionnel)*.[156] Only a medical professional can apply to such a commission, but not patients, relatives, and heirs of the patient, neither criminal prosecution authorities nor other similar bodies. Based on the statements and arguments of a medical professional, the commission ponders the interests and issues a verdict as to whether the physician can disclose information about the patient in that particular case. The

[152] Beauchamp, T. L., & Childress, J. F. (2001). *Op. cit.*, p. 20.
[153] *Ibid.*
[154] del Río Sánchez, C. (2007). Dilemas éticos relacionados con la confidencialidad. *Informació psicològica*, *90*, 12–27, p. 13.
[155] *Ibid.*
[156] Loi genevoise sur la santé (LS) du 7 avril 2006 (K 1 03), Art. 12 (1).

physician is compelled to apply to such an authority in cases when, for example, it may be considered necessary to notify the close relatives of a patient with a serious contagious disease, or to inform the relatives of the deceased patient about the cause of death.

Another example of authorized disclosure is the right to disclosure stipulated by law. This usually involves notifying the traffic safety authority about the patient's inability to drive, or reporting to the appropriate social welfare service or specialized institution about any substance abuse that is harmful to the patient or his/her family and surroundings, or notifying the parent without parenting rights about the condition of the child, or reporting to the child protection service about certain offenses committed against the child. This list is not exhaustive, and also depends on the country, since sometimes the legislation of one country can only authorize a medical worker to disclose information, while the legislation of another country can oblige one to do so in the exact same situation.

Regarding the obligation to disclose information, legislations of most countries require the reporting of crimes and even provide criminal penalty for those who, due to their professional or official duties, found out but failed to report a crime to the appropriate authorities. These limits to the right to privacy are envisaged in the second part of Article 8 ECHR, as well as in the first part of Article 26 of the Oviedo Convention. Thus, national penal laws usually require the physician to report any bullet wounds, gunshot wounds, and other injuries caused by the discharge of a weapon or firearm. When the law establishes a duty to inform justice of physical or psychological injuries without clarifying the circumstances and without even asking for the patient's consent, the patient's right to control his/her information is not recognized against the physician's obligation to report any signs of violence.[157] This obligation also extends to the cases of abuse, violence and life-threatening behavior when the physician has become aware of someone in need, especially children, in order to protect them. In such cases, the law requires the healthcare professional to report the case to the appropriate authority of protection.

Particularly important for public health as a symbol of general interest are cases when a physician encounters a patient infected with dangerous and transmissible diseases. In such a scenario, the regulations containing an exhaustive list of known diseases that pose a particular danger, or the

[157] Martínez-Montauti, J. (2009). *Op. cit.*, pp. 271-272.

characteristics of unknown diseases, indicate the expected course of action from medical personnel, in order to impede epidemics. In some situations, surveillance of specific diseases is regulated even at the international level, especially by the directives and guidelines of the WHO. Depending on the type of virus, the medical worker may have to report either only the incidence of infection, or complete information about the patient. This may include data on how the infection occurred and what the patient's lifestyle is, including information of an intimate nature, as long as it is related to the disease.[158]

This begs the question whether the interests of medical confidentiality will remain paramount in the context of the criminal process when the physician's testimony matters for the resolution of the case. In European legal systems, the physician-patient privilege and obligation to witness are usually addressed by criminal or criminal procedure law, in the same way that general obligation of medical confidentiality is. According to Swiss Code of Penal Procedure,[159] the basic principle allows the physicians to always refuse to be a witness, with the exception of when they are under the obligation to report, for example suspected death, or when they are liberated from their duty of confidentiality by the patient or the relevant authority. However, even in these two cases, criminal authorities have to respect professional secret if the physician proves that the patient's interest overrides the importance to disclose the truth. Similar guarantees are not provided for physicians by Spanish law, where the Criminal Procedure Law (Ley de Enjuiciamiento Criminal, LEC) mentions only the right of lawyers and clergymen not to give testimonies violating their duty of confidentiality.[160] As for medical professionals, the only reference is contained in Article 262 LEC, which obliges them to report public delicts. Thus, despite the provisions of Article 24 of the Spanish Constitution, the lack of special rule exempting a physician from being a witness puts them to a discriminatory position compared to other professions whose relationships are based on client trust.

In the absence of a general rule governing when a healthcare professional can and cannot be silent, in England, both in criminal and civil proceedings, the court decides each time as to whether it is

[158] *Ibid.*
[159] Code de procédure pénale suisse (Code de procédure pénale, CPP) du 5 octobre 2007 (État le 1er juillet 2021), Art. 171.
[160] Real Decreto de 14 de septiembre de 1882 por el que se aprueba la Ley de Enjuiciamiento Criminal. Gaceta de Madrid, 17 de septiembre de 1882, núm. 260, pp. 803 a 806l, Arts. 416, 417.

acceptable to require answers from a physician or medical documents that compromise the confidentiality of patient's information. The law recognizes only privilege of lawyers, as it directly benefits the administration of justice.[161] The court makes a decision balancing public interest in disclosure and non-disclosure, on the basis of proportionality. However, this does not mean that the physician can be exempted from testimony only on the basis that it is in the interests of the patient, but rather on the basis of how important his testimony is and is relevant to the case. Protection of information is ensured by the fact that the court can demand only the information that is truly essential for the administration of justice within the proceedings.[162]

As traditionally medical privilege did not exist in common law and there is no federal law governing privileges,[163] in the U.S., medical privilege is governed by the state law.[164] Courts do not support the idea that medical privilege derives from the Constitution, while they do not interpret its provisions as opposed to the recognition of medical privilege by other laws.[165] Today, most states have their own laws recognizing one form or another of physician-patient privilege with various exceptions, and all states recognize psychiatrist-patient privilege, even those that do not recognize a general medical privilege.[166] The main reason why the remaining states do not recognize medical privileges is the protection of public interests in criminal proceedings, which should prevail over the interests of confidentiality, which can only be fully protected outside the courtroom.[167]

2.2.4. Efforts and failures to protect health data

In the issue of ensuring the confidentiality of medical data within the walls of hospitals and private physicians' offices, the daily physical, administrative and technical practices of storing, processing, and using this data are of great importance. There are fewer problems with the storage of information in traditional paper form – the only reliable solution is to store this data in a dedicated

[161] Attorney-General v. Mulholland [1963] 1 All ER 767, [1963] 2 QB 477.
[162] Michalowski, S. (2003). *Op. cit.*, pp. 158-169.
[163] Weissbrodt, D., Pekin, F., & Wilson, A. (2006). Piercing the Confidentiality Veil: Physician Testimony in International Criminal Trials Against Perpetrators of Torture. *Minnesota Journal of International Law*, *15*(1), 43–109, p. 61.
[164] Privilege in General, Rule 501 of the Federal Rules of Evidence.
[165] Michalowski, S. (2003). *Op. cit.*, pp. 229-234.
[166] Weissbrodt, D., Pekin, F., & Wilson, A. (2006). *Op. cit.*, p. 64.
[167] Michalowski, S. (2003). *Op. cit.*, pp. 240-241.

safe under lock, preferably in a dedicated room. However, the transportation as well as communication of these records have to comply with certain standards. The storage and transfer of electronic medical records require more control.

The exact requirements are always contained in regulations, including requirements for the devices on which this data is stored, the devices with which this data is obtained, maximum duration of storage, the need for duplication, etc. Health facilities usually need to develop internal standard operating procedures and technical mechanisms to ensure transfer security, access control and file integrity control, and control for the purposes of audit. Moreover, it is necessary to ensure the protection of workplaces and devices, as well as limiting physical access to their data center only to authorized parties. Employees who process the data must receive proper permission and be monitored, and absolutely all employees of the institution must be trained regarding security issues, the violation of which should incur the appropriate consequences. As a result, it may be said that maintaining confidentiality leads to significant economic costs, the value of which is determined by costs of security systems, encryption and tracking systems, privacy policies and confidentiality agreements and their printing.[168]

However, despite all the requirements, some aspects of the organization or infrastructure of the hospital and lack of adequate training lead to confidentiality breached by all medical personnel, especially physicians. Statistical studies show that physicians often share information about consultations or personal data of patients with medical personnel who are not directly involved in providing medical care to the patient, as well as to persons outside the hospital.[169] As for locations where these kind of breaches are most recorded, more than a third took place in public places inside the hospitals, such as corridors, elevators, canteen, stairs and locker rooms.[170] The physical environment, such as the design of the room, the location of the computer, telephone and fax, and the remoteness of the reception contribute to the violation of confidentiality in enclosed spaces. Overheard disclosure in staff-to-staff or staff-to-patient conversations or overlooked medical documents negatively affect the trust and confidence of patients and may result in disruption in

[168] Martínez-Montauti, J. (2009). *Op. cit.*, p. 274.
[169] Beltran-Aroca, C. M., Girela-Lopez, E., Collazo-Chao, E., Montero-Pérez-Barquero, M., & Muñoz-Villanueva, M. C. (2016). Confidentiality Breaches in Clinical Practice: What Happens in Hospitals? *BMC Medical Ethics*, *17*(1), pp. 1-12. https://doi.org/10.1186/s12910-016-0136-y/
[170] *Ibid.*

the relationship between the patient and the physician.[171] In many cases, this is a manifestation of careless behavior and inattentiveness, and not just a lack of resources to comply with procedures and requirements.

2.2.5. The end of privacy

Aside from the examples of failures to comply with medical data protection requirements, the number of exemptions from the right to medical confidentiality reflect the general tendency to limit privacy. Even history proves a regular invasion of privacy in medical practices, when in the XVI Century physicians had to notify authorities about patients with syphilis, then in the XVIII Century they had to manage demands of patient's family and friend about patient's health, and finally in the XX Century, insurance companies and employers were also granted access to the health data of insured persons and employees, respectively.[172] This problem is related to the fact that the call for privacy is associated not only with a negative fear of unfavorable disclosure of information, but also with a positive hope to control the perception of personal image by others, which is problematic when it comes to hiding socially useful information that exposes a person in a bad light.[173] Thus, privacy indeed seems sometimes overrated, when protecting privacy for the sake of protection can lead, for example, to a plane crash, and subsequent mass casualties caused by a mentally unstable pilot. This is not, however, the only illustration of the boundaries of privacy.

Another threat to privacy is related to the development of information technology. This, of course, includes computer technologies that allow to aggregate, classify, and analyze information based on social network profiles or query tracking in search engines. However, the most dangerous are technologies that allow individuals to share their verified personal information in exchange for any kind of low-cost economic rewards.[174] This phenomenon characterizes the "signaling economy", the type of economy replacing the previous type, or "sorting economy", which has been dominant

[171] Scott, K., Dyas, J. V., Middlemass, J. B., & Siriwardena, A. N. (2007). Confidentiality in The Waiting Room: An Observational Study in General Practice. *The British journal of general practice: the journal of the Royal College of General Practitioners*, *57*(539), 490–493.
[172] Rieder, P., Louis-Courvoisier, M., & Huber, P. (2016). *Op. cit.*, pp. 150-153.
[173] Halper, T. (1996). Privacy and Autonomy: From Warren and Brandeis to Roe and Cruzan. *The Journal of Medicine and Philosophy*, *21*(2), 121–135, p. 124.
[174] Peppet, S. R. (2011). Unraveling Privacy: The Personal Prospectus and the Threat of a Full-Disclosure Future. *Northwestern University Law Review*, *105*(3), 1153–1204, pp. 1553-1157.

for about hundred and fifty years.[175] Now, individuals and firms do not need to analyze a lot of unverified low-quality information at high costs in order to obtain the necessary information, when they can extract fine and inexpensive data directly from the owner of information.[176] When an individual openly transfers his/her information and makes it publicly available, the need for expensive research and surveys or the implementation of data privacy policies loses its purpose. Thus, data collectors only need to find an incentive for people to share their data of interest.

As an example, there are online services that allow students who are looking for jobs to take a drug test at a local collection center, which should improve their resume.[177] Another example is the practice of insurance companies to propose their customers to use their electronic devices while driving to track customers' total driving time, habits and geographical locations of routes, cases of speeding and sharp brakes, usage of seat belts, etc. in exchange for a premium reimbursement or a discount on payments within their insurance plan.[178] Similarly, medical institutions and clinics use remote monitoring devices or applications that provide information on patients' vital signs, their movement and position, the fact of taking or not taking the medicine, blood sugar levels, or even certain symptoms indicating a disease or condition.[179] Although insurance companies still do not receive similar information about patients insured by them, as in the previous example with car insurance, it would be easy for them to motivate customers to disclose information in exchange for a discount.[180]

These models envisage in new light, the problem of economic benefits of information disclosure, which overshadows the problem of control over one's own information itself, even though it was identified decades ago.[181] On the one hand, in such situations, people are more likely to voluntarily agree to share their information with third parties. And to some extent, it even brings them other benefits besides an economic one. Often, people's behavior changes when they become aware that they are being watched.

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[175] *Ibid.*
[176] *Ibid.*
[177] *Ibid.*
[178] *Ibid*
[179] Varshney, U. (2007). Pervasive Healthcare and Wireless Health Monitoring. *Mobile Networks and Application*s, *12*, 113–127, p. 115.
[180] Peppet, S. R. (2011). *Op. cit.*, p. 1155.
[181] *E.g.*, Posner, R. A. (1981). The Economics of Privacy. *The American Economic Review*, *71*(2), 405–409.

Thus, in the first example, the opportunity to improve the resume by taking a drug test indirectly can motivate students to abandon the idea of taking drugs in the first place. In the second example, in addition to discounts and bonuses, drivers can also be more motivated to respect traffic rules, which is beneficial both for them and for society. And finally, in the third case, the use of medical devices can reduce the number of medical errors due to lack of information or lack of access to it at the right time and place.[182] On the other hand, it can be assumed that such a system is mainly designed for vulnerable segments of the population, whose informed consent is compromised by the opportunity to obtain economic benefits.

Another example of the manifestation of the economic value of information that infringes on privacy in general and medical confidentiality in particular, is the commercialization of prescription drug profiles in the United States, which reveals treatments and medications allowing to make certain conclusions about the diagnosis.[183] The sale of this data is carried out for the purpose of manipulating physicians and benefits only pharmaceutical companies, thereby bypassing the rights of patients to medical confidentiality, as their data, albeit in anonymized form, can be decrypted and correlated with a specific person using modern technologies.[184] Unlike previously discussed situations of privacy restrictions, which nevertheless bring indirect benefits to the owner of the information, these marketing tricks do not have any altruistic character. They only lead to the promotion of the drug on the market, an increase in its price, which ultimately puts the burden on the patient, insurance companies or the state budget.[185]

The novels of Zamyatin, Orwell, Huxley and many more have long depicted a picture of the consequences of such tendencies towards complete loss of privacy in the distant murky future. Nevertheless, some people have the opposite point of view,[186] believing that the best way to solve the problem of medical confidentiality is to simply destroy it by revealing all the medical files and data banks. However, in this case, this is likely to lead to a crisis of social problems from which people already suffer. Disclosure of medical records is unlikely to help get rid of discrimination,

[182] Varshney, U. (2007). *Op. cit.*, pp. 113-115.
[183] Martínez-Montauti, J. (2018). *La relación médico-paciente*. Edicions de la UB, pp. 82-83.
[184] *Ibid.*
[185] *Ibid.*
[186] *E.g.*, Brin, D. (1999). *The Transparent Society: Will Technology Force Us to Choose Between Privacy and Freedom?* New York: Basic Books.

since the severity, symptoms and course of diseases vary for everyone, especially in the case of rare diseases or genetic ones but can complicate the process of treatment and maintaining health for, for example, psychiatric patients.

2.3. Interim conclusion

It is fairly clear that there is no consensus regarding the concept of privacy, especially its content and the degree of its importance. Without doubt, the majority accepts the significance of the right to privacy and necessity to respect it in order to provide adequate protection of the personal information of individuals as well as to consider the interests of the society as a whole. The variety of theories about the relationship of privacy with other values, the debate about whether this is an absolute right or not, and the lack of consensus in terminology testify to the fact that this is a very complex and broad concept. Its scope is much wider than any affordable protection offered by legal systems. However, protection of this right can be ensured by assuring more specific rights arising from and inextricably linked with the ideas of privacy, dignity, and autonomy. Otherwise, there is always a risk that legal protection will not be complete.

In medicine, such a concrete right, through the protection of which one of the aspects of privacy can be protected as well, is the right to confidentiality. This right allows the patient to believe that the information entrusted to the medical staff in exchange for receiving medical care will not extend beyond this circle of trust. The principle of confidentiality is one of the fundamental and oldest principles of medical ethics. Nowadays, at the international and national level, there are a considerable number of regulatory documents, laws, and recommendations regarding respect for the confidentiality of patient medical information. Despite this, the perception of the professional duty of secrecy varies in theory and in practice. Due to internal and external factors, healthcare providers belittle the importance of confidentiality to the patient. At times, the inability to properly maintain confidentiality depends purely on technical issues and is not related to the moral and ethical principles of the physician or the lack of an adequate regulatory framework. In some cases, as in relation to insurance companies, the employer, and even with admission to a medical institution, the patient has only a fictitious right to prohibit the disclosure of information. Moreover, there are quite a few exceptions to this rule, which are vital to ensure overriding interests. The legislator may weigh conflicting interests and make a decision for the physician in certain cases,

while in other situations may put the burden of assessment on the shoulders of medical professionals.

On the one hand, the action of disclosing confidential information without the consent of the patient, of course, itself interferes with his/her right to control information about their own health and make their own decisions about it. Most often, the consequences of such a disclosure affect a person's life much more than the infringement of his/her informational autonomy. This is in reference to humiliation, discrimination, loss of job, unwillingness of insurance companies to provide insurance coverage and estrangement of relatives and friends – in other words, the end of a normal life. In such situations, bringing a healthcare worker or medical institution to disciplinary, administrative, and even civil and criminal liability cannot always improve the situation for a patient whose right has been violated. On the other hand, the rapid informatization and the growing behavioral trend of disclosing private life to the public suggest that people themselves no longer value their privacy or give up and adapt to the conditions of hidden universal control. This also applies to health information.

Privacy legislation certainly adjusts to changing realities, although some rules have been applied for decades and may already be out of date in practice. Therefore, the question arises as to whether the current legislation is fully capable of ensuring medical confidentiality as traditional medicine is taken over by genetic technologies. That is to say, what is the fate of genetic information under current law?

3. PRIVACY ISSUES IN THE ERA OF GENETIC MEDICINE

3.1. Role of genetics in modern medicine

3.1.1. What is genetics?

One of the central problems of modern healthcare system and law is how physicians and patients face and are affected by the new wave of genetic information becoming more accessible and being used more prominently. Exploration of this fundamental thesis requires definition of the scope of what genetics and genetic information is, its role in medicine, the approaches made to incorporate genetics in our daily life and routine medical practice, as well as to project how the role and treatment of genetic information can evolve in future.

Genetics, in short, is the study of how living things, including humans, inherit genetic materials, and it is also the study of the effects of genes and the ways in which genes vary or change. The concept of genetics and "hereditary", which is a biological process through which parent generations pass down their genetic information to its offspring, was first introduced through the studies of Gregor Mendel in 1866, where he observed that certain physical characteristics of garden pea were being inherited in a stable manner by its later generations. Rather than genes, Mendel referred to them as "cell elements" *(Zellelemente)*, and believed there were hidden, but physical mechanisms mediating the hereditary process in peas. Mendel, despite not having the means to provide physical evidence of this machinery, used mathematics to introduce hereditary to the world.[1] The term "gene" was coined by the Danish botanist Wilhelm Johannsen in very early XX Century, and etymologically, it comes from the Greek word *genesis* (γένεσις), which means "origin". Over the course of the several decades that followed, however, the definition and concept of genes took many twists and turns through scientific research. One significant claim coming from the classical and neoclassical periods of genetics was that of Hermann Muller, who in 1926 described genes as the basis of evolution and the basis of life.[2] Similar sentiments are observed in modern day discussion of genetics, where genetic information is colloquially referred to as the

[1] Mendel, G. (1865). Versuche über Plflanzenhybriden. *Verhandlungen des naturforschenden Vereines in Brünn, Bd. IV für das Jahr 1865*, Abhandlungen, 3-47. [Translated by Roger Blumberg as part of the MendelWeb project.] Retrieved December 20, 2019, from http://www.esp.org/foundations/genetics/classical/gm-65.pdf/

[2] Portin, P., & Wilkins, A. (2017). The Evolving Definition of the Term "Gene". *Genetics*, *205*(4), 1353–1364, p. 1355.

"blueprint" of life that constructs and operates an organism. During the neoclassical period of genetics, genes became regarded widely as indivisible units of inheritance. Each of these "units" were understood as being points on structures called chromosomes, which scientists knew to exist inside the nucleus of cells but did not have detailed knowledge of due to limitations in their research equipment.

The reports by James Watson and Francis Crick in 1953, where they determined the structure of DNA, is probably the most significant finding that led to neoclassical genetics evolving into modern genetics. In it, Watson and Crick explained that the DNA molecule is comprised of two strands (or ropes) that are arranged in a helical shape, and each rope is a chain of varying patterns of four types of nucleotides, which are the smallest chemical units (or molecules) of genetic information.[3] As there are two chains, one nucleotide chain has a complementary nucleotide on the other chain, thereby existing as nucleotide "pairs". This finding redefined the previous understanding of chromosomes to what it is now today, which recognizes them as long chains of DNA molecules that are folded and bundled into a larger structure. A "gene" is a particular segment of such a DNA chain (chromosome), having a unique order of A, G, C and T, defining a particular physical trait in the organism.

The four types of nucleotides, namely adenine (A), guanine (G), cytosine (C) and thymine (T) are the individual coding units of genetic information, and it is the difference in lengths and order of their arrangement that account for the vast possibilities of genetics. In fact, all life on earth shares these same ingredients to build their genetic material. However, the fact that the order of arrangement of these building blocks differs is why humans and giraffes do not resemble one another. These differences are far fewer within a given species. For example, all human beings share about 99.9% of the same genetic information, but the difference in the 0.1% of remaining genetic information account for why every single human is distinct from one another.[4]

The findings of Watson and Crick not only elucidated the most fundamental units of the genetic machinery, but also opened the floodgates to the era of modern and molecular genetics, which

[3] Watson, J. D., & Crick, F. H. (1953). Molecular structure of nucleic acids; a structure for deoxyribose nucleic acid. *Nature*, *171*(4356), 737–738, p. 737.
[4] What are DNA and Genes? (n.d.). *University of Utah, Introduction to Genetics Program* [Video]. Retrieved December 20, 2019, from https://learn.genetics.utah.edu/content/basics/dna/

sought to explain genetic and cellular behavior based on DNA and molecules that surround it. In a later paper, based on the molecular understanding of DNA, the two biologists explained that DNA is capable of self-replication, which meant that there was machinery in place to help it copy or reproduce itself, which would later serve as the molecular basis of how hereditary happens, passing on the same information from the parent to offspring.[5]

In the years that followed Watson and Crick's reports, a series of findings about cells by different biologists gave an even bigger picture of the scope of functions that genetic materials have. This refers to the discovery of certain proteins, such as tRNA and ribosomes, which help "transcribe" and "translate" the genetic material, respectively, into other functional proteins.[6] In other words, the genetic code written on the "blueprint" that is DNA, would first be transcribed to a temporary medium and is taken to a factory of cellular machinery capable of deciphering and translating the code into an end-product protein. This protein at the end is the entity that imparts on the organism, the physical trait encoded by the genetic material (such as colors of the eyes and hair). Here, it is possible to recognize that while the genetic material is the "brain" of a cell, the proteins around it are the "muscles" that help realize the physical traits protected by the genetic material.

As discussed above, in the biological sense, "genetic material" or "genetic information" is a description of information about physical traits of an organism that is encoded into biological molecules within the body called DNA. The nucleus of a cell contains an organism's "genome", that is, the complete set of genetic material for a given organism. In other words, taking a look at any given cell in an organism is able to show the entire blueprint of how that organism is made and functions. It is therefore clear that there was a need for ways to be able to find and "read" an entire genome, or parts of the genetic information to understand why people and animals look and behave in the ways they do. Significant strides were made in the latter half of the XX Century to devise ways to read genetic materials in various organisms.

One of the biggest of such efforts was the Human Genome Project (HGP), which was a 13 year-long project (1990-2003) conducted jointly between 20 research institutions from U.S., UK,

[5] Watson, J. D., & Crick, F. H. (1953). Genetical Implications of The Structure of Deoxyribonucleic Acid. *Nature*, *171*(4361), 964–967, p. 966.
[6] *E.g.*, Hoagland, M. B., Zamecnik, P. C., & Stephenson, M. L. (1957). Intermediate reactions in protein biosynthesis. *Biochimica et biophysica acta*, *24*(1), 215–216.

Germany, France, Japan, and China. It was a mega project that commanded an investment of 3 billion dollars from the U.S. government alone and was the first effort of its kind in modern biology and genetics. The human genome consists of more than three billion pairs of the four types of nucleotide bases (A, G, C and T), and the aim of the HGP was to obtain a readout of the entire human genome, by deciphering the order in which the nucleotide base pairs are arranged. In the words of the National Human Genome Research Institute, "the HGP gave us the ability, for the first time, to read nature's complete genetic blueprint for building a human being".[7]

The results of the HGP were not just a simple readout of human genetic blueprint. In the vast array of genetic information encoded in the human genome, scientists were able to see that only certain parts are relevant to our physiological makeup and function, while the purpose of other parts still remain unclear. They also saw how genes were placed along the genome sequence, and how certain genes were associated with diseases. The results of the HGP also provided room for retrospective studies, with the biggest influence being on how we understand genealogy and evolution.[8] The genome readout allowed scientists to make comparisons between previous and the hypothesized previous stages in evolution, as well as with other organisms. The fact that certain parts of genetic materials were conserved over time and between organisms strongly suggested that all of today's species descended from a single ancestor.

The progress of HGP, and therefore its end result, owed much to technical advancements made in ways to read the genetic information, also referred to as gene sequencing technologies. High-throughput sequencing is one such by-product of the HGP, which allows greater gene reading in shorter time at lower cost. The fact that what had cost billions to read decades ago is costing thousands today should be an indicator of how far we have become familiarized with the knowledge of our genome, and how accessible genetic information has become.

[7] The Human Genome Research Project. (n.d.). *National Human Genome Research Institute*. Retrieved December 20, 2019, from https://www.genome.gov/human-genome-project/

[8] Hood, L., & Rowen, L. (2013). The Human Genome Project: Big Science Transforms Biology and Medicine. *Genome Medicine*, *5*(9), 79, pp. 1-8.

3.1.2. Genetic basis for human diseases

The work of XX Century biologists provided the world an understanding of genetic material and information, how they are stored and propagated biologically, how they are passed down and are responsible for the physical traits of an organism, and last but not least, how they can be read. Genetics has been able to explain why humans and other organisms look and function the way they do. By extension, it has also been able to explain why the human body may not function as expected at times. This is in reference to the involvement of genetics in human diseases. Any application of genetic principles in medical practice is called medical genetics, a field that is still relatively new, having been formally recognized since the turn of the century.[9] Given how fundamental genetic information is to the appearance and proper function of the body, it is argued that virtually all human ailments other than trauma involve a genetic factor, and should be viewed as such.[10]

The medical community has come to an understanding that there are three categories or types of contributions that genetics has on human diseases, and by extension, to medical practice. The first of this is termed monogenic (or single-gene) disorders. A monogenic disorder is a disease occurring due to an error, or mutation in a single gene in one's genetic material. A mutation in a gene often results in either non-production or production of a faulty version of the protein it encodes, and when a protein is either missing or faulty, it is unable to carry out its inherent function in the body, and ultimately disrupts how the body works.[11] Although each individual monogenic disorder is rare, collectively they make up a significant part of human illnesses. Some of the more common examples of monogenic disorders are cystic fibrosis and sickle cell anemia.[12] Monogenic disorders affect specific genes, and an offspring can inherit a monogenic disorder when one or more of its parents have the disorder. As such, monogenic disorders have a relatively simple

[9] Medical Genetics 101. (n.d.). *American Society of Human Genetics*. Retrieved December 21, 2019, from https://www.ashg.org/education/medical_genetics.shtml/
[10] Korf, B. (2002). Genetics in Medical Practice. *Genetics in Medicine, 4*(6 Suppl), 10–14, p. 10.
[11] Single Gene Disorders. (n.d.). *University of Utah, Introduction to Genetics Program* [Video]. Retrieved December 21, 2019, from https://learn.genetics.utah.edu/content/disorders/singlegene/
[12] Genetic Alliance; District of Columbia Department of Health. (2010). *Understanding Genetics: A District of Columbia Guide for Patients and Health Professionals* (Appendix G – Single-gene Disorders). Washington (DC): Genetic Alliance. Retrieved December 20, 2019, from https://www.ncbi.nlm.nih.gov/books/NBK132154/

pattern of inheritance, which make them easier to track from parent to offspring by genetic testing. This is also the reason why family history factors in heavily on monogenic disorders.

The second type of genetic disorder is called chromosomal abnormalities. As introduced previously, chromosomes are bundles of DNA, and in the case of humans, one's entire genetic material is segmented into 46 chromosomes (made of 23 pairs, or two copies of 23 chromosomes). A chromosomal abnormality is either a structural irregularity in a certain chromosome, or an irregular number of chromosomes, that is, either more or less chromosomes than there should be (a term called "aneuploidy").[13] Structural problems arise when a chromosome breaks and rejoins in an incorrect manner, and these areas that break and rejoin can lead to missing, additional, or incorrect modification of genetic information. The result is similar to monogenic disorders, where missing or incorrect genetic information disrupts the correct function of the body. The most common cases of aneuploidy, or irregular number of chromosomes, are seen in the form of either one missing or one extra chromosome.[14] Perhaps the most well-known example of aneuploidy is Down Syndrome, which happens in people that have an extra copy of Chromosome No. 21. Similar to monogenic disorders, genetic testing is an integral part of the process of diagnosing and confirming chromosomal abnormalities. With the risk of chromosomal abnormalities increasing with the maternal age,[15] there is particular emphasis on family planning and prenatal screening when it comes to this type of genetic diseases.

The third and final category of genetic disorders is what is called multifactorial disorders, and also happens to be the largest category of genetic diseases. Such diseases are caused by an intricate mix of problems in multiple genes, along with lifestyle and environmental factors that are outside the control of genetic machinery.[16] The involvement of multiple genes and other external factors mean that this category of genetic diseases is the most difficult to predict and care for. Unlike monogenic disorders, the pattern of inheritance of gene mutations are also not clear. However, the study of

[13] Genetic Alliance; District of Columbia Department of Health. (2010). *Understanding Genetics: A District of Columbia Guide for Patients and Health Professionals* (Appendix H - Chromosomal Abnormalities). Washington (DC): Genetic Alliance, p. 7. Retrieved December 20, 2019, from https://www.ncbi.nlm.nih.gov/books/NBK132134/
[14] Extra or Missing Chromosomes. (n.d.). *University of Utah, Introduction to Genetics Program* [Video]. Retrieved December 21, 2019, from https://learn.genetics.utah.edu/content/disorders/extraormissing/
[15] Stavljenic-Rukavina, A. 1. (2008). Prenatal Diagnosis of Chromosomal Disorders – Molecular Aspects. *EJIFCC, 19*(1), 2–6, p. 2.
[16] Korf, B. (2002). *Op. cit.*, p. 10.

genetics in such diseases can help identify what is called a genetic predisposition.[17] A genetic predisposition means that the study of one's family history and genetic materials suggest an increased likelihood for developing a certain disease. Even in a mix of multiple gene mutations, certain gene mutations can increase the likelihood of a disease more than other gene mutations, and the peculiarity of a person's genetic material that increases the likelihood of a disease may contribute to the development of the disease, but not be its direct cause. That is why the role of lifestyle practices and environmental factors such as drinking, smoking, diet, exercise level, and chemical exposure all need to be taken into account when examining multifactorial disorders, rather than just the genetic predisposition.[18] Unlike monogenic and chromosomal abnormalities that present clearer inheritance patterns and pathogenesis apparent from the earlier periods of life, there is some age-dependent manifestation to multifactorial diseases that make it more difficult to foresee.[19] The most well-known examples of such multifactorial diseases include Alzheimer's disease, diabetes, coronary heart disease and cancer.

Regardless of the type of genetic disorder concerned, Bruce Korf, in his brief review of medical genetics, argues the importance of the individual and collaborative work of three types of physicians – the primary care physician, the medical specialist and the medical geneticist – when handling genetic diseases. Primary care physician, who is the first point of contact for a patient, is tasked with identifying that a patient's condition may have an important genetic contribution. This requires access to family history and having trained eyes to recognize the disorder. It is often with the help of a medical specialist (such as a neurologist or an oncologist) that a patient's diagnosis begins to take shape. A medical specialist would also need the sort of access to the patient and medical information such as family history, which the primary care physician would have. Today, with the increasing recognition of the genetic component in diseases, the role of medical geneticists is becoming more important. A medical geneticist is often in charge of the interpretation of genetic test results and providing counselling for the medical team as well as the patient and his/her family members. In pediatric diseases, for example, while physicians had traditionally looked to environmental causes of inherited diseases, medical geneticists are prominently involved in

[17] Bartee, L., Shriner, W., & Creech, C. (2017). *Principles of Biology: Biology 211, 212 and 213*, pp. 564-567. Retrieved December 22, 2019, from https://openoregon.pressbooks.pub/mhccmajorsbio/chapter/complex-multifactorial-disorders/

[18] Lobo, I. (2008). Multifactorial Inheritance and Genetic Disease. *Nature Education*, *1*(1), 5.

[19] Korf, B. (2002). *Op. cit.*, pp. 10-11.

providing genetic counselling for such patients today.[20] The nature of increased collaboration between these three types of professionals mean that geneticists, who are experts in interpreting genetic information and family history, are being expected to become familiarized with the process of treatment and care for genetic diseases as well, in order to better advise the patients, family members and the physicians.[21]

Despite the clear evidence of genetic information ameliorating medical practice, the knowledge and use of genetic information is not without difficulty. It has been mentioned that the ability to identify a genetic issue often exceeds the ability to prevent or treat a disease, in what is called a "therapeutic gap".[22] Particularly in the case of multifactorial and late-onset diseases like cancer, there are too many variables involved to make decisions solely based on genetics. This is often cited as the reason for disagreement between lawmaking and medical practice, and an agreement can only come closer by improving how efficiently genetic testing can help overcome a disease.

3.1.3. Modern types of genetic testing and diagnostics

The decrease in cost of genetic testing through the years, along with technical advancements to provide faster and more accurate test results have provided modern medical practice with various ways to study a person's genes and chromosomes. What began as a tool for studying a few rare diseases has now evolved to accommodate analysis of complex diseases resulting from multi-gene mutations in various parts of the genome.[23] In the passages to follow, some of the most common types of genetic tests and their uses are discussed briefly.

Newborn screening is a genetic test that is commonly administered to an infant shortly after birth, by sampling blood, to identify genetic diseases that can be treated during the early stages of life. According to the U.S. National Library of Medicine, all U.S. states currently test newborn babies for phenylketonuria and congenital hypothyroidism, while some states also test for other

[20] Roberts, J. A. (1964). Some Practical Applications of Genetics in Medicine and Surgery. *British Medical Journal*, *2*(5419), 1217–1221, p. 1217.
[21] Korf, B. (2002). *Op. cit.*, p. 12.
[22] Godard, B., Raeburn, S., Pembrey, M., Bobrow, M., Farndon, P., & Aymé, S. (2003). Genetic Information and Testing in Insurance and Employment: Technical, Social and Ethical Issues. *European journal of human genetics: EJHG*, *11*(2 Suppl), S123–S142, p. 125.
[23] Katsanis, S. H., & Katsanis, N. (2013). Molecular Genetic Testing and The Future of Clinical Genomics. *Nature Reviews Genetics*, *14*(6), 415–426, p. 416.

inheritable diseases.[24] Fortunately, due to mandatory nature of these tests, any medical expenses arising from these testing are covered entirely by private medical insurances in the U.S. The EU, on the other hand, has no generalized newborn screening system in place, despite it being recognized and practiced in few of the Member States.[25]

Diagnostic testing is a form of genetic testing performed to confirm or rule out a specific genetic or chromosomal disease. It is typically carried out on a patient that is showing physical signs and symptoms of the disease in question, and genetic testing can provide a definitive answer. The diagnostic testing available may at times be limited by how soon the results are needed and depending on the genetic disease concerned.[26]

Conceptually, carrier testing is a type of genetic test that is not as straightforward as the previous two. It is first important to note that human beings inherit two copies of each gene, one from the father and one from the mother. In certain situations, an individual can inherit a copy of a mutant gene (from the father or the mother) responsible for a disease without actually becoming sick. However, if he/she was to have a child with another individual also carrying a single copy of this genetic mutation, and should his/her child end up with two copies of said mutant gene, it is possible that the child can become sick. Carrier testing is performed to identify individuals like the parents, who carry mutant genes but do not become sick, as it can have implications to future generations. This is done so for people with family history of a specific genetic disease, and for couples that want to assess the risk of a genetic disease being passed down to their child(ren).[27]

As the name suggests, prenatal testing is a type of genetic test that is administered on a fetus during pregnancy, in order to identify any genetic or chromosomal problems. In many situations, this test is performed when a couple has concerns about their child being born with a genetic disease, based on results of prior carrier testing or advanced maternal age. In many cases they are performed

[24] What Are the Types of Genetic Tests? (n.d.). U.S. National Library of Medicine. Retrieved December 26, 2019, from https://ghr.nlm.nih.gov/primer/testing/uses/

[25] Parliamentary Question Subject: Need to ensure newborn screening across the EU. (2019, April 24). *European Parliament*. Retrieved December 26, 2019, from http://www.europarl.europa.eu/doceo/document/E-8-2019-001812_EN.html/

[26] Katsanis, S. H., & Katsanis, N. (2013). *Op. cit.*, pp. 416-423.

[27] What is Carrier Screening? (n.d.). *GoodStart Genetics*. Retrieved December 27, 2019, from https://web.archive.org/web/20140119052338/http://www.goodstartgenetics.com/carrier-screening/

relatively early into the pregnancy to allow decision of whether to maintain or terminate a pregnancy.[28]

Preimplantation testing is a genetic test that is administered at a stage that is even before prenatal testing. It is performed as part of the process of in-vitro fertilization, where an egg is fertilized with sperm outside of the body before being implanted to the mother's uterus. In it, preimplantation tests take a few cells from the embryo and tests its genes to look for any genetic disorders. An embryo is only implanted to a uterus when tests confirm that there is no genetic disorder. This helps to significantly reduce the risk of genetic diseases in the child. Despite this obvious advantage, it is also true that adding on an invasive process like preimplantation testing to an already invasive process like in-vitro fertilization hampers the success rate of pregnancy significantly.[29]

As the name suggests, predictive and pre-symptomatic testing identify mutations of the genes that can make a patient susceptible to a disease later on in life. As many individuals that undergo this type of testing do so while they are healthy and not showing any signs of illness, family history is an important clue in deciding whether or not a patient should be tested. Predictive testing is becoming more and more prominent now with the increasing prevalence of cancer, and early detection of a genetic component linked to cancer allow medical professionals to continuously monitor and advise a patient on how to prevent the disease from actually happening.[30]

While genetic testing itself is already a relatively novel technique in the context of human medicine, its use in pharmacogenomics has been an even more recent development. Pharmacogenomics is the use of genetic information to study the response of individual patients to certain drugs.[31] When there are variations in a particular gene, a patient can respond differently to a particular drug than how another patient having the normal gene or a different variant of a gene responds. Similarly, testing to obtain the genetic information of a patient having a certain disease can help select

[28] The Facts on Prenatal Testing. (n.d.). *John A. Haugen Associates Obstetrics and Gynecology*. Retrieved December 27, 2019, from https://web.archive.org/web/20150402123732/http://www.haugenobgyn.com/prenatal_testing.aspx/
[29] Harper, J. (Ed.). (2009). *Preimplantation Genetic Diagnosis* (2nd ed.). Cambridge: Cambridge University Press, p. 2.
[30] Genetic Testing for Hereditary Cancer Syndromes. (2019). *National Cancer Institute*. Retrieved December 27, 2019, from https://www.cancer.gov/about-cancer/causes-prevention/genetics/genetic-testing-fact-sheet/
[31] Adams, J. (2008). Pharmacogenomics and Personalized Medicine. *Nature Education*, *1*(1), 194.

medications that provide the patient with the best therapeutic response, while at the same time being the safest option(s) for the patient, that is, having the least amount of side effects. Such tailored medical treatment and care based on the genetic information of patients is referred to as "precision (or personalized) medicine". Genetic information obtained by pharmacogenomic testing is central to the success of precision medicine, and the influence of pharmacogenomics is seen most prominently in chemotherapy and treatment of cancer patients, where the cancer in any given patient is different from that of another patient due to any one or combination of many gene mutations in a patient's cancer cell, and therefore resulting in differences in the way that his/her cancer responds to a particular treatment.[32]

While genetic testing may have arguably its greatest influence and output in the field of medicine, it is also important to recognize that that this technique offered by advancement in biology has provided benefits to other fields as well. In saying so, we are referring to forensic and paternal DNA testing based on non-medical motivation. Forensic DNA analysis is based on the idea that individuals can be identified and differentiated based on differences in their genetic information, and in most situations such analysis is performed for legal purposes in criminal cases where the perpetrator of a crime has left behind physical evidence containing his/her DNA at the crime scene.[33] This is a powerful tool that has revolutionized crime-solving to provide quicker and more accurate convictions than the pre-genetic era.

Paternal genetic (DNA) testing, on the other hand, is used to compare the genetic profile of two individuals to discern whether or not they are related to one another. Specifically, such tests analyze the probability that an individual is the biological father of another individual, based on commonality in certain parts of the genetic information. The advancement in genetic testing technology means that it is now possible to discern paternity from more distant relatives of an individual, such as grandfather and cousins.[34]

[32] Vogenberg, F. R., Isaacson-Barash, C., & Pursel, M. (2010). Personalized Medicine – Part I: Evolution and Development into Theranostics. *P & T: a peer-reviewed journal for formulary management*, *35*(10), 560–576, pp. 561-562.
[33] Daeid, N., Rafferty, A., Butler, J., Chalmers, J., McVean, G., & Tully, G. (2017). *Forensic DNA Analysis: A Primer for Courts*. (Primers for Courts; Vol. DES4928). The Royal Society, pp. 18-26.
[34] Adams, J. (2008). Paternity Testing: Blood Types and DNA. *Nature Education*, *1*(1), 146.

3.1.4. Future impacts on medicine

The evolution of gene science has led to increase in accuracy and reduced cost of genetic testing. This has led to diversification of its use, and as improvements continue in accuracy and cost, genetic information will likely penetrate more fields, while in the field of medicine alone, will likely provide physicians a powerful tool for improving patient care. There is also no doubt that, with greater penetration of genetic information, the sphere of accessibility to such information will transform too, going forward.

An important recent shift in the way we think about genetics is the transformation of idea from genetics being simply something to read and understand, towards something that can also be used. This is in reference to the idea of gene therapy, which at present time remains an experimental approach to treat or prevent a disease. Gene therapy involves having to understand the genetic component of a patient's disease by means of diagnostic genetic testing, and introducing fragments of genes into a patient to fix the genetic problem.[35] This may be to replace a faulty gene with a healthy one, to inactivate or "silence" a faulty gene, or to introduce a completely new and synthetic gene to combat a disease in ways a body does not naturally know how to.[36] Essentially, gene therapy would treat patients using genes, rather than by drug or surgery.

Similar to gene therapy, but perhaps more controversial, is the up-and-coming technology of gene editing. The concept of making controlled changes to the genome of an organism is not a new one, as mankind have been playing around with mixing and separating of animal species for scientific and agricultural purposes for long.[37] However, the improved understanding of the human genome and subsequent improvement in genetic engineering technique has brought the world to the cusp of achieving the first totally-controlled gene editing technique, named CRISPR-Cas9. The technology allows to make targeted changes in the genome of an organism, with much fewer errors

[35] How Does Gene Therapy Work? (n.d.). *U.S. National Library of Medicine*. Retrieved December 29, 2019, from https://ghr.nlm.nih.gov/primer/therapy/procedures/

[36] What Is Cell and Gene Therapy? (n.d.). *Novartis* [Video]. Retrieved December 29, 2019, from https://www.novartis.com/our-focus/cell-and-gene-therapy/what-cell-and-gene-therapy/

[37] Lauerman, J. (2021, June 28). Crispr, the Tool Giving DNA Editing Promise and Peril. *Bloomberg*. Retrieved September 13, 2021, from https://www.bloomberg.com/quicktake/gene-editing/

than its predecessor technologies.[38] An error in gene editing could mean unintended and catastrophic consequences to other traits and functions of an organism, and in many cases mean that the organism would not survive. As such, many predecessor techniques were unable to show any promise of animal or human applications and were limited to cells in laboratories. In the context of human medicine, editing the genome could allow scientists and physicians to quickly and accurately fix the root of a genetic disease, thereby treating or preventing such diseases. At this level of gene editing, it would also become possible to edit embryos so that children are born healthy, free of genetic diseases.[39] Scientists project that the technology has the potential to eradicate long-standing problems like Huntington's disease, and being rid of malaria-carrying mosquitos, among other medical and non-medical benefits.[40] While certainly fewer in errors than previous technologies, however, concerns over errors and off-target effects remain with CRISPR-Cas9. The technology itself involves breaking the DNA chains to insert or cut out genes before rejoining the chains, and any inaccuracy in the site and extent of such breaking and rejoining can result in unintended outcomes. While some unintended edits can be predicted or remedied, others can remain undiscovered or lead to more serious pathological consequences like cancer.

3.1.5. Social, ethical, and legal repercussions

Along with the technical difficulties, gene editing carries ethical, social, and legal issues. Ethical issues, in particular, dominate the discussion. Armed with a powerful tool that allows us to edit and potentially even redesign our blueprint, there are concerns over whether application of gene editing can remain limited to the good of mankind, or even extend to more opportunistic uses like in weaponry for the military, and control over physical and cosmetic appearances.[41] Many also believe that the risk to safety from gene editing, in particular when handling new life, cannot be

[38] Reis, A., Hornblower, B., Robb, B., & Tzertzinis, G. (2014). CRISPR/Cas9 & Targeted Genome Editing: New Era in Molecular Biology. *New England Biolabs Inc*. Retrieved January 3, 2020, from https://international.neb.com/tools-and-resources/feature-articles/crispr-cas9-and-targeted-genome-editing-a-new-era-in-molecular-biology/

[39] Lewis, T. (2019, October 21). New Gene-Editing Tool Could Fix Genetic Defects – with Fewer Unwanted Side Effects. *Scientific American*. Retrieved January 3, 2020, from https://www.scientificamerican.com/article/new-gene-editing-tool-could-fix-genetic-defects-with-fewer-unwanted-effects1/

[40] Gribben, R. (2019, January 10). The Controversy Over Gene-Editing. *PharmaTimes online*. Retrieved January 3, 2020, from http://www.pharmatimes.com/web_exclusives/the_controversy_over_gene-editing_1274582/

[41] Greene, M., & Master, Z. (2018). Ethical Issues of Using CRISPR Technologies for Research on Military Enhancement. *Journal of Bioethical Inquiry, 15*(3), 327–335, pp. 326-331.

overcome by the potential benefit of the technology. What is clear is that much remain to be discussed for gene editing, going into the future.

As mentioned previously, the improved accuracy and reducing cost of genetic testing and therapeutics has also the propensity to change the accessibility to such technology. Similar to medicine in general, where increasing number of people worldwide now have access to medical knowledge via the Internet,[42] more and more individuals are gaining access to *in vitro* diagnostics called direct-to-consumer tests, which allows them to test their own genetic information outside a controlled medical environment. Such an attempt has been exemplified by 23andMe, Inc., a private personal genomics company that began offering its Personal Genome Service® since 2007, which is the first ever saliva-based direct-to-consumer genetic test.[43] While providing the general public with tools to privately gain an understanding of their genetic information and health is a positive and exciting benefit of scientific advancements, there are also questions over the prudence of private genetic information being exchanged in large quantities between individuals and privately-held companies.[44]

This new approach to health care involves and affects not only physicians and patients, but all players within the spectrum of theoretical science, pharmaceutical development, and day-to-day medical care. However, while genetic science continues to progress at an increasing rate, the practice of medicine may not always be able to incorporate such advancements as they come. This is because, much like in any form of scientific progress, genetic technology has ripple effects to the social, economic, and legal domains that all need to be addressed for the progress to benefit its recipients. The legal domain is responsible for regulating the application of emerging technologies into clinical practice, balancing its risks and benefits so that it does not hinder the progress of therapeutic benefits, but at the same time ensuring that the technology does not breach the rights and safety of individuals as well as the society in general.

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[42] Korf, B. (2002). *Op. cit.*, p. 12.

[43] *23andMe – About Us*. (n.d.). 23andMe. Retrieved January 3, 2020, from https://mediacenter.23andme.com/company/about-us/

[44] Seife, C. (2013, November 23). 23andMe Is Terrifying, But Not for the Reason the FDA Thinks. *Scientific American*. Retrieved January 3, 2020, from https://www.scientificamerican.com/article/23andme-is-terrifying-but-not-for-the-reasons-the-fda-thinks/

From the perspective of law, the use of genetic technologies in health care is associated with a tremendous increase in the prerequisites for medical negligence. The emergence of application of genetics in medicine brings forth a list of parties who can be put under the spotlight of legal scrutiny. This includes genome sequencers, gene sampling technicians, testing laboratories, pharmaceutical companies, pharmacists, and facilities responsible for storing and maintaining genetic raw materials and results (also referred to as "biobanks"). However, the current approach to defining liability projects an overly skewed degree of responsibility to the physician, who has the most direct access to patients, and oversees the overall diagnosis and treatment of each patient.[45]

Thus, incorporation of genetic technologies into clinical practice requires more from physicians than what conventional medical practice does. Although lack of knowledge does not release a physician from his responsibility, the sheer amount of new information and techniques that genetics brings into day-to-day medical practice is not compatible with the stringency of genetic education provided to physicians. The great number of genetic tests available grows steadily, eventually integrating into the standard of care. However, the medical professionals are not fully prepared to the era of new technologies. For example, most medical schools in the U.S. had only recently, in 2013, started to train their medical students in genetics, and only 29% of physicians reported that they have had such training.[46] This means that while physicians may be expected to provide the most promising course of treatment to patients through genomic medicine, they are not given the appropriate resources to choose the best course, and any errors leave them to bear a great degree of responsibility. Moreover, due to the fact that practice of genetic testing spreads inconsistently, there is no standardization of test, and the result forms are not compatible between different laboratories.[47]

Genetic technology, as any new treatment or diagnostic procedure, influences the standard of care, which is followed by new legal expectations and obligations, and creates new possible scenarios

[45] Brothers, K. B., & Rothstein, M. A. (2015). Ethical, Legal and Social Implications of Incorporating Personalized Medicine into Healthcare. *Personalized medicine*, *12*(1), 43–51, p. 46.
[46] Marchant, G. E., & Lindor, R. A. (2013). Personalized Medicine and Genetic Malpractice. *Genetics in medicine: official journal of the American College of Medical Genetics*, *15*(12), 921–922, p. 922.
[47] Vogenberg, F. R., Barash, C. I., & Pursel, M. (2010). Personalized Medicine – Part 2: Ethical, Legal, and Regulatory Issues. *Journal of Pharmacy and Therapeutics*, *35*(11), 624–626, 628–631, 642, p. 626.

of liability relating to genetic technology with respect to the patients undergoing genetic testing, their relatives and other interested and involved parties. As genetic testing continues to grow exponentially, increased integration of genetic testing in clinical practice could result in a challenging time for healthcare professionals.[48]

Legal cases on expanding professional responsibility indicate a vulnerable position of patients and new ways that their rights are infringed upon. A physician can bear liability for failure to conduct any of the many genetic tests in an appropriate situation or to properly communicate and interpret test results.[49] However, as long as new genetic tests are accepted into standard of care, this type of claims is not that different from those against the physician who violated obligation to diligently provide necessary treatment or committed a technical fault during medical intervention. In the same way, a physician who does not order certain genetic testing before prescribing a drug to see whether the drug fits the patient, can be found guilty too. The decision on *Scholz v. Kaiser Foundation Hospital* case [50] demonstrates the common problems associated with the racial dependence of genetic information, as well as how certain drugs and treatments work for one person but may not work or may cause harm to another. Another ideal example of complaints being made due to the genetic dependency of drug efficacy and safety is Clopidogrel. This drug is the second-most prescribed drug in the world. Every year, more than 2 million patients are prescribed this drug for prevention of a stent-induced blood clot, which is frequent after heart surgery and often accompanied by lethal outcome.[51]

The new knowledge in genetics and the developments in genetic technology bring with them new challenges to traditional notions, especially to the informed consent.[52] Some facets of genetic diagnostics detected few weaknesses in traditional informed consent. For example, it is doubtful that earlier discussed approaches of the "reasonable physician" and "reasonable patient" are compatible with the individualistic nature of genetic information. In order to be well-informed and to make the right decision, the patient needs to understand the information, particularly the risks,

[48] Donovan, M. J. (2010). Legal Issues Stemming from the Advancement of Pharmacogenomics. *UCLA Journal of Law & Technology*, *14*(1), 31–65, p. 53.
[49] Molloy v. Meier [Nos. C9-02-1821 and C9-02-1837] (Minn. 2004).
[50] Scholz v. Kaiser Foundation Hospital [No. RG12614636] (Alameda Sup. Ct. 2012).
[51] Topol, E. J., & Schork, N. J. (2011). Catapulting Clopidogrel Pharmacogenomics Forward. *Nature medicine*, *17*(1), 40–41, p. 40.
[52] Kegley, J. A. K. (2004). Challenges to Informed Consent. *EMBO Reports*, *5*(9), 832–836, p. 832.

consequences, benefits, and alternatives that concern only him/her, instead of what concerns anyone in general who undergoes the same genetic test or what the physician thinks is necessary to understand. The "particular patient" approach seems to be the closest to meet the needs of precision medicine. However, the limits of information, such as established practice to not notify about extremely rare risks, are irrelevant to genetic diagnostics.

The relatively little knowledge that patients have about genetic testing means that physicians need to provide them with more detailed information and options. To the basic set of information that must be provided to the patient, it is convenient to include a disclosure about laboratory ownership and any planned subsequent uses of the biological samples, as well as information about the severity, potential variability, and treatability of the disorder the patient has been tested for.[53] Special attention should be paid to discuss incidental and secondary findings and their communication to the patient. Thus, the Iowa Institute of Human Genetics, for example, organized a multidisciplinary team to develop a more active informed consent process for patients undergoing genetic testing which includes pre-test counseling designed to discuss the test, types of results, benefits, risks and limitations, and post-test counseling intended to assist the patient and the physician in putting the results into a patient-relevant context and address any questions.[54] This is very important as patient's autonomy is even more compromised by genetics-based medicine, which already poses a risk of paternalism and drifting away from the consent entirely.[55]

Focusing on the legal issues, the possible scenarios of professional medical liability with regard to modern healthcare conditions, as exemplified above, show that the implementation of genetic technologies in medicine inevitably affects the patient-physician relationship. In addition to cases of responsibility for technical errors and non-compliance with applicable standards of care, majority of situations more or less twist around the turnover of information. A significant number of difficulties in legal regulation of genetic medicine is associated either with information about the possible genetic technologies available for treatment or care of the patient, or with the

[53] Institute of Medicine (US) Committee on Assessing Genetic Risks, Andrews, L. B., Fullarton, J. E., Holtzman, N. A., & Motulsky, A. G. (Eds.). (1994). *Assessing Genetic Risks: Implications for Health and Social Policy*. Washington (DC): National Academies Press (US), p. 259.
[54] Daack-Hirsch, S., & Campbell, C. A. (2014). The Role of Patient Engagement in Personalized Healthcare. *Personalized Medicine*, *11*(1), 1–4, p. 3.
[55] Parens, E. (2015). Drifting Away from Informed Consent in the Era of Personalized Medicine. *Hastings Center Repor*t, 45(4), 16–20, pp. 17-18.

information obtained during these procedures. Thus, any improper use, storage, or communication of these types of information result in violation of privacy of the patient through infringement of autonomy and breach of confidentiality. This happens, for example, when the physician deals with issues such as the quality of patient's consent to conduct genetic tests or medical care involving genetic technologies, the need to report test results, or the limits of the confidentiality of genetic information.

All these new problems in the relationship between the physician and the patient can be illustrated by the example of the informed consent concept. The weakness of standard informed consent designed for traditional medicine is the fact that it is oriented for an individual, without taking into consideration the fact that genetics concern not just the patient, but his/her relatives as well. The traditional option of taking the informed consent form home and discussing it with the family does not answer the question of who should be involved in the informed consent process, when it concerns genetic information. This peculiarity of genetic information and its significance to other parties will be discussed in detail in the next chapter.

3.2. Nature of genetic information

3.2.1. International and national legislation on genetic diagnostics and research

At the dawn of the XXI Century, as society tried to adapt to the new science and medicine based on genetics, a considerable number of genetics-specific laws emerged. Some of the provisions were aimed at regulating genetic research that had been becoming increasingly relevant, including genetic testing, and editing. The first successful results attracted interest, but this interest was eventually replaced by wariness, then the global community reacted to the emerging social situation by issuing documents that were supposed to determine the main directions of development of genetic science. Due to rapid advancements in biotechnology, the field of genetic engineering, burdened by conflicting conclusions, serious risks, and unpredictable consequences, has become the subject of international law.

The very first documents regulating human genetic manipulation were adopted back in the 1980s. Among such documents, a special place belongs to the Recommendation 934/1982 of the Council

of Europe on genetic engineering,[56] which is regarded as the first document on genetic law in Europe. In it, Article 4 proposed to consider genetic engineering in light of human rights.[57] These provisions were later summarized in one of the core international documents regarding this issue – the Oviedo Convention, especially in Chapter IV (Articles 11-14),[58] which is dedicated to the human genome.[59] While Articles 11 and 12 of the Convention deal primarily with the regulation of prognostic genetic tests strictly limited to use for health purposes, by prohibiting any form of discrimination, Articles 13 and 14 that follow focus on interventions in the human genome. In early 1998, the Council added to the Oviedo Convention the Additional Protocol on the Prohibition of Cloning Human Beings, which became the first and only binding document developed in this area, obliging ratifying countries to bring domestic laws into harmony with this international instrument.[60] Also in 1997, a few months after the agreement on the Oviedo Convention, the UNESCO unanimously adopted the Universal Declaration on the Human Genome and Human Rights.[61] This Convention defines the status of individuals participating in research, treatment, or genetic diagnostics, contains requirements for scientific research to comply with the concept of respect for human dignity, thereby excluding practices like human cloning and sets the conditions for scientific activities. Such international laws that address this innovative activity of human species correction reflected the demands that were made to it by regulated scientific practices while guaranteeing personal integrity and dignity.

International rulemaking was followed by national lawmaking. Following the research on assisted fertilization in the 1980s, Spain was one of the first countries to pass legislation to govern this area. This was Ley 35/1988 on assisted reproduction methods, which served as a key moment in the development of legislation concerning gene-related technologies. In the same year was also adopted Ley 42/1988, which determined the main directions in regulating the donation and use of

[56] Parliamentary Assembly of the Council of Europe. (1982). Recommendation No. 943/1982, Genetic Engineering.
[57] Insanguine Mingarro, F. A. (2018). *Terapia genica. Un'indagine biogiuridica*. Aracne collana Quaderni di biodiritto, p. 43.
[58] Council of Europe. (1997). Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS 164), Chapter IV.
[59] Insanguine Mingarro, F. A. (2018). *Op. cit.*, p. 46.
[60] Council of Europe. (1998). Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (ETS 168).
[61] United Nations Educational, Scientific and Cultural Organization. (1997). Universal Declaration on the Human Genome and Human Rights.

embryos or their cells, tissues, or organs. Due to the backlog of legislation from practical biotechnology, Ley 35/1988 was amended by Ley 45/2003 and, finally, by Ley 14/2006 (Law 14/2006 on Assisted Human Reproduction Techniques). One of the principles for regulating assisted reproduction methods proclaimed by this law is the possibility of preventing and treating diseases of genetic origin, provided that there are sufficient diagnostic and therapeutic guarantees.[62] Soon after, this law was supplemented by the Law 14/2007 on Biomedical Research (Ley 14/2007), which also repealed Ley 42/1988. The new law sets standards for the development of biomedical research, taking into account the safety requirements of research and respect for the rights of the population, and also guarantees the freedom of scientific research,[63] clarifying and defining new situations in the scientific field. Thus, both legal documents adopted in 2006 and 2007, respectively, constitute the regulatory framework for the governing of various forms of genetic research and for the identification of related goals to achieve.

Specialized laws have also been adopted in Switzerland. Human genetics and research are governed by several federal laws, each of which concerns particular uses of genetics in medicine. The Federal Act on Medically Assisted Reproduction, based on the provisions of the Swiss Constitution on the regulation of reproductive medicine and gene technology involving human beings,[64] is one of the first documents regarding this issue. One of the main sources is the Federal Act on Human Genetic Testing (Loi fédérale sur l'analyse génétique humaine, LAGH), adopted in 2004, which defines the conditions under which it is permissible to conduct genetic and prenatal analysis in humans. The main goal of LAGH is to protect the individual and prevent excessive genetic testing. Moreover, its Article 35 established the Expert Commission on Human Genetic Testing, which should independently carry out work for the development of this domain in a given direction.[65] However, this law does not apply to genetic analysis for research purposes. Here, the Federal Act on Research involving Human Beings (Loi relative à la recherche sur l'être humain, LHR) remains crucial. The LHR, which was adopted in accordance with Article 118b of the Swiss Constitution, clarifies the provisions of the latter and is primarily aimed at protecting the dignity,

[62] Ley 14/2006, de 26 de mayo de 2006, sobre técnicas de reproducción humana asistida. Boletín Oficial del Estado, 27 de mayo de 2006, núm. 126, pp. 19947 a 19956, Art. 1 (b).
[63] Ley 14/2007, de 3 de julio 2007, de Investigación biomédica. Boletín Oficial del Estado, 4 de julio de 2007, núm. 159, pp. 28826 a 28848, Art. 2.
[64] Constitution fédérale de la Confédération suisse du 18 avril 1999 (État le 7 mars 2021), Art. 119.
[65] Loi fédérale sur l'analyse génétique humaine (LAGH) du 8 octobre 2004 (État le 1er janvier 2014), Art. 31.

human rights, and health of people in scientific research, determining the basic conditions for favorable, high-quality and transparent research on human subjects.[66]

In 1996, the government of the UK established the Advisory Committee on Genetic Testing (ACGT) to consider public health and consumer protection issues in connection to genetic testing in public and private sectors. The role of the ACGT was to advise the government on the development of genetic testing and on the requirements to be met by the suppliers of genetic testing services. The committee published a lot of reports, one of which was Code of practice and guidance on human genetic testing services supplied directly to the public. Three years later, newly created to ensure the ability to cope with rapid development of the sector and associated issues, the Human Genetics Commission (HGC) absorbed the work of the ACGT. This advisory body elaborated numerous principles and guidelines set out in its reports. One of these documents is the Genes Direct report, which was published in 2003 after consultation with the promise of existing problems and solutions. Any non-consensual analysis of the DNA of a living person became illegal in England according to the Human Tissue Act of 2004.[67] As for the requirements to the performance of genetic testing, there are no specific legal standards for genetic service laboratories, but they are required to comply with other factors such as, accreditation with the UK Accreditation Service. The UK sources of regulated genetic therapy and engineering also include, among others, Human Fertilization and Embryology Act of 2008 and code of practice of relevant authority. Thus, while on the one hand the UK system seems to repeat the system of Spain and Switzerland in many ways, on the other hand, it is distinguished by its approach to pre-marketing analysis, which is more reminiscent of the U.S. approach.

The U.S. opted for quite a different approach from that in Europe, regulating biotechnology not as a phenomenon, but as a development of a product from laboratory to the market,[68] and therefore gene therapy is considered in the system of biological devices and drugs. At the federal level, the U.S. Food and Drug Administration (FDA) has authority under the Public Health Service Act and the Federal Food, as well as the Cosmetic and Drug Act to regulate products and drugs related to

[66] Loi fédérale relative à la recherche sur l'être humain (LRH) du 30 septembre 2011 (État le 26 mai 2021), Art. 1.
[67] The Human Tissue Act 2004, UK Public General Acts (2004 c. 30), Art. 45.
[68] Charo, A. R. (2016). The Legal and Regulatory Context for Human Gene Editing. *Issues in Sciences and Technology*, *32*(3). Retrieved May 10, 2020, from https://issues.org/the-legal-and-regulatory-context-for-human-gene-editing/

genome editing and genetic tests. The direct requirements for conducting genetic testing and their quality are contained in the Clinical Laboratory Improvement Amendment (CLIA), which are devoted to the regulation of laboratory activities. As for gene editing, as such, this activity is not prohibited, but is limited by a variety of restrictions.[69] Similarly, there is no explicit ban on human cloning by in the U.S. legislation, although this does not mean that it is allowed, since it could not be legally realized without violating numerous legal provisions. Thus, genetic technologies fall under the comprehensive regulation of the FDA based on specialized laws, regulations and recommendations aimed at monitoring and guaranteeing the effectiveness and safety of separate types of applications of genetic technologies in health care. Moreover, the FDA's authority extends even beyond the U.S. borders, since the actual prohibition of certain types of research in the country implies, due to technical and human resources, blocking or delaying the development of a technology around the world.[70]

The main cause for above listed norms was the development in biotechnology and the need to regulate any activities associated with the human genome, including a change in the genetic structure. Whereas the provisions on the status of genetic information were elaborated because of the fear and fascination for this new type of information. The main reason for legislating the status of genetic information was the idea of the peculiarity of genetic information, by virtue of which it would demand a particular treatment as well. In the end, this idea of genetic information being significantly different from other types of health information and therefore requiring special protection became the embodiment of the term "genetic exceptionalism", which was coined by Thomas H. Murray.[71]

The theory of genetic exceptionalism advocated the need for stricter security around genetic information compared with general medical information for fear that its disclosure may lead to more adverse consequences for patients than in the case of accidental dissemination of patient health data of a non-genetic nature. The supporters of this theory promoted the adoption of special laws on the processing of genetic information, guaranteeing privacy and prohibiting discrimination

[69] The Omnibus Appropriations Act, 2009 (H.R. 1105, Pub.L. 111–8), Sec. 509 (a).
[70] Insanguine Mingarro, F. A. (2018). *Op. cit.*, p. 61.
[71] Murray, T. H. (1997). Genetic Exceptionalism and "Future Diaries": Is Genetic Information Different from Other Medical Information? In M. A. Rothstein (Ed.), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (pp. 60-73). New Haven, Conn.: Yale University Press, p. 61.

based on genetic differences; opponents were rather skeptical about the expediency of such laws, their application in practice and the justification of financial costs, taking into account the serious problem of separating genetic information from other health data in medical records. Despite the lack of consensus on this issue, it seems that some legislators have nevertheless followed the path of genetic exceptionalism.

The most striking example of this idea at the international level is given by UNESCO.[72] Article 4 of the International Declaration on Human Genetic Data, one of the central instruments of UNESCO in bioethics, attributes status of a special importance to human genetic data. This is because genetic data may identify a genetic predisposition, which may affect an individual's family, or even the group to which he/she belongs, and may contain information of unknown value and may have cultural significance.[73] At the national level, some countries adhere to this idea as well and have enacted specific laws on this matter. However, this issue is beyond the scope of the academia[74] and is causally related to the effectiveness of protecting the rights of individuals and to the functionality of the legal system.

3.2.2. Features of genetic information and its peculiarity

Without delving into the discussion regarding benefits and risks of genetic exceptionalism, we will try to understand if genetic information is somehow distinct from other kinds of medical information by analyzing all criteria and characteristics of genetic information provided by both the supporters and opponents of this idea. For example, members of the Personalized Health Care Work Group of the American Health Information Community highlighted several characteristics of genetic data in the context of developing policies about information protection, especially concerning electronic health records. These characteristics include, among others, the uniqueness of the genetic code as a powerful tool of identification, the predictive ability of genetic information, the perceived immutability of DNA throughout an individual's life, the historical misuse of genetic information as a reason for fear of improper use of the results of genetic analyses, variability in

[72] de Paor, A. (2017). *Genetics, Disability and the Law: Towards an EU Legal Framework* (Cambridge Disability Law and Policy Series). Cambridge: Cambridge University Press, p. 166.
[73] United Nations Educational, Scientific and Cultural Organization. (2003). International Declaration on Human Genetic Data, Art. 4 (a).
[74] Rothstein, M. A. (2005). Genetic Exceptionalism and Legislative Pragmatism. *Hastings Center Report*, *35*(4), 27–33, p. 27.

public knowledge and prospects regarding the role of genetics, and the potential impact of genetic information on blood relatives.[75]

However, these features, in general, are not exhaustive and not entirely unique for this type of information.[76] They represent practical and technical issues associated with obtaining and using genetic data. Instead of revealing the very essence of genetic information, these characteristics rather describe it. For example, with regards to the uniqueness of genetic information for identification purposes, it would be wrong to assert that the rest of the medical information lacks this quality to a greater or lesser extent. Arguing against the special quality of immutability of genetic data, some opponents of genetic exceptionalism cite as an example the immutability of non-genetic diagnoses, such as the diagnosis of multiple sclerosis or Alzheimer's disease.[77] Other characteristics of genetic information, such as its predictive ability and consequences for the family, also lend themselves to criticism. Nevertheless, this criticism concerns rather the exclusivity of these characteristics and their sufficiency for a special attitude towards genetic information, without denying any of its inherent qualities.

Another criteria to separate genetic from other non-genetic medical information is based on how the consequences of each type of information differ for an individual, family and society.[78] A peculiarity of genetic tests and the information obtained as a result of them is that, unlike most medical tests, they can reveal a hereditary disease in an apparently healthy person before any symptoms appear, some of which may also not have treatment available, or unforeseen unwanted information like non-paternity.[79] As a result, for some people, possession of such information can be an impetus in order to change their behavior and attitude to health, get rid of bad habits and go for more regular medical check-ups, while for others it can become a source of negative thoughts, anxiety and fear, which can even accelerate course of the disease.[80] As for the effect on family

[75] McGuire, A. L., Fisher, R., Cusenza, P., Hudson, K., Rothstein, M. A., McGraw, D., Matteson, S., Glaser, J., & Henley, D. E. (2008). Confidentiality, Privacy, and Security of Genetic and Genomic Test Information in Electronic Health Records: Points to Consider. *Genetics in medicine: official journal of the American College of Medical Genetics*, *10*(7), 495–499, pp. 496-497.
[76] *Ibid.*
[77] Evans, J. P., & Burke, W. (2008). Genetic Exceptionalism. Too Much of a Good Thing? *Genetics in medicine: official journal of the American College of Medical Genetics*, *10*(7), 500–501, p. 500.
[78] Sarata, A. K. (2011). *Genetic Exceptionalism: Genetic Information and Public Policy*. CRS Report for Congress, pp. 2-3.
[79] *Ibid.*
[80] *Ibid.*

members, patient's genetic tests for inherited markers may reveal the risks that all his/her relatives may have and may even prevent the disease, in case if they want to be tested or know their results.[81] In the context of significance for society, qualities as the ability of genetic information to change the idea of what is normal and what is not normal are important, as in the case of lactose intolerance, as well as the ability of genetic information to associate a person with a certain group or heritage.[82] Nevertheless, these qualities concern not only the genetic information itself, but also the features associated with the conduct of genetic tests and genetics itself, as scientific knowledge.

Unfortunately, these examples show that it is not that easy to draw a clear line between genetic information and general health information. However, the main problem that led to all these vague descriptions and contradiction is the absence of a clear definition and understanding of what genetic information is and what it includes.

3.2.3. Definition of genetic information

There are various views on it, and almost all attempts to define genetic information in the context of the law had some issues or were unsuccessful. As a result, molecular biologists understand this term as one thing, while the rest of the society, lawmakers and politicians have a different understanding. This causes anxiety about practicality of privacy laws. In existing legislation, there is a whole range of definitions of genetic information from the narrowest in meaning to the unreasonably broad, each of which has its own strengths and weaknesses.

Some laws link the definition of genetic information with the results of genetic tests.[83] However, this definition is very narrow and fails to cover a significant part of data. Genetic information comes not only from DNA, RNA, and amino acid sequencing, but also from clinical evaluations, non-genetic tests, family history, and medical anamnesis.[84] Long before genetic testing was developed, observation of patient condition and state of health of his/her relatives made it possible to draw accurate conclusions about certain hereditary diseases. Information like high blood

[81] *Ibid.*, p. 4.
[82] *Ibid.*, p. 5.
[83] *E.g.*, Loi fédérale sur l'analyse génétique humaine (LAGH) du 8 octobre 2004 (État le 1er janvier 2014), Art. 3 (l); ORS § 192.531 (2011).
[84] Suter, S. M. (2001). The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation? *Washington University Law Quarterly*, *79*(3), 669–751, p. 702.

pressure, diabetes, and cancer among family members can show hereditary predispositions regardless of genetic tests. Similarly, evidence that a relative of the patient was diagnosed with Huntington's disease (HD) predicts the patient to carry a 50% risk of the disease, even though no genetic tests are required to obtain this information. In combination with similar clinical observations, diagnostic imaging, and other biochemical analyses of non-genetic substances, and even a routine blood test for cholesterol can reveal genetic disorders. Such a definition of genetic information automatically makes it part of the medical information, as it exclusively relates to the health of the individual. Moreover, an attempt to define genetic information by defining genetic tests is not the best approach, because there is no consensus on the meaning of the latter.

In contrast to the first restrictive approach, some laws use a broader wording to define genetic information, such as information about genes, gene products, [85] or inherited traits.[86] On the one hand, this solves the problem of under-inclusion and covers examples of a family history of HD and certain types of cancer, etc.[87] Also, this definition includes data on multifactorial genetic diseases, such as diabetes, most oncological diseases, heart diseases, asthma and some mental disorders, which are the result of the interaction of changes in several genes in combination with the influence of environmental factors and lifestyle.

On the other hand, the genetic information defined in this way goes already beyond the scope of the concept of medical information, as it contains excessive data that in no way relates to the state of health, such as information about the height, eyes and hair color, and sex. Although these data are genetic, it would be wrong to mix them together with, for example, a predisposition to life-threatening or mental diseases, since they are not of special interest to be protected compared to truly sensitive personal information. Of course, if we talk about the use of genetic information for the needs of forensic medicine, then height, hair color, eye color and sex will be of completely different value.

[85] *E.g.*, NC Gen Stat § 95-28.1A (2005); NJ Rev Stat § 17B:30-12 (2013).
[86] *E.g.*, Ley 14/2006, de 26 de mayo de 2006, sobre técnicas de reproducción humana asistida. Boletín Oficial del Estado, 27 de mayo de 2006, núm. 126, pp. 19947 a 19956, Art. 3 (j); United Nations Educational, Scientific and Cultural Organization. (2003). International Declaration on Human Genetic Data, Art. 2 (i).
[87] Suter, S. M. (2001). *Op. cit.*, p. 703.

No matter how broad the second approach may be, it nevertheless overlooks some data, which, oddly enough is covered by the first narrower definition of genetic information. The concern is that those laws[88] emphasize the heredity of genetic information, excluding from it any acquired genetic characteristics. Mutations of genes can be generative (hereditary) and somatic (acquired). The latter occur in a person throughout his/her life and are present only in certain cells, not in every cell in the body, and cannot be passed to the next generation. They depend on the negative impact of external factors – stress, bad habits, improper lifestyle, as well as by environmental factors such as ultraviolet radiation from the Sun, or can occur if a copying error arises in the process of DNA replication in cell division, and the error remains uncorrected.

For example, in diagnosing of cancer, using a blood test and tumor tissue makes it possible to determine which mutation led to the formation of a tumor. Blood DNA analysis makes it possible to understand whether a mutation is hereditary, while DNA analysis of tumor tissue allows somatic mutations to be identified, and provides an idea about their nature. Both types of mutations cause a permanent change in the DNA sequence, which distinguishes it from the structure of the gene found in other people, therefore it is not at all correct to exclude one of these from the definition of genetic information. Among all laws, normative acts, and regulations we have examined, this nuance is taken into account only by the GDPR.[89]

Another inaccuracy in the definition of genetic information can be highlighted in some regulatory documents. Many laws that use extended meaning include genetic test results from family members or family history as sources of genetic information. However, some of them do not specify that this applies specifically to blood relatives. According to the Genetic Information Nondiscrimination Act of 2008 (GINA), the U.S. Federal Law protecting individuals from genetic discrimination in health insurance and employment, genetic information includes, in addition to the information about the genetic tests of an individual, the genetic tests of his/her family members

[88] *E.g.*, NC Gen Stat § 95-28.1A (2005); NJ Rev Stat § 17B:30-12 (2013); Ley 14/2006, de 26 de mayo de 2006, sobre técnicas de reproducción humana asistida. Boletín Oficial del Estado, 27 de mayo de 2006, núm. 126, pp. 19947 a 19956, Art. 3 (j); United Nations Educational, Scientific and Cultural Organization. (2003). International Declaration on Human Genetic Data, Art. 2 (i).

[89] Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), Art. 4 (13).

and the manifestation of a disease or disorder in family members.[90] The same section of the GINA contains the definition of a family member as a dependent of an individual or a relative of the individual or his/her dependent from the first to fourth degrees of kinship.[91]

Likewise, the regulations issued by the Equal Employment Opportunity Commission clarify that person can be a dependent "as a result of marriage, birth, adoption, or placement for adoption".[92] From these provisions, it follows that genetic tests or medical history of, for example, an individual's spouse, as well as spouse's great-grandparents, grandparents, uncles, aunts, parents, siblings, half-siblings, cousins, should also be considered genetic information of the individual. This inconsistency between the legal definition and the biological definition is confusing and cannot protect the rights of the individual concerned. Moreover, such extended notion of genetic information is unfounded and impractical.

In this light, special attention should be paid to the case *Poore v. Peterbilt Bristol, L.L.C.* concerning a company employee, who was dismissed in the absence of any complaints about his performance three days after filling out a health-insurance questionnaire on his family's medical history and medications, in which he indicated that his wife was diagnosed with multiple sclerosis.[93] According to the letter of the law, information about the wife's multiple sclerosis is genetic information within the framework of the GINA. However, the court backed out of the statutory language of the GINA,[94] referring to the main purpose of this act to prohibit employers from making "predictive assessment concerning an individual's propensity to get an inheritable genetic disease or disorder based on the occurrence of an inheritable disease or disorder in family member".[95] The key features of genetic information in this argument are its predictivity and heredity, which are not reflected in the wording of the Section 201 of the GINA adopted by Congress and which do not characterize any health information obtained from non-blood relatives.

[90] 42 U.S. Code § 2000ff (4) (2008).
[91] *Ibid.*, § 2000ff (3).
[92] Genetic Information Nondiscrimination Act, 29 CFR § 1635.3 (2008).
[93] Poore v. Peterbilt of Bristol, L.L.C. [852 F. Supp. 2d 727] (W.D. Va. 2012).
[94] Suter, S. M. (2018). GINA at 10 Years: The Battle Over 'Genetic Information' Continues in Court. *Journal of Law and the Biosciences*, *5*(3), 495–526, pp. 507-508.
[95] H.R.Rep. No. 110–28, pt. 3, at 70 (2007), 2008 U.S.C.C.A.N. 112, 141, as cited in Poore v. Peterbilt of Bristol, L.L.C. [852 F. Supp. 2d 727] (W.D. Va. 2012), at 730.

Therefore, we have identified four main issues with the definitions of genetic information found in international regulations as well as in national laws of the analyzed legal systems concerning the regulation of data protection – 1) reducing the concept exclusively to genetic tests, 2) overloading with non-sensitive information that does not require the same protection, 3) neglecting somatic mutations that are not hereditary, and 4) extending the term to family members not related by blood. Therefore, we propose our version of term of genetic information, based on the definitions analyzed, in order to take into account all these discrepancies. Hereinafter, (individual) genetic information shall be understood as information relating to:

- the inherited genetic characteristics of an individual or his/her family member which give individual predictive information about the physiology or the health of that individual or his/her family member which result from genetic analysis of a biological sample of that individual or his/her family member, family medical history of that individual or other scientific and medical examinations of that individual or his/her family member; (AND
- the acquired genetic characteristics of an individual which provides an insight into the physiology or the health of that individual and which result from genetic analysis of a biological sample of that individual.)

Although, the term "family" usually encompasses blood relatives of first, second, third and fourth degree of kinship, we will elaborate on this issue in the chapters to come. The "individual" component is used as opposed to the familial sharing of inherited genetic information. However, the proposed terminology cannot be universally applied to any relationship emerging around genetic information. This definition should be used for the purposes of regulating medical confidentiality and privacy and should not be mixed with genetic information used for the prevention and investigation of crimes, as well as the identification of persons who committed them, or for the purposes of scientific research. For example, genetic profiling by matching DNA patterns, which is used for forensic purposes to compare samples expected to be received from the same suspect, is the most individual form. This test, which identifies repetitive coding sequences unique to each person, is different from genetic tests for medical purposes. The information obtained as a result of such tests differs in its essence and objective from genetic information decoded for health purposes.

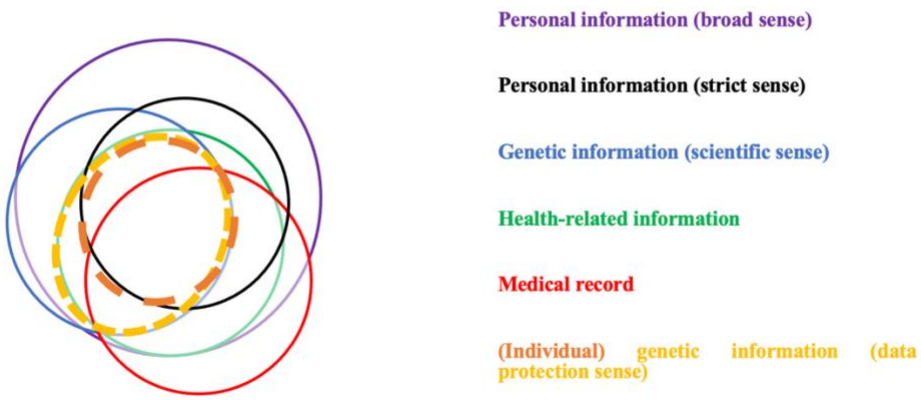

Figure 1. Genetic information and other types of personal information.

For clarity, there is a correlation between genetic information and other types of information related to the individual (Figure 1). In this outline, personal information in the broad sense means the same as in the privacy and data protection legislations analyzed earlier, namely, protected personal information about an individual by which he/she can be identified directly or indirectly, that is, any information that concerns this individual in one way or another. This covers a very wide range of data, which includes information that can be personal to another individual at the same time. For example, information about a child being born with fetal alcohol syndrome is not only personal information of the child, but also of the mother, as it indicates the use of alcohol during pregnancy. For this reason, within this general term, we have outlined the boundaries of a narrower concept of personal information in the strict sense as information exclusively about the individual. This example also shows that health-related information is part of personal information in the broadest sense but goes beyond personal information in the strict sense.

Unlike medical information, not all genetic information in the scientific sense is personal, such as those parts of the DNA that are identical for all humans. The same applies to the information contained in medical records, as they may contain information beyond the patient's access, like physician's personal notes or health information about other people. At the same time, genetic

information according to the definition that we are proposing belongs to the category of medical information. Individual genetic information, on the other hand, is limited to the scope of personal information in the strict sense and applies exclusively to the individual.

On the basis of this unified concept of genetic information, we can now distinguish its true particularities that other types of medical information do not possess – the familial nature of genetic information and its predictivity. Since most genetic information is transmitted by inheritance, with the exception of somatic mutations, genetics is able to explain the general physical traits of the patient as well as of his/her relatives. In addition to detecting rare genetic diseases, of which there are several thousands,[96] genetic technologies make it possible to identify predispositions to diseases, responses to drugs, the effectiveness of a particular treatment, incompatibility with substances and products, and much more. Differences in the genetic makeup of people, individually or in combination, as well as under the influence of external factors, such as the environment and lifestyle, make everyone more susceptible or less susceptible to the same disorder.[97] Since part of this genetic makeup of each person passes down from generation to generation in his/her family, there will be some shared pattern in their susceptibility. Accordingly, genetic information is of great value both for the patient himself/herself and for each family member, which other types of medical information do not represent to the same extent.

3.2.4. Who is the owner of genetic information?

What exactly happens to health-related information, including genetic data, after a patient undergoes medical examination, receives the results of an analysis or a genetic test, or after completion of a genetic study? Initially, there were three points of view regarding to whom this data belongs – to the patient, to the physician or to the medical institution. Based on the point of view that health information, like other types of personal information, is an element of such an intangible benefit as private life or privacy, and concerns the patient, it is the patient who is the logical owner. Moreover, medical records are created for the benefit of the patient.

[96] Jackson, M., Marks, L., May, G. H. W., & Wilson, J. B. (2018). The Genetic Basis of Diseas. *Essays in biochemistry*, *62*(5), 643–723, p. 643.
[97] *Ibid.*

However, this information assumes completely different forms when the patient receives medical services. Information about the patient's health contained in medical records represents systematized results of the intellectual activity of the physician, and not just a transcription of data or news about the patient. In this sense, medical information represents an element of the database. At the same time, due to labor reasons, the result of the work of the physician becomes the property of the institution, which is responsible for maintaining medical records. In addition to providing care to patients, healthcare institutions use medical records for business purposes in order to pay taxes and receive payment from insurance companies, and to protect against malpractice cases, as well to transfer them in case of merging, etc.

In this context, some legislators clearly distinguish intangible medical information from tangible medical records, as well as from the patients' right to access their health information, which was already discussed in previous chapters, and ownership of this information. Naturally, certain variations in legal regulation are present in different systems. Medical records are generally considered the property of a healthcare provider – either private medical practitioner, or healthcare institution. These rules are characterized by a high degree of uniformity, even with a patchwork approach, based on state legislative schemes in the U.S.[98] Despite the lack of special federal provisions on this matter, a lot of states have granted ownership of medical records created or obtained in the process of treatment to physicians and/or healthcare facilities.[99] Some of these regulations refer to physical transfer of the records, such as paper, film, and radiographs.[100]

These provisions do not give healthcare providers complete dominance over medical records and the information contained therein, but limits this ownership right, rather obliging them to act as a trustee for the benefit of the patient.[101] Based on this, it is often presumed that the information contained in the records belongs to the patient. Yet, only the law of a single U.S. state – New Hampshire – explicitly recognizes all medical information contained in the medical records to be the property of the patient,[102] while majority of states as well as the federal law provide the patients

[98] Dwyer, C. (2013). Comparing Medical Record Ownership and Access: Australia, Canada, UK, USA. In R. G. Beran (Ed.), *Legal and Forensic Medicine* (pp. 1699-1716). Berlin: Springer, p. 1710.
[99] *E.g.*, SC Code § 44-115-20 (2020); 22 CCR § 70751 (b) (2008).
[100] *E.g.*, 052-3 Wyo. Code R § 3-4 (2019).
[101] Dwyer, C. (2013). *Op. cit.*, p. 1710.
[102] NH Rev Stat § 332-I:1 (1996).

with the right to access their health-related information. In those states, courts tend to recognize the patient as having a limited interest in owning medical records.[103] At the same time, genetic information, which is a type of medical information, is considered the private property of individuals in several states.[104] In this model, medical records are not presented as a whole, but rather as a composite, where different sides have different claims on each component. Despite the fact that not enough attention is paid to the problem of the patient's ownership of the data in these records, and legislation focuses only on its use and patient's access, a clear distinction is made between the form and content of medical records.

In the UK, this issue was first addressed in 1979, identifying the Secretary of State as the owner of all personal medical records of patients who underwent treatment within the NHS system.[105] Similarly, in modern days medical records are not considered property of patients themselves. The law only defines the procedure for accessing information and obtaining only copies of the record, without mentioning the ownership of the information itself. A different situation has developed in Spain and Switzerland, where there are specific regulations and requirements concerning maintenance, use and access to medical records, rather than property issues. Whether the patient's ownership of medical information is recognized by law or not, in reality, all the rules governing the procedure to access one's own health information, including the requirements of request, deadlines and payments, indicate that the information may belong to anyone but the patient.

The days when physicians kept patients' records in multi-colored folders and updated them by hand have almost passed, and disputes over the possession of medical information have been brewing since the emergence of computers, especially with the widespread use of the Internet,[106] and finally the switch towards electronic health records (EHR). Although some state legislators in the U.S. envisage personal property interests in medical information, it is impossible to talk about the traditional ownership in these situations, since the information does not meet the criteria for the content of property rights. Being one of the oldest legal institutions, property primarily pertains to the possession, use and power of disposition of a thing *(res)*. Traditionally, information does

[103] Roach, W. H. Jr. (2003). *Medical Records and the Law* (3rd ed). Jones & Bartlett Learning, p. 89.
[104] *E.g*., CO Rev Stat § 10-3-1104.7 (2017); Fla Stat § 760.40(2)(a) (2018).
[105] Dwyer, C. (2013). *Op. cit.*, p. 1708.
[106] Contreras, J. L. (2019). The False Promise of Health Data Ownership. *New York University Law Review*, *94*, 624–661, p. 626.

not belong to the category of things, and the courts are reluctant to recognize the information as an object of property while considering the recognition of property interests in various intangible assets.[107] Moreover, the example of established schemes for regulating the status of medical information shows that none of the stakeholders has exclusive and monopolistic opportunities of possession and control over it.

Nevertheless, it is not surprising that the issue of ownership of information has become one of the main topics concerning health-related information, and not only because of appeals to autonomy and privacy, but due to the economic interests as well. Clinical data are increasingly valuable not only to the patient, but also to the healthcare professional, medical institution, public and private sector, etc. Aside from the patient, other parties have their own powerful political, economic and scientific interests concerning these health-related data.[108] Trading data from EHR, including physician's notes, prescriptions, laboratory tests, insurance claims, has become quite a prosperous and profitable business, which however excludes the patients themselves, and rather builds on exploiting them.[109] Without established ownership, all these data exchange operations take place in the absence of a clear understanding of who is entitled to conduct such transactions, therefore they are not suitable for building a truly effective health data economy.[110] In order to balance this information asymmetry, various platforms and servers offer patients the opportunity to regain ownership of their information by storing, managing, sharing and benefiting from their data.[111] Currently, blockchain technology acts as a promising tool to guarantee patient privacy within the EHR system, which would prevent the spread of information without patient's authorization, thereby returning ownership back to the patient.[112]

To ensure that such rights are legally enforceable, it would be necessary to build from scratch a completely new legal property framework. Just as how these kinds of relationships do not fall

[107] *Ibid*., pp. 633-636.
[108] Ballantyne, A. (2020). How Should We Think About Clinical Data Ownership? *Journal of Medical Ethics, 46,* 289–294, p. 290.
[109] *Ibid.*
[110] Kish, L., & Topol, E. (2015). Unpatients – Why Patients Should Own Their Medical Data. *Nature Biotechnology*, *33*(9), 921–924, p. 923
[111] *E.g.*, The Hub of all Things https://www.hubofallthings.com; Savvy https://www.savvy.coop; Healthbank https://www.healthbank.coop/
[112] Chawdhuri, D. R. (2019). Patient Privacy and Ownership of Electronic Health Records on a Blockchain. In J. Joshi, S. Nepal, Q. Zhang & L.-J. Zhang (Eds.), *Blockchain – ICBC 2019.* (Lecture Notes in Computer Science, vol 11521). Springer International Publishing, pp. 95-99.

under traditional property rights, they are unlikely to receive protection under intellectual property rights. However, despite good intentions, such exclusive control over medical information can negatively affect the development of science, hinder research, and lead to the reduction of public benefit in advanced health care. In addition, this model does not take into account the fact that not all information regarding the patient's health concerns exclusively him/her. This is especially true for genetic information. Since there is talk about securing patient's property rights over the information, instead of individual property rights it should be a question of establishing collective ownership, in which all members of the family would have equal rights to its control and use, and have equal participation in the disposal of benefits. Otherwise, the goal of equitable distribution is unlikely to be achieved. At the same time, such a model would be absurd, since an attempt to determine the circle of owners without leaving anyone overboard, as well as to ensure the participation of everyone in the process of decision making, can hardly be successful. Under the guise of protecting privacy and autonomy, the commercialization of health information risks to make its primary goal – to provide proper care to the patient – unattainable.

3.2.5. What about direct-to-consumer genetic tests?

The direct-to-consumer (DTC) genetic tests (DTC-GT), which are conducted outside of the organized healthcare environment, deserve a special attention. Products of previously mentioned 23andMe, as well as Ancestry DNA, Living DNA or many more similar companies have become incredibly popular. The services of only one of these companies have already been used by more than 12 million people.[113] These DTC-GT kits are quite affordable and can satisfy curiosity about ancestry or concerns about health risks and predispositions for a relatively small amount of money. These companies managed to make genetics closer and more accessible to ordinary people, allowing people to take greater responsibility for their health and future, which favorably affects the implementation of their autonomy and self-determination.[114] Despite this benefit, their activity raises many questions.

[113] *23andMe – About Us*. (n.d.). 23andMe. Retrieved June 2, 2020, from https://mediacenter.23andme.com/company/about-us/

[114] Jales, C. F., & Borry, P. (2013). Direct-to-Consumer Genetic Testing Services: Policies and Challenges. In R. G. Beran (Ed.), *Legal and Forensic Medicine* (pp.1583-159). Berlin: Springer, p. 1585.

Along with doubts about the reliability of such tests and their real medical significance, there are concerns that such high-tech companies, not being physicians and not obeying the same ethical principles, are not able to guarantee the privacy of their clients. Many DTC-GT companies are currently sharing their customer data with researchers for scientific reasons such as developing treatments for serious diseases. Although DTC tests are not truly medical because of their limitations and doubts about the reliability and predictive value of the results,[115] interest of other parties, especially pharmaceutical companies, in such data is no less than in medical records. While some companies in their Terms and Conditions explain how they will use the data obtained in the future, the rest are less transparent in this regard.[116] The customers report not only data about their genetic makeup, but in many cases also the information about the state of their health, family history, lifestyle, and behavior, as well as potential future conditions which are not necessarily accurate when based on some DTC-GT.[117] Certainly, this is not compulsory, and users do it voluntarily on the basis of a contract, although they do not always understand the consequences of the secondary use of this data. At first glance, in such a relationship between individuals and DTC-GT companies, the individual appears to be in full control of managing his/her own information. However, this kind of consent looks more like a veiled agreement on transfer of rights, or even waiver of rights, rather than an informed consent. To remedy this situation, some companies started to give individuals the sole right to own their own data, allowing them to sell and benefit from it financially.[118]

The raw genetic information obtained from these tests does not form part of the medical records. At the same time, legislation regarding DTC genetic testing varies widely from country to country – from the complete prohibitions of testing outside the clinical setting to free access to such tests. In general, national legislations only partially apply to DTC genetic testing, as they are not

[115] *Ibid.*
[116] Laestadius, L. I., Rich, J. R., & Auer, P. L. (2017). All Your Data (Effectively) Belong to Us: Data Practices Among Direct-To-Consumer Genetic Testing Firms. *Genetics in medicine: official journal of the American College of Medical Genetics*, *19*(5), 513–520.
[117] Christofides, E., & O'Doherty, K. (2016). Company Disclosure and Consumer Perceptions of the Privacy Implications of Direct-To-Consumer Genetic Testing. *New Genetics and Society*, *35*(2), 101–123, p. 104.
[118] *How does Nebula Genomics compare to other DNA Tests?* (n.d.). Nebula Genomics. Retrieved June 2, 2020, from https://nebula.org/whole-genome-sequencing/

specifically intended to address the issues with these services.[119] Moreover, the information shared and exchanged through DTC-GT companies often does not fall under the privacy regulations, which puts the users themselves and their relatives in a vulnerable position. Neither in the case of opt-in exchange, nor in the case of proclaimed customer's ownership of genetic information, are there any systems to protect the genetic privacy of the customer's family. Since the individual who purchased the DTC genetic testing services shares with his/her blood relatives some part of the genetic code, each time he/she allows access to his/her own data, he/she implicitly shares the data of the family members. Thus, the system in which these high-tech companies operate only creates the appearance that the power of control over the information lies in the hands of customers themselves, while being merely another step towards the end of privacy.

3.3. Interim conclusion

Genetics, in short, is the schematic and blueprint that governs how our body appears and functions. Decades of studies by biologists have revealed that this blueprint is codified, and that different parts of the code is responsible for determining different features about the appearance and function of the cells and the body as a whole. The Human Genome Project which followed, provided the first look at the complete set of all genetic information held in human DNA, and gave an insight into the sort of stories that genetic information tells, whether it be regarding genealogy or pathogenesis. The genetic basis for human diseases, as revealed through the works of the HGP and subsequent studies, defined that the genetic disorders responsible for diseases can be largely classified into three groups, and the most important proportion of diseases arise due to a multifactorial relationship between genetics and lifestyle. Over the past years, genetic technologies have been developed in science and to date have already been integrated into practical medicine.

The use of genetic technologies and the emergence of new types of therapy and care based on genetic technologies are unambiguously associated with enormous positive and dangerous aspects. Like any innovation, they are associated with certain ethical, social, economic, and legal problems.

[119] Kalokairinou, L., Howard, H. C., Slokenberga, S., Fisher, E., Flatscher-Thöni, M., Hartlev, M., van Hellemondt, R., Juškevičius, J., Kapelenska-Pregowska, J., Kováč, P., Lovrečić, L., Nys, H., de Paor, A., Phillips, A., Prudil, L., Rial-Sebbag, E., Romeo Casabona, C. M., Sándor, J., Schuster, A., Soini, S., … Borry, P. (2018). Legislation of Direct-To-Consumer Genetic Testing in Europe: A Fragmented Regulatory Landscape. *Journal of community genetics*, *9*(2), 117–132, p. 117.

The main burden falls on the law since it is necessary to adapt existing standards and work out the missing ones to ensure that the rights and interests of patients are primarily respected. In view of this, special laws have been adopted at the international and national levels that regulate both the technical side of the process and the related rights and freedoms of people. Particular attention was paid to the problem of ensuring the confidentiality of genetic information. Due to the huge number of genetics-related questions that are still not answered, and fear of unknown, the idea of genetic exceptionalism was born.

The importance of regulating confidentiality of genetic information can be explained by the same arguments as the importance of keeping personal information confidential, especially sensitive data, since the disclosure of such information can lead to undesirable consequences for its owner. The main example of such consequences is discrimination based on genetics, which sometimes can manifest itself much more strongly than other forms of discrimination, since it includes discrimination based on future presumptive signs, such as the possibility of developing a certain disease in a few years. However, this does not mean that genetic information is some completely new kind of information that deserves special attention.

The main problem is that inaccurate understanding and definition of genetic information for the purpose of ensuring medical confidentiality led on the one hand to overlapping and on the other hand to gaps in privacy regulations. With an accurate understanding of what is meant by genetic information, it becomes clear that, in terms of medical confidentiality, current privacy laws do not seem to comply with these new genetic technologies. This generally follows from the fact that they are designed to regulate the circulation of medical information within the circumstances of traditional medicine. They do not take into account or do not sufficiently take into account the peculiarities of genetic information and the interests of other persons, that is, family members who share the same genetic code. Thus, the rules on protecting the confidentiality of genetic information from a family member of a patient raise many questions. Since genetic information can indicate a predisposition of relatives to a genetic disease, the transfer of such information to the at-risk family members is necessary to guarantee them the possibility to make their autonomous decision regarding their health, which after all can save their lives.

4. CONFLICT OF INTERESTS

4.1. One more exception to the right to privacy

4.1.1. Autonomy and personal interests of patient's family members

In certain situations, which have already been discussed in previous chapters, the right to privacy of an individual may be in conflict with other fundamental rights of other people. For this reason, the right to privacy is not absolute in the sense that in some rare and quite limited situations it may be restricted in order to guarantee the fulfillment of the preponderant interests of third parties. Anyway, the interference, whether in the public interest or according to the law, should be carefully analyzed for necessity, legitimacy, and proportionality. In this chapter, we will focus on one specific case where the right to privacy in the context of the provision of medical services, namely the patient's interest in maintaining the confidentiality of information about his/her health, may contradict with the right of relatives to autonomy, namely their interest in receiving the information, which is related to their health as well, based on which they would make informed decisions about potential treatment and any other plans for future life. This chapter addresses the rules of medical confidentiality and privacy and the principle of autonomy in the context of family relationship.

The idea of autonomy, which became central value in the Kantian tradition of moral philosophy, generally refers to the capacity of an individual to be his/her own person and live a life based on own motives and reasons without external pressure and manipulations.[1] Along with the concept of privacy and dignity, respect for individual autonomy has become an integral message of modern human rights as well. While autonomy is recognized as one of the unlisted constitutional rights of citizens in many jurisdictions,[2] the Universal Declaration on Bioethics and Human Rights explicitly acknowledges this right and the obligation to respect it in its Article 5, as well as other international instruments such as the Convention on the Rights of Persons with Disabilities, in its Article 3. Despite the importance of the principle of autonomy in bioethics and the fact that it is now often considered only in the context of health care and informed consent, this principle is not

[1] Christman, J. (2019). Autonomy in Moral and Political Philosophy. In E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy*. Retrieved June 9, 2020, from https://plato.stanford.edu/archives/spr2018/entries/autonomy-moral/
[2] Campbell, L. (2017). Kant, Autonomy and Bioethics. *Ethics, Medicine and Public Health, 3*(3), 381–392, p. 383.

limited to the medical domain, and it plays a fundamental role for the life of all people, regardless of their status.

Originally referring to the independent city-states, the term "autonomy" comes from Ancient Greek, as a result of the combination of two words – *autos* (own, self) and *nomos* (rule, governance, law). Then, this term began to be applied to people, in the sense of an autonomous person who acts according to his/her own choices, as opposed to having these things imposed. Since then, various meanings have been imparted on this term, being equated with liberty, freedom, integrity, independence, responsibility and many more other notions and features.[3] Such a variety of contexts indicates that the concept of autonomy itself is very vast and there is a number of different situations that refer to distinct elements of this concept and which have unequal relevance and content.[4]

However, in general, it is understood as an individual's self-government, which consists of two elements, namely *liberty*, or independence from controlling influences and interventions of third parties, as well as *agency*, the ability to deliberate actions, free from personal restrictions.[5] Thus, the concept reflects both an internal factor, which depends on the person's ability to understand, analyze and make decisions, and an external factor, independent of him/her, which is expressed in someone's power or actions that interfere with the individual's self-determination. A mentally incapacitated person is an example of such internal constraints for making an autonomous decision when the disease limits the capacity to acting intentionally.[6] This person might not be under any pressure or control but is still lacking free will in majority of his/her actions. In contrast to this, a prisoner might enjoy a high level of free will while having an extremely limited liberty as the correctional institution imposes certain frameworks which influences choices.[7] The autonomy of the decision made can be assessed in terms of whether the person is sufficiently developed to act

[3] Dworkin, G. (1988). *The Theory and Practice of Autonomy* (Cambridge Studies in Philosophy). Cambridge: Cambridge University Press, p. 6.
[4] Arpaly, N. (2004). *Unprincipled Virtue: An Inquiry into Moral Agency*. New York: Oxford University Press, p. 118.
[5] Beauchamp, T. L. (2005). Who Deserves Autonomy, and Whose Autonomy Deserves Respect? J. Taylor (Ed.), Personal Autonomy: New Essays on Personal Autonomy and its Role in Contemporary Moral Philosophy (pp. 310-329). Cambridge: Cambridge University Press, p. 310.
[6] Beauchamp, T. L., & Childress, J. F. (2001). *Op. cit.*, p. 58.
[7] *Ibid.*

as an agent, and whether external influence was exerted on him/her and prevented from being pure in his/her agency.

Without getting deep into the debate, it is important to note that there are two main lines of conceptualizing autonomy – Millian and Kantian accounts.[8] The first approach suggests that an individual is autonomous to the extent he/she directs his/her life according to his/her own values. On John S. Mill's argument, there is value in making original choice as given that "person possesses any tolerable amount of common sense and experience, his own mode of laying out his existence is the best, not because it is the best in itself, but because it is his own mode".[9] As for the rationality of actions, this assessment of autonomy does not depend on the assessment of values that underlie such decisions, as long as the decisions are individual. Regardless of the concepts of good and evil and other judgments, any human decision made by will, with understanding and without coercion, must be respected.

In this sense, autonomy implies that competent people who have complete information, without anything hidden from them or being lied to, have the right to make bad decisions such as bad habits and bad investments.[10] On the one hand, no matter how unreasonable this decision may seem to others, it should be respected, since in general each person knows what is better in his/her own interests than anyone else.[11] On the other hand, the integrity of the choosing agent prevails over welfare, emphasizing his/her responsibility for the decision, as well as the relevance of this decision to the system of values chosen by the agent.[12]

In its relationship to rationality, the Millian approach seems to diverge from the Kantian approach. While Mill emphasized individuality of a decision, rationality is a central feature of Kant's concept of autonomy. As we have established earlier, for Kant, autonomy is a property of rational agents. This means that a person can make autonomous decisions or choices if he/she is solely directed by

[8] Savulescu, J. (2010). Autonomía, vida buena y elecciones controvertidas. En B. Mendoza Buergo (Ed.), *Autonomía personal y decisiones médicas. Cuestiones éticas y jurídicas* (pp. 35-60). Cizur Menor, Civitas y Universidad Autónoma de Madrid, p. 35, as cited in García Manrique, R. (2021). *Se vende cuerpo*. Barcelona: Herder Editorial, p. 182.
[9] Mill, J. S. (2001). *On Liberty*. Kitchener: Batoche Books. (Original work published 1859), p. 63.
[10] Dworkin, R. (1994). *Life's Dominion: An Argument about Abortion, Euthanasia, and Individual Freedom*. New York: Vintage Books, p. 222.
[11] Buchanan, A., & Brock, D. (1986). Deciding for Others. *The Milbank Quarterly*, *64*(2 Suppl: Medical Decision Making for the Demented and Dying), 17–94, p. 28.
[12] Dworkin, R. (1994). *Op. cit.*, p. 224.

his/her reason and is not affected by external factors or factors inessential to himself/herself, including desires. Thus, autonomous decision requires abstracting from any personal inclinations and interests as their validity is limited to a single individual.[13] In the Kantian account, autonomy stands for the ideal of free will and implies compliance with universal principles which would be accepted by and valid for all agents under similar circumstances.

Although these two accounts of autonomy are often considered irreconcilable, Ricardo García Manrique does not find them to essentially differ one from another.[14] The Kantian concept assents to Mill's idea in the sense that a rational decision must necessarily be individual, since a rational decision imposed from the outside can in no way be considered autonomous.[15] The Millian concept, in turn, does not reject the supremacy of reason, conditioning the choice by whether it can be attributed to a rational subject.[16] According to García Manrique, the emphasis should be placed on the fact that these models serve different purposes – Mill's model is aimed at regulating private choices about the life plan, while Kant's idea is built around a moral obligation between people.[17] Nevertheless, Kant's autonomy does not exclude a choice about one's own life, and Mill's formulation does not draw a line between a life plan and universal principles, considering only the choice of a valuable life plan based on objective criteria.[18]

For the purposes of our research, there is no practical interest in separating the abovementioned concepts of autonomy. It is important to note that most people seek medical help to either support or improve their own health or the health of their families. Therefore, medical information, including genetic information, is primarily needed in order to make decisions that directly or indirectly relate to maintaining or improving health or adjusting life plans to the future state of health. Most medical decisions affect the patient as well as his/her relatives. Thus, the access to genetic information can help an individual not to be a hostage of a particular situation and to make a choice which can be considered autonomous in both Kantian and Millian senses. This would still require medical professionals to be willing to try to understand the patient's choice even if at first

[13] Campbell, L. (2017). *Op. cit.*, p. 387.
[14] García Manrique, R. (2021). *Se vende cuerpo*. Barcelona: Herder Editorial, p. 182.
[15] *Ibid.*, p. 183.
[16] *Ibid.*
[17] *Ibid.*
[18] *Ibid.*, pp. 184-185.

glance it might seem unreasonable. For this reason, in later chapters, we will attempt to draw a line between what is reasonable and unreasonable with regard to health-related choices, especially when it comes to the dilemma between quantity and quality of life.

Keeping in mind that not all people are able to act in an autonomous manner because of their immaturity, incapacity, dependence, and other factors that affect consciousness, right now we are going to focus on those factors that depend not only on the person himself/herself, but on the outer environment, such as lack of knowledge, repression, forcing, limited choices provided, and other external circumstances. The value of autonomy stems from what it protects, that is, the ability to create and express one's own character in life.[19] Thus, autonomy is inextricably linked to life in biographical sense – full of plans and freedom of thoughts, choices, and actions, – rather than in a merely biological sense of existence.[20]

Crucial to autonomy is the possession of knowledge and understanding that maximize the ability to make independent decisions. There are several dimensions of autonomy, which include opportunities to act, the cost of each act, self-control, and the resources available.[21] Therefore, information as a resource is a particularly important tool for ensuring autonomy. Knowledge is the opposite of lack of information. Information is the building blocks of knowledge, which is formed through the comprehension of information and the ability to use it in the process of solving any problem. In the process of cognition, information is assimilated and processed by a person, forming as a result a knowledge system that has meaning and significance.

The quantity and quality of available information is directly proportional to the aptitude to draw conclusions and choose. A poorly informed person is always easier to impose control over. Therefore, if a person who does not have adequate information makes a decision, at first glance it may seem an independent decision, but it will most likely be as a result of prejudices, imposed beliefs, and patterns of action. By nature, information is objective and exists independently of a person. The unwillingness to comprehend it and the preference to agree with the already

[19] Dworkin, R. (1994). *Op. cit.*, p. 224.
[20] Schermer, M. (2002). *The Different Faces of Autonomy: Patient Autonomy in Ethical Theory and Hospital Practice*. Dordrecht: Springer, pp. 14-15.
[21] Kultgen, J. (1995). *Autonomy and Intervention: Parentalism in the Caring Life*. New York: Oxford University Press, p. 90.

established beliefs and principles is in itself an example of self-determination but being restricted on access or receiving false information leads a person to taking a wrongful position regarding any questionable situation. In this case, the desires, values, and emotions of a person cannot be authentic and, therefore, independent, in order to be able to act at his/her own discretion.

This certainly applies to the health information that relates directly to the individual. In the context of providing medical care, information about the disease, possible treatments, severity of side effects, prognosis, and other information regarding the treatment program for a specific disease is necessary so that the patient can agree or refuse treatment, and also have a definite idea of the consequences of his/her choice. The informed consent process is a guarantee of respect for patient autonomy. As for people who are unaware of ongoing diseases or predispositions to certain conditions, the availability of relevant information could significantly affect their daily decisions, starting from the decision to make an appointment at the hospital and ending with a lifestyle and family planning. Due to the fact that the genetic information of one patient contains important data about his/her relatives, such information becomes one of the elements of autonomy of the patient's relatives.

Failure to provide the necessary information is a kind of disrespect for the autonomy of the person to whom this access is limited or denied. Respect for autonomy presupposes a certain form of positive action and is not limited only to the negative obligation of non-interference, leaving people alone.[22] This positive action involves cooperation on the part of the relevant parties so that the person has several options to choose from, just as the physician must provide the patient with all the information that the patient would need in order to make a choice in favor or against a particular treatment.

Similarly, there should be a positive action from the other party capable of such an action – physician, medical institution, or patient himself/herself – to provide all the information to the relatives that the information directly concerns. Genetic data contained in medical record of the patient is a unique, valuable, and legitimate source of knowledge for patient's relatives due to several reasons. First of all, genetic testing is still not quite accessible for everyone, as well as it is costly. Besides, the problematic reliability of the DTC-GT makes it impossible to decide on serious

[22] Beauchamp, T. L., & Childress, J. F. (2001). *Op. cit.*, p. 63.

health questions based on them. Moreover, genetic information covers a wider range of information, including family history and the conclusions of non-genetic diagnostics, rather than just the results of genetic tests. Finally, in some cases, such as when selecting an effective cancer treatment, only previous experience of relatives, if any, can help save time and immediately discard inappropriate and useless combinations.

However, such information is not accessible to the patient's family, as it relates to the patient's private life and falls under the protection of patient privacy. In this case, privacy is understood, based on the various definitions and content of the concept of privacy discussed earlier, as the ability to manage one's own information and determine the circle of people to whom it might be available. Thus, the right of the patient to control information about his/her health comes into conflict with the right to autonomy of the patient's relatives, making it impossible to respect this right by providing them with the access to the information that may be an important factor in the organization of their lives. Since privacy and autonomy are intertwined and interrelated concepts, on one side of the scale is the right to an autonomous decision with respect to the management of information, and on the other is the right to an autonomous decision with respect to plans for life.

In some cases, patients include their relatives in an intimate circle, whereas in other cases they prefer not to share diagnoses with them, and sometimes they take the path of paternalism and decide what, in their opinion, is in the interests of relatives. Familial communication studies have shown that most patients who had just discovered that they have a risk of developing a genetic condition such as breast cancer or Lynch syndrome agreed to share this information with their relatives.[23] But in some cases, patients did not agree to share the genetic results with families because of guilt, inability to communicate accurately, fear and desire for privacy or estrangement from family members.[24] At the same time, this conflict involves, in addition to the patient and his/her relatives, a third party – the physician, whose duty to maintain the confidentiality of patient

[23] Dheensa, S., Fenwick, A., Shkedi-Rafid, S., Crawford, G., & Lucassen, A. (2016). Health-Care Professionals' Responsibility to Patients' Relatives in Genetic Medicine: A Systematic Review and Synthesis of Empirical Research. *Genetics in Medicine*, *18*(4), 290–301, p. 290.

[24] Suarez, R. (2012). Breaching Doctor-Patient Confidentiality: Confusion Among Physicians About Involuntary Disclosure of Genetic Information. *Southern California Interdisciplinary Law Journal*, *21*(491), 491–521, p. 492; Vavolizza, R. D., Kalia, I., Erskine Aaron, K., Silverstein, L. B., Barlevy, D., Wasserman, D., Walsh, C., Marion, R. W., & Dolan, S. M. (2015). Disclosing Genetic Information to Family Members about Inherited Cardiac Arrhythmias: An Obligation or a Choice? *Journal of genetic counseling*, *24*(4), 608–615, p. 613.

information, arising from a patient-physician relationship, is confronted with another obligation of the physician to prevent harm.

4.1.2. Physician's conflicting duties

The trust on which the relationship between the physician and the patient should be built is ensured by the cloak of confidentiality surrounding the transmitted information. As we have already discussed, this is not the only professional and ethical obligation of the physician. Therefore, in some situations, the medical professional may be at a crossroads, trying to make a decision compliant with all his obligations. The same conflict can occur between the obligation of confidentiality, arising from the principle of autonomy and satisfying the patient right to privacy, and the obligation of prevent harm, following on from the principle of beneficence and corresponding to the patient's relatives' autonomy.

There is a point of view that confidentiality is an unexceptional and unconditional element.[25] For this reason, a professional obligation to prevent harm to third parties does not apply in the context of confidentiality established between the physician and the patient.[26] According to Kenneth Kipnis, who is one of the advocates of this idea, the obligation of confidentiality is rather absolute in nature, and therefore, it prevents any transmission of patient's information in all circumstances, even when the life or health of a third party is seriously threatened by the patient's behavior.[27] Therefore, healthcare workers should put aside all moral and personal values and do not confuse them with the principles that are established to fulfill their collective professional duties to patients and society.[28] Justified patient trust is the highest value, compared to the protection of third parties, and is sufficient reason for the absence of any exceptions to the principle of confidentiality. Kipnis also claims that a system which involves more patience and is built on unwavering trust will in fact provide greater protection for third parties.

[25] *E.g.*, Kottow, M. H. (1986). Medical Confidentiality: An Intransigent and Absolute Obligation. *Journal of medical ethics*, *12*, 117–122.
[26] Kipnis, K. A (2006). Defense of Unqualified Medical Confidentiality. *The American Journal of Bioethics*, *6*(2), 7–18, p. 8.
[27] *Ibid.*
[28] *Ibid.*, pp. 10-11.

However, this approach is quite audacious to agree with, and has some issues. It artificially emphasizes the obligation to maintain confidentiality, belittling, regardless of the situation, the significance of all other principles on which the medical profession had been built on for centuries. First of all, this refers to the principle of beneficence. Although this is one of the fundamental principles of medical ethics, it goes far beyond the scope of medicine. Beneficence is a kind of extension of non-maleficence, which is the minimum moral basis for relations between people. It ascends to the most human qualities such as kindness, love, altruism, mercy, and includes any actions to help other people.[29] In contrast to the negative obligation not to harm, beneficence does not imply a ban, but the implementation of actions to prevent and correct harm. In the framework of relationships among people in all spheres of life, this principle is often optional, rather than an obligation to benefit people on all occasions, and therefore it should not contain severe sacrifices by overriding personal interests over the benefits of the society.[30] It is commendable to follow this moral ideal, but one cannot be blamed for refusing to do so. However, many acts of beneficence which can be carried out without posing additional risks and incurring costs are understood as obligatory from the point of view of ordinary morality, such as protecting the rights of others and helping people with disabilities, and constitute moral rules of obligation.[31]

According to Beauchamp and Childress, all these acts of beneficence can be categorized as general or specific. General beneficence refers to actions intended to help all people in general who are in need. Such actions are not always feasible, sometimes even dangerous, as they may interfere with the performance of duties regarding those to whom a person has special moral ties, such as family and friends.[32] An example of the latter actions relates precisely to the category of specific beneficence, which is directed to the specific individuals due to certain relationship or role responsibilities. These moral obligations are reflected in the criminal law of many jurisdictions, which stipulate liability for failure to provide assistance to the needy under certain circumstances.

[29] Beauchamp, T. L., & Childress, J. F. (2001). *Op. cit.*, p. 166.
[30] *Ibid.*, p. 167.
[31] Beauchamp, T. (2019). The Principle of Beneficence in Applied Ethics. In E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy*. Retrieved June 10, 2020, from https://plato.stanford.edu/archives/spr2019/entries/principle-beneficence/
[32] Beauchamp, T. L., & Childress, J. F. (2001). *Op. cit.*, p. 169.

Most issues in medicine deal with specific beneficence which is achieved through the fulfillment by the physician of the prescribed duties.

Some scholars believe that the principle of beneficence applies only to the relationship between the physician and the patients, without affecting the interests of society as a whole or selected third parties. However, the tradition of quarantining contagious patients, which has been common in medical practice for centuries, emphasizes that physician's altruistic services go beyond his direct responsibilities to the patient.[33] Other public health interventions follow from the principle of beneficence as well, such as reporting to authorized bodies about certain infectious diseases, as well as measures to prevent abusive treatment of children and the elderly, which is usually reflected in legislation. Similarly, the duty to warn is rooted in beneficence and presumes the limited confidentiality of patient-physician relationship when the third party is in danger.

Legal duty to warn was established for the first time in 1976, as we have already mentioned in the previous chapters, in the often-cited case of *Tarasoff v. Regents of University of California*.[34] This decision settled a basis for justifying a limited exception to the rule of patient confidentiality in the U.S., however it still varies from state to state. Overall, this duty envisages the obligation to inform the third party at-risk under circumstances which outweigh the duty of confidentiality. Likewise, courts make decisions in cases involving genetic disorders and allegations of medical negligence for failure to warn potentially affected relatives, although they do not relate to murder or other violent acts, as the *Tarasoff* case does. In any case, the healthcare provider may only disclose information to the potential victim or the relevant law enforcement authorities to the extent necessary to prevent the threat of clear, serious bodily harm to the identified person in the imminent future.

The main counterargument against the duty to warn is the assertion that confidentiality and absolute control over personal information are one of the natural human rights, and their violation constitutes an encroachment on human dignity. That is why the obligation to maintain confidentiality, as well as the principle of patient autonomy supporting it, must be absolute in all

[33] Mills, M. J., Sullivan ,G., Eth, S. (1987). Protecting Third Parties: A decade After Tarasoff. *The American Journal of Psychiatry*, *144*(1), 68–74, p. 70.
[34] Tarasoff v. Regents of University of California [17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14] (Cal. 1976).

circumstances. Breach of confidentiality is indeed a manifestation of disrespect for dignity. But as we have already concluded, the category of dignity has a social component as well. Therefore, it is difficult to imagine that a patient who convincingly informs his/her physician about planning a murder or, in relation to genetic diagnostics, ignoring the fate of his/her family members, especially if there is an available treatment for a threatening disease, can count on the physician's inaction just because of the principle of confidentiality.[35]

Presuming the supremacy of the latter also ignores the ethical principle of justice[36] and neglects the balance between all fundamental principles of medical ethics. The principle of autonomy, on which the obligation to keep patient information in secret is based, is one of the *prima facie* principles along with the principle of beneficence and justice.[37] Therefore, no one automatically repel or efface the significance of the other, and each of them is binding unless they are in conflict with equal or stronger principle.[38] Some moral norms are virtually absolute and do not require balancing, such as prohibition of torture or cruelty, but they are rare compared to the number of norms that are subject to balancing and specification.[39] The necessity to resolve the conflict engages the physician into the process of moral deliberation. From case to case, this is up to the physician to weigh all interests as well as to decide what is exactly beneficious for the third party.

The history of medicine and the development of the relationship between the physician and the patient has shown that paternalism has always, until very recently, been its basis. Even now, to some extent, paternalistic idea manages to coexist, sometimes even dominate over the obligation to respect the patient's autonomy. As for third parties, the information regarding which this whole problem is being created is necessary for the interested person to exercise his/her right to autonomy. Therefore, before disclosing information, only a physician can decide what will benefit the patient's family, as well as the cost-to-benefit ratio to achieve it. In this case, the physician relies only on his own values and judgments about the situation and about the needs of the patient's relative. For this reason, it is absolutely impossible that a physician may put aside all his morality

[35] *E.g.*, Chayet, N. L. (1966). Confidentiality and Privileged Communication. *The New England Journal of Medicine, 275*(18), 1009–1010, p. 1010.
[36] Gibson, E. (2006). Medical Confidentiality and Protection of Third Party Interests. *The American Journal of Bioethics*, *6*(2), 23–25, p. 23.
[37] Beauchamp, T. L., & Childress, J. F. (2001). *Op. cit.*, p. 166.
[38] *Ibid.*, pp. 14-15.
[39] *Ibid.*, p. 19.

when performing his work, as was suggested by Kipnis. Thus, the decision always involves some degree of appreciation when analyzing how much the patient's behavior puts the third party at risk or how violent his/her intentions and actions are, and how serious this danger is for the third party.

4.1.3. Definition of a serious genetic disease

In order for the interests of the patient's relative to prevail over the patient's right to keep his/her genetic information confidential, the predisposition to and the genetic disease itself must be serious, otherwise there will be no serious harm or danger. Many laws use the category of serious or grave genetic diseases without determining its content. The lack of a clear definition and understanding of what exactly constitutes a serious genetic disease lead both ordinary people and medical personnel to become confused about their rights and obligation regarding the disclosure of confidential medical information, including genetic data. Some time ago, Dorothy C. Wertz and Bartha M. Knoppers conducted a study where they asked all the U.S. board-certified genetics services providers and all members of the European Society of Human Genetics (ESHG), Canadian College of Medical Geneticists (CCMG), and Ibero-American Society of Human Genetics (IASHG) to list three conditions they considered lethal, three that were serious but not lethal, and three that were not serious.[40] The considerable overlaps in the categories proposed showed that there was no consensus among the respondents on how to classify genetic conditions.[41]

What a serious disease is tends to vary from the generally accepted concept to what is individually perceived by a particular patient. Therefore, even the experts interviewed during the abovementioned study were against the uniform legal definition of what a serious genetic disease is and including certain diseases in this list.[42] Different people perceive differently, both physically and emotionally, the manifestations of genetic diseases, and by extension, making an objective decision on how severe the condition is would be unfair to those who really suffer from them.

[40] Wertz, D. C., & Knoppers, B. M. (2002). Serious Genetic Disorders: Can or Should They Be Defined? *American Journal of Medical Genetics*, *108*, 29–35.
[41] *Ibid.*
[42] *Ibid.*

There are principles to distinguish genetic conditions, which include a proposal to link the severity of condition with indications for prenatal screening based on criteria such as treatment effectiveness, age of onset, likelihood of manifestation of the disease, and impact on the child and family.[43] According this classification, Huntington's disease, polycystic kidney disease, and a lot of hereditary predispositions to cancer, should not be considered serious, as they are late-onset conditions and do not affect children.[44] Nevertheless, it is precarious to apply these classifications to the situations of disclosure of confidential health information. While it is easy to identify acts dangerous for the whole society, such as crimes listed in the penal codes, it is more difficult to compile a complete list of grave infectious diseases, and it would be impossible to determine objectively the quality of life for a person with a genetic condition. Once these kinds of categorizations are employed, there can be no question of any guarantees of autonomy for both the patients themselves and their relatives.

4.1.4. Solutions provided by current law

To facilitate the process of balancing physician's duties and patient rights, some jurisdictions have considered family members' interests and attempted to adopt laws to specifically address the regulation of genetic information and its disclosure to patients' relatives. At the international level, this question was addressed by the Council of Europe, the UNESCO, and the WHO. In 1992, the Committee of Ministers of the Council of Europe, which has been very active in the bioethics field,[45] issued the Recommendation No. (92) 3 reminding to protect genetic information "on the same basis as other medical data by the rules of medical data protection" (Principle 9) and admitted the possibility to inform family members about severe genetic risks.[46] Another document of the Council of Europe called the Additional Protocol to the Convention on Human Rights and Biomedicine, which was opened for signing in 2008, also prescribes in its Article 18 to inform

[43] Botkin, J. R. (1995). Fetal Privacy and Confidentiality. *The Hastings Center Report*, *25*(5), 32–39, p. 38.
[44] *Ibid.*
[45] Soini, S. (2012). Genetic Testing Legislation in Western Europe – A Fluctuating Regulatory Target. *The Journal of Community Genetic*s, *3*, 143–153, p. 145
[46] Council of Europe, Committee of Ministers. (1992). Recommendation No. R (92) 3 of the Committee of Ministers to Member States on the Genetic Testing and Screening for Health Care Purposes.

family members about the results of relevant genetic tests. However, this provision does not force a patient to communicate a familial risk to relatives.[47]

The UNESCO has developed several international normative standards for biomedical applications. The Universal Declaration on the Human Genome and Human Rights of 1997 invokes to respect data confidentiality under conditions set by law and admits the possibility to limit it for overwhelming reasons.[48] Notably, the provisions of Article 9 can be read a lot more broadly than the intention of the drafters of the Declaration. On the one hand, the meaning of this article can be interpreted to be consistent with certain necessary restrictions of confidentiality and consent, in order to ensure public health. On the other hand, the original idea was to greatly limit the possibility of restricting the double principle of consent and confidentiality.[49] It was stipulated that such restrictions could be provided only by law and only for compelling reasons, for example, when administering a genetic test to determine paternity in civil proceedings or for the purposes of genetic analysis in criminal proceedings for murder or rape.[50] Six years later, the UNESCO adopted another document, the International Declaration on Human Genetic Data that encourages to protect confidentiality of genetic information of an identifiable person and advises to not disclose genetic information to third parties, including family, unless there is important public interest or expressed informed consent of the patient.[51] This article, in comparison with Articles 7 and 9 of the Universal Declaration on the Human Genome and Human Rights, is much more accurate and complete, in the sense that it indicates the need to protect the confidentiality of the genetic information of the people to whom it relates, and also indicates to whom exactly such data cannot be transferred.

The WHO specifically recognizes the impact of genetic information on an entire family, and recommends physicians to encourage patients, whose genetic diagnosis indicated risk to their relatives, to notify them and to ask to seek medical advice. The primary duty to inform rests with

[47] Manai-Wehrli, D. (2013). *Droits du patient et biomédecine*. Berne : Stämpfli, p. 424.
[48] United Nations Educational, Scientific and Cultural Organization. (1997). Universal Declaration on the Human Genome and Human Rights, Arts. 7, 9.
[49] United Nations Educational, Scientific and Cultural Organization. (1997). *Drawing up of a Declaration on the Human Genome: Report by the Director-General [29 C/21]*. General Conference, 29th [1069], p. 14.
[50] *Ibid.*
[51] United Nations Educational, Scientific and Cultural Organization. (2003). International Declaration on Human Genetic Data, Art. 14 (a), (b).

patients who are responsible for communicating possible risks to blood relatives. In case a patient refuses, a physician is allowed to directly contact the patient's relatives, when preventive measures or an appropriate treatment exists, "bearing in mind that the information provided should concern only their own genetic risks, not the genetic status nor the identity of the relative who refused to inform them".[52]

Following the regulation of this issue proposed by the international community, national legislators too have developed specific norms. In Spain, communication of genetic data to biological relatives is regulated by the Law on Biomedical Research – Ley 14/2007. This law establishes the patient's right to make decisions about finding out the results of genetic tests, including incidental findings, except when the information implies serious harm to the patient's health or the health of his/her relatives, in accordance with the attending physician's criteria.[53] In this case, the next of kin or legal representative should be informed after consultation with the health committee. The law limits the amount of information disclosed to exclusively necessary data.

The treatment of genetic data is subject to data protection regulations on federal and cantonal levels in Switzerland, as stated in Article 7 of the Federal Act on Human Genetic Testing. The communication of the genetic data is regulated by Article 19 LAGH.[54] In Paragraph 1 of this article, the legislator emphasizes on the importance of the patient-physician relationship and confidentiality of the patient's information, allowing a physician to disclose genetic tests results only to a patient or his/her legal representative, in case the patient is incapable of judgement. Through respect to this relationship, whenever patient's relatives are at risk, physicians are expected to convince the patient to convey the message to the relatives.[55] If the patient consents to inform his/her family members, the physician can share the results with them too in accordance with the Paragraph 2 of Article 19 LAGH.

[52] WHO Meeting on Ethical Issues in Medical Genetics (1997: Geneva, Switzerland) & WHO Human Genetics Programme. (1998). *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services: Report of WHO Meeting on Ethical Issues in Medical Genetics*. Geneva, 15-16 December 1997, p. 9. Retrieved April 16, 2021, from https://apps.who.int/iris/handle/10665/63910/

[53] Ley 14/2007, de 3 de julio 2007, de Investigación biomédica. Boletín Oficial del Estado, 4 de julio de 2007, núm. 159, pp. 28826 a 28848, Arts. 4, 49(2).

[54] Loi fédérale sur l'analyse génétique humaine (LAGH) du 8 octobre 2004 (État le 1er janvier 2014), Art. 19.

[55] Manai-Wehrli, D. (2013). *Op. cit.*, pp. 425-426.

Should the physician fail to convince the patient and the patient improperly refuses to warn family members, Paragraph 3 of the same article gives the physician a possibility to appeal to the competent cantonal authority to be released from his/her professional duty to uphold confidentiality, as stipulated in the aforementioned Article 321 of the Swiss Penal Code, if the importance of patient's relatives being informed about this information outweighs the interest to maintain the patient's confidentiality. The process and designation of the authorities are regulated by cantonal laws. After receiving a request from the physician, the competent cantonal authority judges the case and correlates the interests of the patient and concerned kin. When necessary, competent cantonal authorities can turn to the Expert Commission on Human Genetic Testing for an opinion.[56] If the interests of the relatives prevail, the physician's professional secrecy may be lifted. Thereby, physicians can have some support and assistance in such complicated cases which require independent and equitable assessment.

In the UK, professional guidelines regulate situations where it is possible to share genetic information with at-risk relatives. The General Medical Counsel (GMC) justifies disclosing information to others without consent "if failure to do so may expose others to a risk of death or serious harm".[57] With regard to genetic information, the GMC regulates this in the same way, clarifying that if a patient refuses to disclose relevant information to relatives, physicians should balance their responsibilities so that caring for their patient becomes their first concern versus their duty to help protect another person from serious harm.[58] The Joint Committee on Medical Genetics supported adequate use of genetic information "to benefit the clinical management of family members" and advises to receive patient's consent for its communication before genetic testing.[59] If such consent was not obtained, the Joint Committee justifies disclosure under special circumstances to avoid a serious harm. While English law and professional guidelines require physicians to proceed with caution in trying to notify a patient's relatives by focusing on

[56] Loi fédérale sur l'analyse génétique humaine (LAGH) du 8 octobre 2004 (État le 1er janvier 2014), Arts. 19 para. 3, 35 para. 2 (g).
[57] General Medical Council. (2017). *Confidentiality: Good Practice in Handling Patient Information*.
[58] *Ibid.*
[59] Royal College of Physicians, Royal College of Pathologists and British Society for Human Genetics. (2011). *Consent and Confidentiality in Clinical Genetic Practice: Guidance on Genetic Testing and Sharing Genetic Information* (2nd ed). Report of the Joint Committee on Medical Genetics. London: RCP, pp. 20-22.

confidentiality, they also impose disciplinary actions against physicians who violate the guidelines, and courts may order physicians to compensate patients for breach of confidentiality.[60]

The U.S. Privacy Rule of the HIPAA created requirements for security of health-related information, including genetic information. In general, these regulations are not different from those which were analyzed above, representing strict nondisclosure policy with "public interest exceptions".[61] For example, physicians are allowed to share personal patient information if "there is a serious and imminent threat to a person or third party" and if they are capable of averting serious harm.[62] Yet, it is unclear whether genetic mutation constitutes a "serious and imminent" threat for a relative, falling under the public interest exception of the privacy rule.[63] Majority of states also have their own legislation to protect privacy of genetic information to restrain related discrimination. While also providing exceptions, these laws do not create explicit or implied duty for physicians to notify patient's family or legal guardian of genetic test results.[64] Several professional organizations have also provided guidance on these questions, agreeing that physicians have an obligation to notify patients about potential genetic risks to their family members.[65]

4.1.5. Insufficiency of current regulations

Despite these laws and guidelines, the issue of when genetic information can be disclosed to family members is still highly controversial and subject to legal challenge.[66] Provisions fall under privacy and data protection laws and reaffirm the confidentiality of genetic information, but fail to consider its familial and predictive nature, instead considering family members in the same manner as other

[60] Lucassen, A., & Gilbar, R. (2018). Alerting Relatives About Heritable Risks: The Limits of Confidentiality. *British medical journal (Clinical research ed.)*, *361*, k1409, p. 3.
[61] 45 CFR §164.512(j) (2002).
[62] Offit, K., Groeger, E., Turner, S., Wadsworth, E. A., & Weiser, M. A. (2004). The "Duty to Warn" a Patient's Family Members About Hereditary Disease Risks. *JAMA*, *292*(12), 1469–1473, p. 1471.
[63] Blumenthal, S. J., & Pendyala, P. (2011). The Promise and Perils of Personalized Medicine. *Harvard Health Policy Review*, *12*, 13–16, p. 14.
[64] Sudell, A. (2001). To Tell or Not to Tell: The Scope of Physician-Patient Confidentiality When Relatives Are at Risk of Genetic Disease. *The Journal of Contemporary Health Law and Policy*, *18*(1), 273–295, p. 289.
[65] Shah, S. K., Hull, S. C., Spinner, M. A., Berkman, B. E., Sanchez, L. A., Abdul-Karim, R., Hsu, A. P., Claypool, R., & Holland, S. M. (2013). What Does the Duty to Warn Require? *The American Journal of Bioethics*, *13*(10), 62–63, pp. 62-63.
[66] Heaton, T. J., & Chico, V. (2016). Attitudes Towards the Sharing of Genetic Information with At-Risk Relatives: Results of a Quantitative Survey. *Human Genetics*, *135*, 109–120, p. 110.

third parties. As timely warning about hereditary disease risks may be a matter of life and death, physicians face conflicting obligation of confidentiality and hypothetical duty to prevent possible harm and promote benefit to patient's relatives. Although physicians are considered to be responsible only for patients with whom they have entered into a professional relationship, the failure to inform a patient's family about predisposition to a genetic disease has already resulted in several lawsuits against physicians.

In the U.S., at least three cases in record have focused on the specific question of whether physicians who treat patients with genetic disorders owe a legal duty to disclose a risk to unsuspecting relatives. Case law is still scarce, but it represents the lack of clear regulation which courts attempt to balance by increasing physician's responsibility to protect the health of patient's family members. In *Pate v. Threlkel*, the plaintiff was diagnosed with medullary thyroid carcinoma, the same condition for which her mother was receiving treatment three years before. Her mother was not informed by the physician that this is a heritable disease, and that her children should be tested.

The plaintiff had no patient-physician relationship with her mother's physician, but she filed a suit against the physician because if she had been informed earlier of her risk, she could have taken preventive measures and the disease would have been avoided or detected at an earlier and curable stage. With this condition, early detection enables thyroid gland removal for prophylactic purposes before cancer is detected, after which thyroid hormone administration should be prescribed.[67] As "prevailing standard of care was obviously developed for the benefit of the patient's children as well as the patient", the highest state court in Florida unanimously declared that physicians had a duty to warn a third party about a risk of inheriting a genetic disease, but concluded that this duty could have been simply satisfied by educating patients about familial implication of a genetic disorder.[68]

The second case that confronted the discrepancy between physician's obligation of confidentiality and duty to warn was *Safer v. Pack*, where the Superior Court of New Jersey held that physicians

[67] Offit, K., Groeger, E., Turner, S., Wadsworth, E. A., & Weiser, M. A. (2004). *Op. cit.*, p. 1469.
[68] Pate v. Threlkel [661 So. 2d 278] (Fla. 1995).

have even more extensive duty to directly notify third parties known to be at genetic risks.[69] The facts were similar to *Pate*'s case. The plaintiff sued the estate of a physician who had previously treated her father for multiple polyposis with adenocarcinoma of the colon. She claimed that the physician failed to fulfill his professional duty to inform the genetic nature of this condition that inexorably leads to colon cancer. Around thirty years after her father's diagnosis, the plaintiff presented with colorectal cancer. She contended that if she had been informed about her elevated risk at the time when she was a child, she could have taken necessary actions for early detection to avoid progression to metastatic cancer. In familial adenomatous polyposis, prophylactic colectomy in late adolescence remains the intervention of choice, although recent studies indicate beneficial role of certain anti-inflammatory medications.[70]

Unlike the *Pate* court, the duty to warn was not limited just to patient's children and was extended to members of the immediate family. However, the court failed to define what immediate family is. Most importantly, the *Safer* court declined the holding that the duty to warn can be satisfied by informing the patient and recognized the physician's responsibility to directly inform family when it is not feasible or effective to do so through the patient.[71] The court obliged the physician to undertake "reasonable steps" to assure that the information reach those who are likely to be affected, but did not define what these steps constitute, leaving ambiguous the manner in which the duty to warn should be fulfilled.[72]

In 2004, the Minnesota Supreme Court ruled on a litigation process started by a parent against several physicians who had treated her child more than 10 years earlier. [73] In *Molloy v. Meier*, the plaintiff noticed that her 3-year-old daughter had apparent mental retardation and, fearing that it was a genetic problem and concerned about the health of future children, asked the family pediatrician to perform genetic tests and to discuss the results with her. The physician communicated results of other tests that were normal, and the plaintiff assumed that it included

[69] Safer v. Pack [677 A2d 1188, 683 A2d 1163] (NJ 1996).
[70] Blumenthal, S. J., & Pendyala, P. (2011). *Op. cit.*, p. 14
[71] Song, K. (2016). Warning Third Parties of Genetic Risks in the Era of Personalized Medicine. *U.C. Davis Law Review*, *49*(5), 1987–2017, p. 2001.
[72] Denbo, S. M. (2006). What Your Genes Know Affects Them: Should Patient Confidentiality Prevent Disclosure of Genetic Test Results to a Patient's Biological Relatives? *American Business Law Journal*, *43*, 561–607, p. 585.
[73] Molloy v. Meier [Nos. C9-02-1821 and C9-02-1837] (Minn. 2004).

testing for fragile X syndrome too. However, the pediatrician failed to order this test, as did two other physicians, who were both pediatric neurologists.

Later, the plaintiff gave birth to another child, who, upon showing signs of delay, was tested properly, and was found to have fragile X syndrome. The plaintiff claimed that the pediatrician failed to warn her and her husband about future risks based on the developmental disability presented on her first daughter. She and her husband stated that they would not have conceived another child if they knew about this hereditary condition. The court recognized that physician's duty regarding genetic testing and diagnosis "extends beyond the patient to biological parents who foreseeably may be harmed by a breach of that duty".[74] Nevertheless, the decision did not explicitly mention the extension of this duty beyond the biological parents, who can be harmed by negligence to perform the duty of care, because they rely on genetic testing and diagnosis.[75]

These decisions demonstrate that physician's liability has evolved. The U.S. courts have been moving towards the expansion of physician's obligations. As science advanced to a new level to clarify the link between an individual's genetic abnormalities and risk to blood relatives, the physicians' duty has expanded with the requirement to advise their patients about disclosure of genetic information to family members of concern. From there the duty advanced even further, to oblige direct counseling of patient's relatives on preventive care upon identification of genetic mutations in the patient.[76] Finally, the legal duty of care to persons other than the tested patient was taken to the next step by extending it to biological parents of the patient.[77] Such revolutionary points are based on the duty of health professionals to warn about foreseeable risks. In any case, physicians who treat patients with genetic diseases should be careful about disclosing genetic information to third parties because of state laws pertaining to confidentiality.[78]

[74] *Ibid.*, § 719.
[75] Denbo, S. M. (2006). *Op. cit.*, p. 583.
[76] Burke, T., & Rosenbaum, S. (2005). Molloy v Meier and the Expanding Standard of Medical Care: Implications for Public Health Policy and Practice. *Public Health Reports*, *120*, 209–210, p. 210.
[77] Hallberg, M., & Fariss, T. (2005). Molloy v. Meier Extends Genetic Counseling Duty of Care to Biological McClain Parents and Establishes that Legal Damages Must Occur Before a Wrongful Conception Action Accrues for Statute of Limitations Purposes. *William Mitchell Law Review*, *31*(3), 939–956, p. 956.
[78] McAbee, G. N, Sherman, J., & Davidoff-Feldman, B. (1998). Physician's Duty to Warn Third Parties About the Risk of Genetic Diseases. *Pediatrics*, *102*(1), 140–142, p. 141.

Any considerations about a similar duty did not exist in England until very recently. The physician's duty to warn a patient's family members in the event the patient refuses to disclose a genetic risk was not considered by the English courts until 2015. [79] In *ABC v. St. George's Healthcare NHS Trust* – the first case in English law to deal with the claim of relatives regarding genetic test results[80] – the Hight Court struck out a claim brought by a daughter of a patient against his physicians for failure to warn about a risk to inherit her father's genetic disease.[81] Her father was convicted of manslaughter for having killed his wife, the plaintiff's mother, on the grounds of diminished responsibility and sentenced to a hospital order. Two years later, he was diagnosed with Huntington's disease, a serious progressive neurodegenerative genetic condition that has a 50% chance of being inherited by children of affected individuals. The condition does not manifest until adulthood, thus, there was a 50% chance that the plaintiff also had the Huntington's disease gene. Her father's physicians sought his consent to disclose the risk to his pregnant daughter, which he refused. Following the birth of her child, the plaintiff found out that she had Huntington's disease too. Given that the plaintiff has the disease, there is a 50% chance that her daughter carries the same gene. According to guidelines that were valid at the time, it was not possible to test the plaintiff's daughter for genetic mutations before she reached the age of 18 years.[82]

The plaintiff argued that if she had known about her father's condition, she would have undergone genetic testing, and once it showed positive, she would have aborted her pregnancy. She contended that she had suffered psychological damage because of the physicians' failure to inform her, and that if her child did have the gene, she would incur expenses which could have been avoided. Her allegations that the physicians acted negligently and violated her rights under Article 8 ECHR by not disclosing her father's genetic information were rejected. The court of the first instance feared to impose a new duty on physicians and did not take the opportunity to develop an existing case law. This decision was overturned by the Court of Appeal,[83] and finally was heard by Justice Yip in the Hight Court.

[79] Chico, V. (2016). Non-disclosure of Genetic risks: The Case for Developing Legal Wrongs. *Medical Law International*, *16*(1-2), 3–26, p. 3.
[80] Gilbar, R., & Foster, C. H. (2016). Doctors' Liability to The Patient's Relatives in Genetic Medicine: ABC v St George's Healthcare NHS trust [2015] EWHC 1394 (QB). *Medical law review*, *24*(1), 112–123, p. 112.
[81] ABC v. St. George's Healthcare NHS Trust [2015] EWHC 1394 (QB).
[82] Gilbar, R., & Foster, C. H. (2016). *Op. cit.*, p. 113.
[83] ABC v. St. George's Healthcare NHS Trust [2017] EWCA 336.

The plaintiff was ultimately unsuccessful against the defendants. However, Justice Yip agreed that physicians are required to ensure the balance between interests of the plaintiff to be informed of her genetic risk and her father's interests and the public interest in maintaining confidentiality.[84] This novel duty of care in negligence, which fell beyond any of the pre-existing duty of care, is neither an independent obligation to disclose information, nor a broad duty of care for a patient's family members concerning the topic of genetic information. Justice Yip did not limit this duty to only issues relating to genetic information but extended it to any confidential medical information. As a result, this decision did not change any of the existing recommendations of the GMC[85] regarding such situations.

In Switzerland and in Spain, there has been no precedent of non-disclosure grievances. Despite this, there is no guarantee that similar cases will never happen as the current law does not take into consideration one of the main goals of medicine of the future, or precision medicine, to eliminate or reduce the risk of developing hereditary diseases and subsequent health injuries. Although the legal grounds of the discussed duty cause controversies and there are certain risks to implement this duty, it can be substantiated from certain perspectives in order to put in balance all related parties. However, by recognizing that the law demands to ignore particularity of genetic information, problem of conflicting duties will not be solved in similar situations in medical practice in future.

It seems that this balance cannot be found according to contemporary law. In those jurisdictions where this duty to warn does not exist, the patient's family will always be in a disempowered position regardless of all the lists of codified fundamental rights. The only thing that they can do is to hope that each of their biological relatives has good intentions and one day might share important information with them. In other jurisdictions, where this duty is recognized, physicians will suffer more disturbance in their practice, since more parties have a reason to hold them accountable in court. The need to balance the interests which are hardly balanceable and the fact that there will always be a side that will be at a disadvantage can adversely affect the physicians' responsibilities to perform care and treatment.

[84] ABC v. St. George's Healthcare NHS Trust [2020] EWHC 455 (QB), §§188-189.
[85] General Medical Council. (2017). *Confidentiality: Good Practice in Handling Patient Information*.

The main problem is that all these laws and court decisions resolve this issue in the same way as the *Tarasoff* case. However, the *Tarasoff* case had two major distinctions. First, there was an element of public interest since murder is a socially dangerous act. As for the risk of developing a genetic disorder, there is no public element, or very small, if one can imagine a situation where the development of a genetic ailment will affect a person's work that implies interaction with people and putting other people at risk. However, the connection between a physician who failed to notify a patient's family member about a hereditary disease and a random person who one day is somehow affected by the same family member's condition is so distant that it will be impossible to trace. Second, the *Tarasoff* case is not related to genetics and obviously does not take into account genetic similarities of biological relatives and the particularity of genetic information. Neither laws nor court decisions pay attention to the fact that the patient's relatives should have all the same rights as the patient himself/herself, since the genetic information is their health information as well and does not belong to the patient alone. Therefore, this issue should be considered from a completely different point of view.

4.2. A new verge of the same right

4.2.1. Joint account model of genetic information

Currently, the regime of medical information, including genetic information, is built on the principle of strict confidentiality, as demonstrated in the previous chapters. Such a regime is also called the personal account model, which envisages that the data is "owned" by a particular person and, as a result, to be private to him/her. Despite the fact that the regime of information about the patient's health hardly resembles classic property regime in all the studied jurisdictions, all health information is strictly protected in accordance with the rules for protection of sensitive data. On the one hand, such a model fully meets the goals of patient-centered medicine since it takes into account the importance of the patient's freedom of choice to control information about his/her health. On the other hand, the nature of genetic information turned out to be incompatible with this approach, which ultimately resulted in insoluble conflicts of professional duties of physicians and led to an increase in the number of medical malpractice cases.

For this reason, a couple of decades ago, Michael Parker and Anneke Lucassen proposed a joint account model, which resembles a regime of information about a joint bank account, which, in

contrast to the personal account model, considers the fact that genetic information is shared by more than one patient.[86] The authors drew a parallel between blood relatives who share some medically significant genetic information, and bank account holders. Just as information about a joint bank account is by default available to all users of that account, genetic information concerning all relatives must also be open to all those relatives. Under the traditional personal account model approach, all of a patient's medical information is considered confidential unless there is a compelling reason to restrict such confidentiality proven by interested third parties, in this case – by blood relatives. On the contrary, in the framework of a joint account model, certain information is openly available for the relevant category of family members, unless the patient provides substantial grounds for restricting this access.

The main advantage of a joint account model, according to the authors, is that it promotes the principle of justice, or reciprocity.[87] In the context of genetic counseling, when assessing the results of genetic testing, an extensive family history plays a special role; however, the anamneses sometimes include information obtained without the consent of relatives.[88] Thus, a joint account model takes into consideration the interests of all members of the patient's family and allows them to enjoy the benefits of genetic diagnostics on an equal basis with the patient being tested. In this case, the full potential of genetic testing could be unlocked, and it could be used to help a lot more people.

Moreover, such a regime is more consistent with the essence of the profession of geneticists, who usually work with entire families, and not just with individual patients. Geneticists are engaged in medical and genetic counseling of patients with congenital and/or hereditary diseases and their relatives, as well as patients from risk groups identified during screening, including the study of hereditary diseases, diagnosing genetic changes and mutations, predicting the possible development of diseases, treating and providing recommendations to prevent the development of diseases, analyzing and interpreting the results of genetic studies. Thus, clinical geneticists have become hostages of ethical and moral dilemmas arising from the particularity of genetic information, since by nature of their work they develop a sense of responsibility for all family

[86] Parker, M., & Lucassen, A. M. (2004). Genetic Information: A Joint Account? *BMJ (Clinical research ed.), 329*(7458), 165–167, p. 166.
[87] *Ibid.*
[88] *Ibid.*

members and for the future of the family.[89] In spite of the fact that physicians of all specializations encounter in one way or another the patient's genetic information in the course of providing treatment, it is the geneticist who most often faces such moral and professional ethical conflicts.

The current personal account model has been functioning well in the absence of a clear concept of genetic information, and rather favored generalization of all medical information, regardless of its source and purpose. At first sight, it seems that categorizing health information and applying different regimes to each category greatly complicates the process of regulating and enforcing the rights of all stakeholders. This suggests that the current regime is clearer and more effective. However, upon a more detailed examination and differentiation of genetic information from other types of information, the idea follows that the personal account model is rather superficial and does not coincide with the object of regulation. In turn, a joint account model, in addition to the advantages set out above, better corresponds to the nature of genetic information as well as taking into consideration the interests of all parties. Therefore, the implementation of a joint account model was intended for solving the issues associated with management of genetic information in the family circle.

Nevertheless, this regime as well as its introduction into the correct practice have faced some criticism. Parker and Lucassen themselves admitted that transition to the joint account model would be controversial and would require a number of adjustments to current practice. They suggested that certain changes must occur in the routine informed consent process. This means that the patient acquiring genetic services must receive a clear explanation and should understand all possible options of use of the information obtained as a result of such services.[90] This would definitely complicate the process of informing the patients, as it can overload them with more complex details. They also emphasized the need to determine the level of risk of harm, which would exclude the access of family members to this information.[91] Under the current personal account model, the risk of harm to a third party is a factor justifying the disclosure of the genetic information to this party, whereas under the joint account model, the risk of even a small harm should be sufficient to deny other parties access to the information. Among other weaknesses of

[89] Parker, M., & Lucassen, A. (2003). Concern for Families and Individuals in Clinical Genetics. *Journal of Medical Ethics*, *29*(2), 70–73, p. 70.
[90] Parker, M., & Lucassen, A. M. (2004). *Op. cit.*, p. 167.
[91] *Ibid.*

this model, some scholars also mention the fact that it implies the creation of additional obligations for physicians to notify relatives and that by referring to genetic information too broadly, the model fails to take into account the different levels of genetic link between different generations.[92]

The disadvantages of the joint account model listed above are not exhaustive. Each of them can be considered objective. Most are amenable to correction and do not render the idea unviable. In our opinion, the main disadvantage of this model is precisely that its understanding of genetic information in the context of personal data protection is too broad. The concept takes into account the entire spectrum of genetic information, excluding spontaneous mutations,[93] and recognizes the interests of family members in it. At the same time, it seems to cover a lot more information that would need to be shared with relatives, such as data that directly identify a particular patient. The model is based on a definition of genetic information that is closer to the scientific one. As we concluded earlier, the scientific definition is too vast for data protection purposes, as it embraces data of vastly different categories and significance to benefit from the same level of protection.

Due to this lack of clarity in definition, the joint account model logically grants to the patient who is seeking genetic counseling much more rights to the information than to the rest of the family. Given that the authors propose to avoid the disclosure of information at the slightest risk of harm to the index patient, his/her relatives have the same chance of accessing such information as under the current model of a personal account. At its core, each of the co-owners of this genetic "joint account" has a special certification of disposal rights. However, the set of these rights is inconsistent towards different datasets forming the account, and changes depending on which of the family members becomes the index patient. Thus, despite its progressive thinking in terms of fair data management, the joint account model is riddled with pro-personal echoes. For this reason, its implementation would lead to largely the same results as before.

4.2.2. Theory of group rights

Let us make a small retreat in order to define the concept of group rights and their place in the system of rights. Up to this point, we have looked at the history of the emergence of human rights,

[92] Foster, C., Herring, J., & Boyd, M. (2015). Testing the Limits of the 'Joint Account' Model of Genetic Information: A Legal Thought Experiment. *Journal of medical ethic*s, *41*(5), 379–382, pp. 380-381.
[93] Parker, M., & Lucassen, A. M. (2004). *Op. cit.*, p. 166.

focusing primarily on the civil and socio-economic rights borne by individuals. These rights are determined by the individual interests of each person. It is generally accepted that these rights can take an exclusively individual form. Earlier, when classifying human rights, we mentioned the third group. These special rights are associated with solidarity and form the so-called third generation of rights. It is believed that within the framework of human rights one cannot speak of collective rights. Therefore, the extension of human right to three generations always causes a lot of controversy and disagreement.

Humans are also social beings with certain collective interests, which can be common for all people or depend on the groups, collectives, or communities they belong to. The theory of social contract, which occupies a central position in the theory of political and legal doctrines, implies the existence of certain rights in the collective of individuals bound by such a contract. As for the legalization of such rights, the American Declaration of Independence of 1776 and the Declaration of the Rights of Man and the Citizen of 1789 mentioned the rights of the people as a special community. Nevertheless, collective rights and obligations, other than obligation to pay taxes, have not received attention in law for a long time due to the prevalence of a liberal-political approach to legal status of individuals in Europe and North America.[94]

In the XX Century, the focus shifted from individuals to groups. During that era, fascist regimes and communist dictatorships denied elementary rights and freedoms, based on the affiliation of certain individuals to such groups as Jews, the bourgeoisie, the intelligentsia. For the first time, the collectivist approach to human rights was clearly expressed in the form of a class approach in Soviet and other socialist constitutions. One of the starting points was the thesis about the primacy of society and the state being over the individual, the rights of the collective being over the rights of the individual and the rights of workers (as a group) being over the rights of exploiters.[95] It is interesting to note that the connection between the rights guaranteed to a particular individual and his/her belonging to a certain group is not at all new. There are ample examples in history when rights were extended exclusively to representatives of a clearly defined circle of people, as in Antiquity – to free people, in the Middle Ages – to the privileged, and in early modern period – to

[94] Chirkin, V. E. (2011). Individual Rights, Collective Rights and Rights Exercised Collectively. *Citizen and Law, 3*, 3–14 [Чиркин, В. Е. Индивидуальные права, коллективные права и права, осуществляемые коллективно. Гражданин и право, № 3, 2011, стр. 3–14.], p. 4.
[95] *Ibid.,* p. 6.

the citizens of certain states. Although the latter examples certainly illustrate the linking of individual rights to belonging to a particular group, rather than collective rights, they confirm the perennial history of the division of society into groups.

After World War II, international human rights legislature deliberately avoided any reference to group rights after the traumatic failure of the League of Nations to secure minority rights. The UN did not want to provoke the resentment of its members, especially that of the newly independent states formed after decolonization, and wanted to ensure that attempts to protect certain communities did not seem a threat to democratic governance or the sovereignty.[96] Despite this, the echoes of the collectivist approach of socialist constitutions can be found in constitutions of a number of capitalist countries that contain provisions on the rights of workers, labor union rights and on the rights of other groups or communities.[97] These are non-universal individual rights, access to which directly depends on belonging to a designated group. However, this tendency indicated that the regulation of human rights had moved slightly from a strictly individualistic approach. In addition to this type of rights, in this context, it is also necessary to distinguish between collectively exercised individual rights and group rights as such, which will be discussed in more detail below.

The idea of group rights has divided scholars into three categories – the opponents of the theory who deny such a phenomenon, the moderate supporters who explain group rights through the rights of group members and refer to group rights as "collective" rights, and finally the strong supporters of the idea, who define these rights as "corporate". Unlike collectively exercised individual rights, by admitting the category of group rights, we acknowledge that a group can act independently or, at least, possess rights different from the rights of its individual members. An excellent way to illustrate group rights is using the analogy of a pile of books – a pile of books is quite heavy, although each individual book is very light, which means that the pile acquires a property that none of the individual books have.[98] In this case, the pile, or the group, is characterized by new qualities

[96] Segesvary, V. (1995). Group rights: The Definition of Group Rights in the Contemporary Legal Debate Based on Socio-Cultural Analysis. *International Journal on Minority and Group Rights*, *3*(2), 89–107, p. 90.
[97] Chirkin, V. E. (2011). *Op. cit.*, pp. 6-7.
[98] Floridi, L. (2017). Group Privacy: A Defence and an Interpretation. In L. Taylor, L. Floridi & B. van der Sloot (Eds.), *Group Privacy: New Challenges of Data Technologies* (pp. 83-100). Cham: Springer International Publishing, p. 89.

and properties arising from the interaction of parts (books), or the individuals, within a certain system. In this case, the concept of group resembles the idea of "general will" in the theory of the social contract, which does not coincide with a simple aggregate of private interests and expressions of individual wills of citizens. However, there is a big difference between the moderate and strong positions, particularly when it comes to the relation with human rights.

Moderate supporters understand group right as a right that is common or shared within a group of individuals, however, no individual has this right outside the group. According to the moderate, or collective rights position, the group right is not just a set or sum of rights that members of the group have individually, but a new right, conditioned by common interests.[99] Joseph Raz identified three conditions that such a right must meet in order to be able to exist: 1) the presence of people's interests that justifies imposing an obligation on a person, 2) these interests relate to the public good in which the members of the group are engaged, 3) the interest of just one member of the group is not sufficient to impose an obligation on another person.[100] According to this position, the group does not acquire its own moral status, and the interests that require protection through the guarantee of one or another collective right can be of both individual and public nature.[101] Therefore, members of the group enjoy the benefits of this right, but do not possess it.

Collective rights, by definition, are held by communities rather than by separate individuals. An example can be seen in Article 27 ICCPR, which explicitly states that it concerns the rights of ethnic, religious, or linguistic minorities. Particular significance of community for freedom of religion is highlighted in Article 18 UDHR. Cultures and languages are group phenomena that involve interacting with other group members in some kind of a collective activity.[102] This highlights how the practice of religion almost always has a group dimension, especially in the performance of rituals and ceremonies.[103] Some elements of such jointly used rights are still available to individuals, as each person can enjoy reading in his/her native language or praying in

[99] Jones, P. (1999). Human Rights, Group Rights, and Peoples' Rights. *Human Rights Quarterly*, *21*(1), 80–107, pp. 83-85.
[100] Raz, J. (1986). *The Morality of Freedom*. Oxford: Clarendon Press, p. 208.
[101] Jones, P. (2016). Group Rights. In E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy*. Retrieved October 28, 2020, from https://plato.stanford.edu/archives/sum2016/entries/rights-group/
[102] Jones, P. (2013). Groups and Human Rights. In C. Holder & D. Reidy (Eds.), *Human Rights: The Hard Questions* (pp. 100-114). Cambridge: Cambridge University Press, pp. 103-104.
[103] *Ibid.*

accordance with canons of religion.[104] Therefore, these rights can be viewed both through the prism of individual rights, and through the prism of group rights, or collective rights. However, if we go back to the third generation of human rights, it becomes clear that there is little in common between those solidarity rights and the collective rights exemplified above. In order for the right to peace, the right to a healthy environment, the right to development and other similar rights to be categorized as collective, there needs to be some kind of a group whose members can share this right. That is why they should rather be considered universal human goals, rather than collective rights.[105]

At the same time, there are many international legal documents dedicated to the rights of children, persons with disabilities, foreign citizens, stateless persons, and many other categories. It does not mean, however, that all these provisions necessarily refer to group rights. The right of children of a certain age to kindergarten, the right of pensioners to receive a pension or the right of persons with disabilities to equal opportunities do not relate directly to the group of children, pensioners, or persons with disabilities, respectively, as to a separate independent subject of law, but represents the exercising of an individual right by members of this groups. In this case, these categories of persons do not form, as such, groups with common goals or interests, which would otherwise serve as a basis for granting them group rights. The presence of certain characteristics in a certain category of people is a condition for the possession of an individual right.

It is important to distinguish between collective rights and individual rights that are exercised collectively. Certain political and social, economic, and cultural rights are just examples of the latter. These include the right to strike, freedom of assembly, the right to other public events and the right to association, which are determined by the unity of interests and the unity of will on certain issues and require collective action.[106] Some of these rights, on the contrary, are exercised only individually, for example, the right to rest, or there is a choice of how to exercise a particular right – individually or collectively – such as being able to publish a personal letter in a newspaper about the fact of corruption or act collectively instead.[107]

[104] *Ibid.*
[105] Jones, P. (1999). *Op. cit.*, pp. 95-96.
[106] Chirkin, V. E. (2011). *Op. cit.*, pp. 6-7
[107] *Ibid.*

Strong advocates of group rights give the group *qua* group a moral status separate from that of its members, believing that group rights are rights that are held by the group as a single right-holder, rather than by its individual members.[108] This is a traditional view on the nature of the group rights. Here, we provide the most common examples of group rights, which are usually viewed in the corporate sense. The first example is the right of revolution, or right of rebellion *(jus resistendi)*, which was first mentioned in the American Declaration of Independence of 1776. This right is now reflected in the preamble to the UDHR and in a number of constitutions. The right of peoples to self-determination, which is also one of the fundamental principles of international law, is another example of this category of rights. This thesis received particular recognition after World War I.[109] The third example of corporate right, which historically originated with the beginning of the collapse of colonialism, is the right to freely dispose of their natural wealth and resources,[110] as stated, in particular, in Article 1 (2) ICCPR of 1966.

According to this understanding of corporate rights, a group is considered a unitary right holder who also bears responsibilities that derive from these rights. Moreover, a group is seen not just as a collective of people but a corporation, with a clear system and organization. The interests of a group do not have to coincide with the interests of its members. Unlike the concept of collective group rights, the concept of corporate rights does not imply that there must be a common interest between all members, and rather raises the exclusive interest of the group itself. Therefore, not only can the interests of the members of a group and a group itself as a unitary subject diverge, but the rights of a group may also well infringe on the rights of its members. By their very nature, corporate rights do not coincide with the morality of human rights, which calls into question the ability to grant such rights to groups.[111]

4.2.3. Concept of group privacy

Perhaps, in order for a joint account model to work and balance the conflicting individual rights of each family member with respect to the shared information, the existing individualistic doctrine developed by the international community might need to be revised. The variations of the concept

[108] Jones, P. (2016). *Op. cit.*
[109] Chirkin, V. E. (2011). *Op. cit.*, p. 8.
[110] *Ibid.*, p. 10.
[111] Jones, P. (1999). *Op. cit.*, p. 107.

we have explored earlier reduce privacy to a strictly individual right. These concepts reveal the essence of the right to privacy through values such as honor, dignity, autonomy, freedom, self-determination – that is, values that are inextricably linked directly to the individual. This is why, for a long time it has been assumed that only individuals, and not groups or entities, can enjoy the protection of the right to privacy.

This is exemplified by confidentiality rules and data protection regulations, which is one of the dimensions of privacy. According to data protection legislation, data subjects are only natural persons,[112] and only they are guaranteed protection. In comparison, information that belongs to legal entities is not subject to data protection legislation. Thus, information that meets the criteria to be considered a business secret, or "know-how", is regulated by intellectual property laws, and most information directly concerning the company is usually available to the public. At the same time, any information shared by groups of people, united on various grounds and by various characteristics, does not fall under the scope of data protection laws, nor intellectual property laws. This approach, which ensures the well-being of the group as a whole by caring for each member of the group separately, underlines European legislation.[113]

It was this joint account model that defined genetic information as information that is shared between a certain group of people – blood relatives. This type of information links certain individuals to a defined group. However, the concept is based on the conventional idea of privacy. It presumes that each member of the family has an individual right to privacy with regards to their genetic data. That is why, within this group, there will always be one conflict or another regarding such individual rights, until the group itself is considered a single subject of data protection law. To resolve this conflict, it might be necessary to overcome the strictly individualistic position that has been established.

Group privacy is not a novel concept. The idea dates back to XX Century. Edward J. Bloustein was one of the first advocates of this idea and argued that an individual's right to privacy should be applicable to a group context as well. He introduced the concept of group privacy as "the right

[112] *E.g.*, Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), Art. 4 (1).
[113] Floridi, L. (2014). Open Data, Data Protection, and Group Privacy. *Philosophy & Technology*, *27*, 1–3, p. 2.

to huddle"[114] whereas almost a century before that, Warren and Brandeis characterized the right to individual privacy as "the right to be left alone". According to Bloustein, group privacy means a "form of privacy that people seek in their associations with others" and represents "an attribute of individuals in association with another within a group, rather than an attribute of the group itself".[115] Group privacy protects people when they come together and share feelings, plans and other information with each other, breaching their individual privacy and relying on the group members to keep the shared data secret outside of the circle.[116]

This right extends to both associations having formal and stable structure like a marriage or a football team, and informal casual relationships such as that between strangers witnessing a traffic accident.[117] If this concept is considered in light of the previously mentioned model of private life divided into three spheres – general private, confidential and, finally, intimate – group privacy is focused on the first two spheres of private activity of an individual, leaving the latter intimate sphere within the framework of individual privacy. At the same time, if we are to focus only on the sort of information that this right concerns, then based on our classification of types of personal information (Figure 1, page 130), the right to group privacy is designed to protect personal information in a broad sense, as well as personal information in a strict sense, voluntarily shared with one circle of people or another. Being quite progressive, this idea takes into account all levels of privacy and admits that private life of one person can be at the same time private to another. Based on the previously mentioned approaches to group rights, we can conclude that Bloustein's approach rather coincides with the collective interpretation of group rights. That is why, some criticize it for insufficient abstraction from legal individualism, since this concept ignored the corporate aspects of privacy, concentrating once again on the individual rights of each distinct member of the group, when acting not alone, but within a particular group.[118]

The idea of group privacy received more attention and was developed further as we entered the age of digital technologies. In modern society, human behavior and preferences are constantly

[114] Bloustein, E. J. (2003). *Individual & Group Privacy* (2nd ed.). New Brunswick: Transaction Publishers, p. 123.
[115] *Ibid.*, p. 124.
[116] *Ibid.*, p. 125.
[117] *Ibid.*, p. 126.
[118] Helm, P. (2016). Group Privacy in Times of Big Data. A Literature Review. *Digital Culture & Society*, *2*(2), 137–151, p. 140.

analyzed for various purposes. Representatives from a wide range of domains have been exploring how different aspects of the environment can affect human behavior in order to influence people's knowledge or achieve their own goals. This kind of information can be used, for example, by government for security reasons. It can also be used by companies to improve their everyday operations and make better economic decisions in future. Thus, using location-tracking technologies, retailers can now trace their clients near or inside a store and then expose them to customized advertisements on such platforms as Facebook and Google.

Over time, such data accumulates and unites people into groups according to certain criteria. Based on the data generated as a result of interacting with network devices, platforms, and organizations, it became possible to form algorithmically-collected groups.[119] The criteria might vary as well as the nature of the groups people are classified into – whether it be cat or dog owners, consumers of a particular product, shoppers in a particular store, or even carriers of a particular disease, etc.[120] Intellectual analysis establishes correlations between data, identifying common attributes between individuals.[121] Thus, these individuals form a group, and these common attributes represent a profile of this group.[122] This allows organizations to make decisions not on the basis of individuals, but on the basis of an entire group. In this case, each person is viewed not as an individual, but as a member of a particular profiling group, which leads to each person having his/her own profiling identity. The problem here is that people are grouped by offline identifiers, which do not necessarily coincide with classes or attributes already shielded by privacy or discrimination laws.[123] This led to the idea that such algorithmically-collected groups, whose members are of interest solely because they belong to one group or another and do not need be identified in order to be targeted, should enjoy separate protection along with protection of individual privacy rights.[124] Since algorithmic classification envisages collecting data about people, distributing them into groups without their knowledge and, probably, against their will, as well as imposing certain information on them that influences their everyday life choices, such as consumer habits, it can be

[119] Mittelstadt, B. (2017). From Individual to Group Privacy in Big Data Analytics. *Philosophy & Technology*, *30*, 475–494, p. 476.
[120] Floridi, L. (2014). *Op. cit.*, p. 1.
[121] Hildebrandt, M. (2008). Defining Profiling: A New Type of Knowledge? In M. Hildebrandt & S. Gutwirth (Eds.), *Profiling the European citizen* (pp. 17-45). Dordrecht: Springer, p. 20.
[122] *Ibid.*
[123] Mittelstadt, B. (2017). *Op. cit.*, p. 476.
[124] *Ibid.*, pp. 477-481.

inferred that this practice violates their privacy. However, due to the fact that analytics does not use personal identifiers such as name, ID number, address, individuals are no longer considered as subjects of the right to privacy and cannot be protected.

In response to big data analytics, Luciano Floridi offered a new privacy paradigm, moving away from "their" towards "its" privacy for groups.[125] Bloustein's idea that group privacy protects people's outer sphere rather than inner sphere echoes[126] as well in Floridi's ideas. However, in contrast to Bloustein's theory of group privacy, Floridi considered the right to group privacy to be held by a group as a whole, and not separately by individual members of collective. He argues that it is necessary to overcome the current approach, which is too "anthropocentric" and "atomistic", in order to anticipate and prevent underestimated risks involved in sharing anonymized data with the public.[127] Notice that in this chapter we refer to privacy in a much narrower sense than the general concept, as to control over the access to information about self or about the group.

Plausibility of group privacy is conditioned by three problems – the nature of the group, the possibility to attribute rights to groups and possibility to attribute the right to privacy to groups.[128] At the root of these problems lies a fundamental and longstanding debate between nominalists, who believe that groups are invented, and realists, who believe that groups are discovered, about the existence of groups and whether groups can be only subjective and dependent on the observer, or also objective and independent of the observer.[129] This happens because of the people's need to ascribe an independent existence to abstract concepts, to consider general properties, relationships, and qualities as independently existing objects. However, Floridi demonstrates that they are neither invented, nor discovered, but designed as they exist as a real concept in our mind, resulting "from the choices we make of the observables we wish to focus on, for specific purposes, and from the constraining affordances (data) provided by the systems we are analyzing".[130] Since profiling is

[125] Taylor, L., Floridi, L., & van der Sloot, B. (2017). Introduction: A New Perspective on Privacy. In L. Taylor, L. Floridi, & B. van der Sloot (Eds.), *Group Privacy: New Challenges of Data Technologies* (pp. 1-12). Cham: Springer International Publishing, p. 2.
[126] Bloustein, E. J. (2003). *Op. cit.*, p. 125.
[127] Floridi, L. (2014). *Op. cit.*, pp. 2-3.
[128] Floridi, L. (2017). *Op. cit.*, p. 83.
[129] *Ibid.*, pp. 85-86.
[130] *Ibid.*

such a designing process, it is this process that spawns the group, giving the selected members, who may not even know they belong to the group, to act together as a group.[131]

Floridi, being a strong proponent of group privacy, argues that this right belongs exclusively to a group *qua* group and is not derived from the rights of its members. To show that group privacy is not a sum of the individual properties of group members, he cites the example of a private funeral. According to Floridi's reasoning, regardless of what the reason is for organizing a secluded funeral strictly by invitation, it does not mean that all relatives and friends of the deceased are entitled to a private funeral.[132] This analogy clearly demonstrates that this is a case of common privacy inherent to the whole group, and not a set of identical individual rights.[133] Each participant in the funeral does not pursue the goal of protecting their feelings and emotions from other participants, and, at the same time, all of them, as a group, might want to hide themselves from the outsiders who were not included in this group of invitees. Thus, within this group, gathered on the basis of a specific criterion – participation in a funeral – any generally-accepted boundaries of privacy are not applicable. However, the boundaries that exist between an entire group of invitees and their surrounding environment are the same as those respected between the private life of an individual and the public.

When referring to group privacy, Floridi points to the privacy of information that constitutes the identity of a group. This allows us to look at the nature of the right to inviolate privacy in light of preserving the sphere of information, either of an individual or of a group. Depending on which qualities or characteristics unite the group, certain information will constitute its identity. In the case of a private funeral, any memories, feelings, emotions of mourners, or even some rules and traditions will erase all boundaries within the group, thereby turning all of it into the group's "private life" relative to the outside world. Aside from the case of private funerals, there are many examples of similar group privacy, including those within the family. According to contemporary practice, the integrity of family life is protected within the framework of individual privacy. Nevertheless, after looking at family privacy through Floridi's point of view, the prevailing model of protection seems somewhat illogical, since family being a special group, has its own established

[131] *Ibid.*, p. 89.
[132] *Ibid.*, p. 91.
[133] *Ibid.*

sphere of information with blurred boundaries within it. Therefore, each individual family member, in theory, can count on respect for family privacy only as a member of the family – by analogy with being invited to a private funeral – and only relative to outsiders. Just as individual privacy is a prerequisite for an individual to develop his/her own individuality,[134] group privacy "shields the group's identity".[135]

Floridi does not specify what constitutes a group as a right holder. In literature, there can be found several types of groups, which established membership of individuals according to common background. In general, the essential condition for a group to be potentially capable of holding rights is its exhibited integrity.[136] Some theories emphasize that an internal structure and organization is necessary for a collective of individuals to be recognized a group,[137] while others require groups to have identity that is independent from changes in membership,[138] or a sense of solidarity among members.[139] One of the classifications provides three types of groups – collectives, ascriptive groups and *ad hoc* groups.[140] The first category of groups includes people with common interests, traits, or goals that have been intentionally united, whereas the criteria for membership in the second category of groups are characteristics that have been inherited or developed accidentally.[141] The third category is the newest and most relevant in the advent of digital technology. It is this category of groups that bring together members according to characteristics established by interested third parties and have the most volatile membership.[142] The first two categories of groups (collectives and ascriptives groups) were legally recognized and empowered in certain contexts, especially in international law. However, there is no one situation foreseen by modern legislation where any of these groups is considered a single subject of human rights.

[134] Loi, M., & Christen, M. (2020). Two Concepts of Group Privacy. *Philosophy & Technology*, *33*(2), 207–224, pp. 215-216.
[135] Floridi, L. (2017). *Op. cit.*, p. 95.
[136] Jones, P. (2016). *Op. cit.*
[137] French, P. (1984). *Collective and Corporate Responsibility*. New York: Columbia University Press, p. 13.
[138] Newman, D. G. (2004). Collective Interests and Collective Rights. *The American Journal of Jurisprudence*, *49*(1), 127–163, pp. 128-129.
[139] Segesvary, V. (1995). *Op. cit.*, p. 98.
[140] Mittelstadt, B. (2017). *Op. cit.*, p. 484.
[141] *Ibid.*
[142] *Ibid.*, p. 485.

Another classification of groups has particular importance in the concept of group privacy. Thus, Michele Loi and Markus Christen have suggested a classification of groups into the following two types:

- Groups consisting of natural persons with an interaction history and/or collective goals in the sense of displaying some meaningful form of agency, as a group, e.g., through intentional coordination, or at least awareness of themselves as a group, with which they identify. (Type-a groups.)
- Groups consisting of natural persons with one or more features in common, who do not have the property in (a) setting aside the trivial case of shared goals, which are pursued without a common plan, or for the common good, e.g., smokers share the goal to smoke. (Type-b groups.)[143]

Comparing this classification with the previous one, it seems that Type-a groups correspond to collectives and ascriptive groups, while Type-b groups resemble the so-called *ad hoc* groups. Based on this classification, the authors also deduce two types of group privacy – the "what happens in Vegas stays in Vegas" (WHVSV) privacy and inferential privacy – to which Type-a groups and Type-b groups are entitled, respectively.[144] Building upon Floridi's work, they advocate that the first variation of privacy is a form of privacy in a strong sense that belongs to a group independently of individual privacy rights of its members.[145] The second is more important for big data analytics as it refers to inferences that can be drawn about group members based on common characteristics and should represent, on the contrary, a form of derived privacy.[146] However, since the family, or blood relatives in our case, clearly falls under the definition of Type-a of groups, the nature of the WHVSV privacy appear to have the strongest connection with privacy in the field of genetics.

The essence of WHVSV privacy is reflected through the concept of the famous slogan, the meaning of which is that whatever happens to visitors in Las Vegas during their vacation will remain unknown to anyone outside in order to avoid any condemnation. This type of privacy, in turn, can also take the form of one of the variations, namely seclusive privacy and antagonistic

[143] Loi, M., & Christen, M. (2020). *Op. cit.*, p. 208.
[144] *Ibid.*
[145] *Ibid.*
[146] *Ibid.*, pp. 218-222.

privacy. Seclusive WHVSV privacy is less common and assumes the variety of facts about one or all members of the group that are known exclusively within its circle.[147] A more common variation is antagonistic WHVSV privacy, which involves facts about one or all members of the group that are known within the group, as well as by someone outside of that group, but not known to another specific group.[148] This variation pursues Bloustein's example of group privacy mentioned above, illustrated as the American football huddle, when players discuss strategies and the team's advantage persists as long as the opposing team does not learn about it before the next move.[149] To which of all these types of group privacy then, could genetic privacy be attributed, if at all?

4.2.4. Genetic group as a right holder

As already noted, human beings share most genetic data, certain genetic data unite blood relatives, and only a minimal percentage of the information is truly unique. That is why, on the basis of certain genetic characteristics and criteria, it is possible to segregate people into an unlimited number of groups, which, however, will have a different status in terms of consistency and stability. In terms of social and legal framework, there are two main types of genetic groups – genetic classes and genetic categories.[150] Genetic classes are highly recognizable groups, the common traits of members of which could have been identified even before modern advancement in genetic science, such as ethnicity.[151] This type of genetic groups falls under the concept of ascriptive groups or Type-a groups, specified in the previous chapter. Genetic categories, in turn, have much in common with algorithmic groups,[152] or *ad hoc* groups or Type-b groups.

Based on the parallels drawn between these categories of groups, it becomes clear that the genetic class as a group has its own identity, as its members are aware that they form one or another group and in some cases are even familiar with other members. By contrast, members of a genetic category are unlikely to always be aware of their belonging to the group and even less likely to suspect about other members of the group. Genetic categories are deprived of that very identity

[147] *Ibid.*, pp. 211-212.
[148] *Ibid.*, p. 213.
[149] Bloustein, E. J. (2003). *Op. cit.*, p. 126.
[150] Hallinan, D., & De Hert, P. (2017). Genetic Classes and Genetic Categories: Protecting Genetic Groups Through Data Protection Law. In L. Taylor, L. Floridi & B. van der Sloot (Eds.), *Group Privacy: New Challenges of Data Technologies* (pp. 175-196). Springer International Publishing, p. 179.
[151] *Ibid.*
[152] *Ibid.*

and collective personality due to the lack of the ability of members to understand the meaning of group membership and the associated inability to share experiences and communicate.[153]

Genetic classes can also closely overlap or even coincide with cultural or political groups. Let us revisit the examples of group rights such as the rights of ethnic, religious, and cultural minorities, or even the right of peoples to self-determination. Despite the fact that these rights are of a different nature, nevertheless, the subjects of these rights often represent groups that have their own genetic architecture. That is, we are talking about genetic classes with different stability, consistency of membership and, of course, different level of cohesion and scale, since members of an ethnic minority will share more genetic characteristics than members of such a group as a region or a state in a country. Contrasting the genetic characteristics of the subjects of these rights with general human genetic characteristics, it is noticeable how much narrower genetic groups, namely genetic classes, they form. Certainly, these precise group rights do not have any subtext related to genetics, however, there is some link between genetics and formation of groups as right holders.

What category does the family belong to? Depending on the socio-cultural views of a particular state, the generally accepted concept of a family may vary. Moreover, not all legal systems have an official legal definition of what family is. An elementary, or nuclear family traditionally includes parents, married or not, and their own and/or adopted children, while a single parent family has one parent and their child. It is obvious that the concept of a family in the socio-legal sense differs from the concept of a family in the genetic sense. Since a family is understood only as blood relatives from the viewpoint of genetics, members of the same family in the social sense can belong to different genetic classes.

In most cases, blood relatives have a history of communication and identify themselves as a group. They share a significant amount of genetic information with each other, which, as we have established, is unreasonable to consider exclusively personal. If all relatives understand how important this information is for their health as medicine advances and increasingly relies on genetic technologies, they will also be united by a common goal in this area – maintaining and improving health with the help of personalized and, as a result, more effective types of treatments. It follows from this that the family as a genetic class may have its own interests regarding the use

[153] *Ibid.*, p. 180.

of its genetic information. In contrast to the examples of the group rights of minorities and the right of peoples to self-determination, the hypothetical right of blood relatives as a group directly follows from their genetic affiliation.

4.2.5. A new dimension of informational privacy

Theory of group rights is very complex and requires further study. Our goal is neither to thoroughly explain the essence and place of all types of group rights in the system of rights, especially human rights, nor to identify all possible criteria for considering a group as a unanimous holder of this kind of rights. We will follow all existing ideas discussed in the previous chapter in order to derive a new right or even just a new dimension of the right to privacy, and not in a general sense, since the concept of privacy is very multifaceted and includes many relations arising from the private life of an individual. This new dimension of the right to privacy concerns exclusively genetic information, namely the right to use and dispose of it – within the group without interference from the outside and outside the group at the discretion of the group members.

Perhaps the idea of genetic privacy as a form of group privacy looks strange at first glance. However, those who advocate that genetic classes may have claims about their information constitute a small but growing group supported both by legislation and legal practice.[154] Thus, Article 10 of the Universal Declaration on the Human Genome and Human Rights appeal to the protection of fundamental rights and dignity of groups of people when conducting research concerning the human genome and other investigations in this area, especially in the fields of biology, genetics and medicine.[155] Another striking example of the recognition of the group rights of a genetic class is the *Havasupai Tribe v. Arizona State University Board of Regents* case.[156] In the 1990s, researchers at Arizona State University collected blood samples from members of the Havasupai tribe to study their genetic predisposition to diabetes, a condition prevalent in the tribe. However, it later turned out that scientists did not limit their use of samples to the study of diabetes. For the Havasupai tribe, blood has a spiritual meaning and represents an integral piece to their

[154] Hallinan, D., & De Hert, P. (2017). *Op. cit.*, p. 181.
[155] United Nations Educational, Scientific and Cultural Organization. (1997). Universal Declaration on the Human Genome and Human Rights.
[156] Havasupai Tribe v. Arizona State University Board of Regents [204 P.3d 1063, 1070] (Ariz. Ct. App. 2008).

sense of identity and cultural cohesion.[157] That is why the abuse of blood had serious consequences not only for an individual member of the tribe, but for the tribe as a whole, including even those who did not initially donate blood for research, leading to harming of dignity, encroachment on autonomy and moral integrity.[158]

We believe that trying to fit genetic information into an individualistic concept of data protection law fails to provide both adequate protection and freedom to dispose of such information. First, in such conditions, some information, such as eye color or hair color is overprotected, while other more important information may simply elude protection, as in the case of a hereditary disease in identical twins, when the illness of one sibling is a hundred-percent confirmation of the illness of another, but they have different views on keeping it in secret. Second, it contradicts the essence of privacy to protect individuals from public interference and to ensure autonomous decision-making, which is impossible due to the fact that current legislation itself is an obstacle to access information that directly concerns blood relatives, because it is mistakenly considered as strictly personal and belonging to the individual who underwent the genetic test. This leads to the third issue – this approach cannot guarantee a life with dignity for some or all family members of concern. And finally, fourth, the present model is illogical, since on the one hand it allows several levels of private life – from intimate circle to interactions with friends or in the office, and on the other hand it applies the same regulatory scheme to all three levels of private relationships. The assumption that privacy in the field of genetics has a group dimension and goes beyond the interests of individual people would allow all these problems to be solved. Moreover, the assumption would also solve existing conflict of individual rights of family members, by guaranteeing a fair information space within the group and removing unnecessary boundaries that inhibit the exchange of information and may even cost someone life or health.

The interests of all blood relatives collectively regarding genetic information are much broader than the interests of an individual family member. The family as a genetic class can be considered

[157] Drabiak-Syed, K. (2010). Lessons from Havasupai Tribe v. Arizona State University Board of Regents: Recognizing Group, Cultural, and Dignitary Harms as Legitimate Risks Warranting Integration into Research Practice. *Journal of Health & Biomedical Law*, *VI*(2), 175–225, pp. 217-224.
[158] Van Assche, K., Gutwirth, S., & Sterckx, S. (2013). Protecting Dignitary Interests of Biobank Research Participants: Lessons from Havasupai Tribe v Arizona Board of Regents. *Law, Innovation and Technology*, *5*(1), 54–84, p. 55.

a single right holder, since it is the entire group of relatives that will be characterized by a certain genetic pattern, which, like a puzzle, consists of many interrelated characteristics of individual relatives (Figure 2). This puzzle represents the group's identity. Therefore, their claims to genetic privacy can be considered as those of a group *qua* group. However, we cannot argue that such rights may be of a corporate nature. First, because the family in the genetic sense, despite having a certain structure, presumes that all members have equal importance and, accordingly, rights and responsibilities, without the need to distribute organizational powers and assimilate the structure of a corporate organization. Second, by accepting the idea that genetic privacy is a group right in the corporate sense, we run the risk of jeopardizing the individual rights of family members in the name of the group, which in no case should be allowed.

Figure 2. Genetic group privacy and individual privacy.

Consequently, we propose that the right to genetic privacy is considered a right of blood relatives as a group, as if complementary to the individual right to privacy. It shall be distinguished from collectively exercised rights, as each and every family member does not have the same right outside the group. They may have limited claims on their own elements of the big "puzzle", but in order to enjoy the right fully they would need to do it together. In our opinion, such a model would

be able to take into account the real nature of genetic information and ensure the interests of all concerned parties and the group as a whole. In comparison to the models of group privacy that have been presented, genetic privacy would best fit into the framework of the WHVSV privacy, with some reservations. This idea of genetic privacy should not contradict any of the previously described concepts of general privacy.

4.3. Interim conclusion

Most people discuss their illnesses and treatments to their families. The majority is willing to share sensitive information, especially if they are told that the life and health of their relatives are in danger and they understand that this information might help. When a patient does not want to or cannot notify his/her family members, this must be done by the physician. However, the physician is bound by a professional obligation of secrecy, and it is generally considered that the disclosure of information, including genetic data, to family members conflicts with his duty of confidentiality. According to current legislation, the access of the index patient's blood relatives to genetic information obtained through tests conducted on the patient is not considered as their right, but rather an exception to the patient's right to confidentiality of information about his/her health due to the prevailing interests of a third party. In this case, the right to privacy of a particular patient is judged against right to autonomy of his/her blood relative.

Today, this is how physicians and judges of most jurisdiction solve this issue – by weighing interests and case-by-case. When it comes to a curable disease and a matter of life and death, this dilemma is usually resolved in favor of relatives, since their life and health ultimately prevails over the privacy of the patient in the sense of controlling and hiding information about themselves. Yet, in other cases, when in the opinion of the physician, ethical commission or judge, the relative's interest is not serious enough, access will be denied. This happens because genetic information is considered personal and the established individualistic approach to the nature of rights is simply not able to resolve this conflict of rights and obligations in another way.

Such a model of weighing interests loses its relevance if we assume that the right of the patient's relatives to access the patient's genetic information is not an exception to the right to privacy but constitutes another dimension of the same right to privacy, just on another and more complex level.

The right to privacy of genetically related relatives can be viewed through the concept of group privacy. The acceptance of possible right to group privacy causes a lot of controversy and disagreement. Nevertheless, this concept has been already finding practical application in modern society, gaining a foothold on many communication platforms, such as private groups on social networks and group chats in instant messengers.[159] These technologies are based on the group's right to determine the boundaries between insiders and outsiders. The right to genetic privacy has a lot of similarities and a lot of differences from other examples of group privacy.

Parker's and Lucassen's joint account model most closely reflects the genesis of genetic information and claims around it. If we look at it in light of group privacy, it will look exactly like a bank account, where holders have the same rights, and the bank can block one or some holders in a strictly defined scenario of violations or threats to other users. Of course, at the same time as solving certain problems, the implementation of such a model will be a big step away from individualistic approach and, in turn, may encounter certain difficulties. For example, there is a need to figure out who will perform the function of the so-called "bank" to notify or restrict a group and its members, how to resolve a possible conflict between individual rights and group obligations, and what the responsibilities of a group are, as a right holder. In the chapters to follow, we will analyze these questions and other related issues.

[159] Loi, M., & Christen, M. (2020). *Op. cit.*, p. 222.

5. INDIVIDUAL AUTONOMY AND GROUP PRIVACY

5.1. Scope of group privacy

5.1.1. Classification of goods

Analyzing the right to genetic privacy as a sociocultural artifact of the Era of Big Data, we are going to outline its essence from the point of view of the theory of rights. Many works have been devoted to the issue of group and collective rights, which have raised discussions regarding the legal basis for such categories of rights and their nature. Generally, this issue is raised in the light of multiculturalism, minority rights, and affects the spheres of constitutional and international law, which we also clearly showed from a historical excursion into the development of the idea of group rights. The doctrinal side of the problem of collective rights is that the main concepts of the theory of human rights are formulated from the standpoint of individualism, therefore they cannot be easily extended to collective rights, which requires a different approach that threatens to confuse these concepts within the framework of legal science.[1] For this reason, we want to focus on bringing the individual right to privacy into a group dimension, rather than classify it based on collective right theories.

First and foremost, it is important to establish what rights are. Rights are one of the most important categories of the theory of law. Rights determine the measure and limits of the possible or permitted behavior of the subject. In this light, there is distinction between legal rights and moral rights. Legal rights exist under the legal systems and legal authorities who decide what is legal or illegal.[2] They are embodied within legal documents and enjoy recognition and protection of the law. Moral rights, better thought of as moral claims, are universal and timeless and constitute, to some degree, part of "the nature of things".[3] Clearly, these two categories of rights overlap, and a moral right can be a legal right as well when the relevant rule requiring recognition and

[1] *E.g.*, López Calera, N. M. (2000) *¿Hay derechos colectivos? Individualidad y socialidad en la teoría de los derechos.* Ariel Derecho.
[2] Campbell, K. (2017). Legal Rights. In E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy*. Retrieved April 19, 2021, from https://plato.stanford.edu/archives/win2017/entries/legal-rights
[3] Feinberg, J. (1992). In Defence of Moral Rights. *Oxford Journal of Legal Studies*, *12*(2), 149–169, pp. 151-152.

enforcement has been duly enacted into law.[4] However, many important writers did not directly address moral rights and the relation between moral and legal rights.

For example, Wesley N. Hohfeld confined his analysis on the different types of rights and duties, which became highly influential in legal theory, entirely to legal rights. His analysis showed that rights consist of internal elements that form their structure. The four main elements are rights (or claims), privileges, power, and immunity.[5] Thinking that the word "right" is overused, Hohfeld linked the problem of inadequate and ambiguous terminology to conceptual obscurity.[6] In his discussion, the term "right" is only used in the sense of claim, as the correlative of a duty in at least one duty-bearer. Bodily rights and property rights have this element of claim in their core.[7] The second Hohfeldian element – privilege, unlike claims, is the correlative of a non-duty and exists when there is no compellation or restriction to act in certain way. Some other scholars, when writing on rights, preferred the term "liberty" to "privilege".[8]

According to Leif Wenar, the first two main elements, namely claims and privileges, refer to what Herbert L. A. Hart called "primary rules"[9] – the rules that require people to "do or abstain from certain actions, whether they wish to or not".[10] The latter two elements, powers and immunities, correspond to Hart's "secondary rules", which can be considered rules about the primary rules.[11] As per Hohfeld, power represents "one's affirmative "control" over a given legal relation as against another".[12] Thus, power enables a power holder to alter his/her own or another's Hohfeldian incident. Finally, the fourth and the last element is immunity, which represents freedom from

[4] *Ibid.*
[5] Hohfeld, W. (1917). Fundamental Legal Conceptions as Applied in Judicial Reasoning. *The Yale Law Journal*, *26*(8), 710–770, p. 716.
[6] *Ibid.*, p. 717.
[7] Wenar, L. (2021). Rights. In E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy*. Retrieved April 20, 2021, from https://plato.stanford.edu/archives/spr2021/entries/rights/
[8] *Ibid*.
[9] *Ibid.*
[10] Hart, H. L. A. (1961). Law as the Union of Primary and Secondary Rules. In H. L. A. Hart, J. Raz & P. A. Bulloch (Eds.), *The Concept of Law* (3rd ed., pp. 79-99). Oxford: Oxford University Press, p. 81.
[11] Wenar, L. (2021). *Op. cit.*
[12] Hohfeld, W. (1913). Some Fundamental Legal Conceptions as Applied in Judicial Reasoning. *The Yale Law Journal*, *23*(1), 16–59, p. 55.

power or means that no one agent has an ability to alter the immunity holder's Hohfeldian incidents.[13]

When we casually think about a right in our mind, we always designate for ourselves who has this right and what this right is – either a right to something, or the right to do something. From here, it follows that any particular right affects the behavior of people.[14] It can be the behavior of those who are around the right holder, restricting their actions or, on the contrary, prescribing certain actions towards the right holder. It can also be the behavior of the right holder himself/herself when the right allows to act in certain way. In some cases, the two behaviors are interrelated, as the right of one right holder is often secured by a reciprocal obligation of the others. In this situation, we are referring to rights as claims. In other cases, the person with the right does not find a counter obligation. Here, rights take the form of privileges or liberties. This differentiation of rights depending on the elements originates in the Hohfeldian analytical system. In part, it also corresponds to Dworkin's theory of rights, who classified claims as rights in a "strong" sense, and privileges and liberties – as rights in a "weak" sense.[15] Such types of behavior are formed with respect to certain goods and interests and represent relationships that are regulated by the rule of law. Therefore, it is generally accepted that these relationships appear to be the objects of corresponding rights.

However, only those goods for which there is a very important moral reason to be protected give rise to rights.[16] In Dworkin's formulation, people have rights only when individual interests surpass collective goals, which for some reason cannot justify the denial of these rights or the damage connected with them.[17] According to Raz, only the well-being of the individual or his/her interests that are sufficient to put others under a duty yield rights.[18] At the same time, these interests are generated by needs that are important for individuals as members of society. Consequently, goods are associated with the needs of people and as they represent a means to satisfy human

[13] *Ibid.*
[14] Hartney, M. (1991). Some Confusions Concerning Collective Rights. *Canadian Journal of Law & Jurisprudence*, *4*(2), 293–314, p. 302.
[15] Dworkin, R. (2013). *Taking Rights Seriously*. London: Bloomsbury Academic, pp. 228ff.
[16] Hartney, M. (1991). *Op. cit.*, p. 303.
[17] Dworkin, R. (2013). *Op. cit.*, p. 6.
[18] Raz, J. (1984). On the Nature of Rights. *Mind, 93*(370), 194–214, p. 195.

needs.[19] If there are no needs, there are no goods to protect, and accordingly there is no legitimate claim to have rights legally established.

The classification of goods is very diverse. One of the most fundamental classification of goods is their distinction based on material content. Material goods that are of particular interest to economics, are understood to be those tangible objects that are usually subject to monetary valuation and are expressed in form. These goods are used by people in the process of life and include man-made products, natural resources, money, etc. Non-material, or intangible goods, on the other hand, are devoid of economic content, accurate monetary value, and physical shape, and are also inseparable from the carrier. They ensure the physical and psychological well-being of the individual and guarantee his/her individuality and autonomy in society.

Despite the fact that from the point of view of moral justification, goods acquired an individual character, from the point of view of other characteristics, goods can be collective as well.[20] One of the most common examples to distinguish public goods is based on the nature of consumption. The key feature of public goods is non-exclusion, since during their distribution it is impossible to control the circle of final potential beneficiaries and exclude someone from this circle – if these goods are provided, everyone will be able to enjoy its benefits. Another defining characteristic of public goods is that consumption of these goods by one individual does not reduce the level of these goods for others, which makes them non-rival.

Public goods are often used synonymously with common goods, but this generalization has its opponents. Some of them argue that the main difference between public and common goods is that if every member of society benefits from the first, the latter may conflict with the egoistic interests of some members of society.[21] Thus, if it is beneficial for a baker that customers do not know how to make cupcakes and come to buy them from the bakery, the common good of having cookbooks in open access in a library will benefit everyone but the baker.[22] Others take the common good

[19] Menger, C. (2007). *Principles of Economics*. Alabama: Ludwig von Mises Institute. (Original work published 1871), p. 52.
[20] Hartney, M. (1991). *Op. cit.*, p. 298.
[21] Waheed, H. (2018). The Common Good. In E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy*. Retrieved January 27, 2021, from https://plato.stanford.edu/archives/spr2018/entries/common-good/
[22] *Ibid.*

beyond the economic categories of goods, defining it as the shared good of society.[23] Each person is a part of society, and by achieving individual goods, everyone contributes to the common good. Thus, the common good is not opposed to the individual good, but only refers to such individual good that is attainable only at the cost of the common good.[24]

Within the category of public goods, Denise Réaume proposed to single out "participatory goods" that consist of collective activity.[25] Unlike many public goods, these goods represent participation in a certain activity rather than the end product of this activity. These goods combine production and consumption and are necessarily publicly available for participants. Such goods include, for example, friendship and a cultured society. A cultured society is not a set of achievements in a field of culture, like paintings, music, books, but is rather the process of their creation, which is endless and involves the work of many people, and not just of one particular individual.[26] As a result of participating in this kind of activities, there may be a personal return[27] in the form of wages or fame, recognition, or reputation. However, these material and non-material goods are protected by other rights and not by the right to live in cultured society.

It should also be noted that there are other types of non-individual goods. For example, the so-called "group goods" combine characteristics of public and participatory goods but are available only for members of a particular group. These goods "contribute to the well-being of individuals because of the latter's membership in a certain community or group".[28] Such classifications of goods are closely related to the classification of rights into individual and collective, as it concerns another understanding of collective rights other than the nature of the right holder.[29] The question whether individuals can have claims to public goods is somewhat controversial.

Raz, for example, supports the idea that public goods cannot give rise to individual rights. Being a proponent of the theory of interest, he argues that no collective interest could justify imposing

[23] Argandoña, A. (2011). The Common Good. *IESE Business School Working Paper* (WP-937). Retrieved January 27, 2021, from https://media.iese.edu/research/pdfs/DI-0937-E.pdf/
[24] *Ibid.*
[25] Réaume, D. (1988). Individuals, Groups, and Rights to Public Goods. *The University of Toronto Law Journal*, *38*(1), 1–27, p. 10.
[26] *Ibid.*
[27] Hartney, M. (1991). *Op. cit.*, p. 298.
[28] *Ibid.*
[29] *Ibid.*, p. 311.

duties on others in relation to public goods.[30] Réaume disagrees with Raz and stresses the importance of analyzing this issue from the point of view of the production and use of public goods.[31] This is why it is crucial to distinguish participatory goods from other public goods. As we have seen, a central aspect of participatory goods is participation in their production, which makes them unsuitable as objects of individual rights. According to Réaume, while each person can individually breath clean air, which, at the same time, cannot be individually produced, it is impossible to individually enjoy a cultured society. Juan Antonio Cruz Parcero gives an example of football games, drawing a parallel with a life in a cultured society – a person cannot have the right to play football by forcing others to play with him/her, in the same way, a person cannot have the right to live in a cultured society by compelling others to engage in certain activities to provide such a person with such a society.[32] The rights to participatory goods are a kind of rights of "insiders" against "outsiders" so that the latter do not prevent and interfere with the collective good of the group.[33]

5.1.2. Public value of privacy

Returning to the right to privacy, it is logical to note that the object of the right to privacy is private life. Private life is one of non-material intangible goods, or values, like health, reputation, dignity, name. Inviolability of private life is guaranteed by the right to privacy. Traditionally, privacy is considered an individual good as it relates to individuals and their ability to keep their personal life away from others. Like other individual intangible goods that belong to an individual from birth or by virtue of the law, privacy is inalienable and untransferable in any other way. We always concentrate on personal loss and damages from breach of privacy. However, there is public interest in it as well, especially when it comes to digital technologies. Based on the ideas of Floridi discussed earlier that the right to privacy is a group right, it seems that privacy should be treated as a non-individual or public good to receive appropriate protection.

[30] Raz, J. (1986). Right-Based Moralities. In M. Friedman, L. May, K. Parsons & J. Stiff (Eds.), *Rights and Reason* (pp. 177-196). *Law and Philosophy Library, 44*. Dordrecht: Springer, p. 188.
[31] Réaume, D. (1988). *Op. cit*., p. 11.
[32] Cruz Parcero, J. A. (1998). Sobre el concepto de derechos colectivos. *Revista internacional de filosofía política, 12,* 95-115, p. 107.
[33] Jones, P. (2016). *Op. cit.*

Privacy is quite extensive; it covers and regulates a wide range of legal relationships. When accurately analyzing legal relationships unfolding in relation to privacy, it is clear that they all relate, to one degree or another, to information or knowledge about oneself. Thus, information appears as an object of many specific rights that constitute the right to privacy and can be generalized as informational privacy rights. Limited access to the self and control over personal information are equally interesting aspects of privacy in terms of practical application and regulations. Often, only the latter is given due attention. However, forgetting about the right not to be observed can lead to the fact that we will continue thinking about complete privacy even under circumstances of total surveillance.[34]

Earlier, we discussed how technology has led to ubiquitous surveillance resulting in aggregated information. This information is used as raw material for profiling, which then serves to influence and manipulate a targeted population. Therefore, each individual can find himself/herself in a situation where his/her privacy depends on the position of people just like him/her – if other people, similarly based on an infinite number of characteristics, willingly provide their information, data collectors infer knowledge as well about those who became hostages of someone's else choice.[35] Afterwards, this information can then be employed in any domain, such as insurance,[36] in various ways against a particular individual. Such "relational leakages" represent "externalities" of privacy, which in turn are critical to understanding privacy as a public good.[37]

At the same time, under the state of modern surveillance that is indirect and non-strategic, people do not even suspect that they are targeted, which lead to lack of choice regarding control over their information.[38] As an example, the ongoing COVID-19 pandemic has transformed transportation, education, health systems, and other services and institutions into extensive surveillance networks.[39] The potential danger of uncontrolled and unrestricted collection of information, which,

[34] Sætra, H. S. (2020). Privacy as an Aggregate Public Good. *Technology in Society*, *63*. https://doi.org/10.1016/j.techsoc.2020.101422
[35] *Ibid.*
[36] Morozov, E. (2013). The Real Privacy Problem. *Technology Review*, *116*(6). Retrieved February 3, 2021, from https://www.technologyreview.com/2013/10/22/112778/the-real-privacy-problem/
[37] Sætra, H. S. (2020). *Op. cit.*
[38] *Ibid.*
[39] Tisné, M. (2020). *The Data Delusion: Protecting Individual Data Isn't Enough when the Harm Is Collecti*ve (M. Schaake, Ed.). Stanford Cyber Policy Center. Retrieved February 3, 2021, from https://cyber.fsi.stanford.edu/publication/data-delusion/

among others, proved by the revelations of Edward Snowden, goes beyond the exploitation of consumers and even undermine democratic processes.[40] Such information serfdom always finds justification with momentary problems and fears, slowly leading to the fact that all these technologies are created not for people, but the other way.

On the one hand, privacy is becoming more and more important for individuals in the modern world. On the other hand, we increasingly come across statements that privacy has already turned into a cast. Indeed, in such an environment of surveillance, securing one's right to privacy is like playing football when no one else wants to play, or wanting to breathe fresh air while others want to benefit from driving cheap, polluting cars. Martin Tisné draws a parallel between data and carbon dioxide, comparing the magnitude of data-related harm to climate change. [41] Therefore, individual claims are powerless. For this reason, there are more and more supporters of the idea to consider and accordingly regulate privacy as a public good, non-excludable and non-rival, which, like other public goods, is prone to market failure without sufficient support.

When categorizing privacy as a public good, Henrik S. Sætra refers to Barrett's typology of public goods, which relates to global public goods such as environmental issues.[42] Scott Barrett reveals the essence of his concept through the example of a group of rowers who try to propel a boat, for which the speed depends not on the physical abilities of individual rowers, but on their joint efforts.[43] Problems such as pollution, overfishing and other environmental issues are associated with aggregate goods and require collaborative efforts. This concept of aggregate goods is somewhat similar to Réaume's concept of participatory goods in that both emphasize the importance of collective activity. The end result of such collaborative work matters not only for the participants, but also for the outsiders. Thus, books, music, libraries, and museums, as artifacts of a cultured society, are hypothetically available to everyone, just as a football match and an orchestral performance are of interest to spectators and listeners. These benefits, according to Réaume, are by-products of joint activities and parasitize on core participatory goods.[44] It is

[40] Fairfield, J. A. T. & Engel, C. (2015). Privacy as a Public Good. *Duke Law Journal*, *65*(3), 2015, 385–457, p. 432.
[41] Tisné, M. (2020). *Op. cit*.
[42] Sætra, H. S. (2020). *Op. cit.*
[43] Barrett, S. (2007). *Why Cooperate? The Incentive to Supply Global Public Goods*. Oxford and New York: Oxford University Press, p. 74.
[44] Réaume, D. (1988). *Op. cit*., p. 10.

possible to apply the same logic to fresh air, animal diversity, green forests, and clean ocean, as effects of an aggregate good of better environment. With regard to clean air, even if not all, if enough people participate in the production or maintenance process, clean air will be available to everyone without exception. Same is true for a guaranteed level of privacy – without government intervention this good will be under-supplied, if it is supported only by those who are interested and willing to fight for it, who sufficiently understand modern tools used to ensure control over data, especially over electronic data.[45]

Such classifications are to some extent arbitrary. However, regardless of which theory is preferred, it is clear that privacy as a good does not exclusively have the characteristics of an individual good, but rather combines the features of both individual and public goods. We previously agreed to divide private life into at least three levels – intimate, confidential, and finally general private (as non-public). All three levels are associated with completely different degrees of openness and involvement of other participants, and, accordingly, with corresponding interests and needs of an individual. Legal relationships concerning privacy are thus spread out in three different dimensions with different scope of social component. Nevertheless, all these three levels are perceived in the same way within the framework of lawmaking.

For instance, let us briefly analyze another individual intangible good – health. Health, being one of the primary goods, is vital in order to be able to enjoy other material and non-material goods, to be in conditions of attainable mental and physical comfort and to interact with the world. Therefore, health is inseparable from the individual, its carrier, and is of value only to him/her. Only an individual can take advantage of the opportunities that his/her own state of health provides. To have the highest attainable standard of health, certain costs must be incurred. Thus, health has the main features of individual goods – it is both rivalrous and excludable. Those who have a need and an opportunity to pay a fairly established price for their health – they have it; and those who cannot pay or do not want to – they do not. Health is the object of the right to health. The right to health includes both the freedom to direct and control one's body and the level of one's health, as well as the right to equal access to and use of the healthcare system.

[45] Sætra, H. S. (2020). *Op. cit.*

On the one hand, health of all members of society is not such a component that entails the loss of the connection between health and the personality of the individual carrier. Personal health is always individual good and does not pass into an associated state of aggregate good. On the other hand, we often hear such concepts as public health, the health of a nation, or global health. In certain situations, the health status of individuals who are concerned about their health directly depends on the health status of those who are not interested or unable to ensure an adequate level of health. Then, the only solution is government intervention to allocate resources through the centralized healthcare system. These measures include the development of the state insurance system, guarantee of the opportunity to receive free medical care, eradication of diseases, especially class diseases, vaccinations, support for medical education, and more.

The health of a nation takes on the features of a public good. The costs of producing this product are borne by the state. At the same time, the good should be available to all citizens, without exception, under normal functioning of the system. Despite the fact that not all countries have a healthcare system that in practice has all the hallmarks of a classic public good, the approach to regulation proves that human health and the health of a nation are different sides of the same coin.

This does not mean at all that the right to health must now become a collective right. The right to health, as well as right to life, and to dignity and privacy, will be always individual. However, this should not interfere with the understanding that if a person can satisfy his/her individual needs for certain individual goods through individual claims, other goods have a more complex structure and are closely related to public goods, which is already difficult or impossible to guarantee with individual rights.

Today, some of these goods are the subject of national or even international goals, such as ensuring peace, a healthy environment, and a healthy population. It is difficult to talk about collective rights to such goods, if only because there is no specific subject that can hold these rights, as the general population is too vague a notion, lacking stability and unity in order to exercise any rights. However, accepting that such public goods need to be provided to ensure individual rights is already a step towards greater human rights guarantees. Despite the fact that there cannot be such a collective right as a nation’s right to health, at the same time, it cannot be said that an individual can have an individual right to life in a healthy country. If not, then how can he/she use his/her

right to health, if all around him/her are sick? Just as we divided the levels of privacy, we can divide health into at least three levels: the individual level – the health of a particular person, the group or collective level – the health of the region, the public level – the health of the nation. If the second and third levels are excluded from regulation, the first level will be impossible to achieve. Why then are we trying to provide privacy in some other way, when the outcome is the same?

5.1.3. Genetic privacy as an object of right

In health care, the relationship between a patient who is seeking protection of his/her right to confidentiality of medical information, the physician and the medical institution that provides care to the patient, develops around the patient's medical information. That is why information is one of the final objects of the right to privacy. Similarly, the regulation of the right to genetic privacy as the right to manage and control the use, access, circulation, and all possible ways to manipulate genetic data, including extracting and modifying it, is directed towards information as well. Which category of abovementioned goods can we refer genetic privacy to?

Information in general, and genetic information in particular, is a unique object of law. Information, depending on its kind, can be protected by several different modes. Information that acquires economic value can become an object of property rights. Information that is the result of intellectual property is protected by intellectual property rights. Finally, personal data are object of regulation by privacy laws. Usually, information is considered an intangible good, although by its nature it is difficult to fit information under the characteristics of goods according to economic theory. Since personal data, based on traditional definition, are information of any type about a specific natural person who is considered the data subject, they fall into the category of personal intangible goods as a component of privacy. Genetic information seems, not only based on our concept, but also from the point of view of legislations discussed previously, to not fall either under the definition of personal data or under the characteristics of an individual good.

Despite the fact that modern legislation takes into account that genetic information is still different from other personal information, in medical practice it is still treated as an individual good. Nevertheless, genetic information is of much broader interest. Just like having a cleaner and better

environment, which represents an aggregated or global public good, the human genome must be available and serve the benefit of the whole society. Genomics expands the possibilities of epidemiology, pushing for large-scale research, as a result of which the discovery of genes associated with important diseases became possible.[46]

Thus, the previously mentioned Human Genome Project contributed to the development of medicine and human biology. As a result, an open bank of genetic code was created. The availability of the information obtained from the HGP has allowed many researchers to speed up their work. Another important result of the project is compliment to human history. Previously, all data on evolution were gleaned from archaeological finds, and the deciphering of the genetic code not only made it possible to confirm the theories of archaeologists, but in the future, it will allow us to more accurately learn the history of the evolution of both humans and biota as a whole. That is why mankind as a whole should benefit from the information contained in genetic databases.[47] Genetics is a lot more than personal.

Dwelling on the problem of genetic data of an individual patient, the source of such information, with the exception of individual genetic mutations, is not only the patient himself/herself, but also his/her blood relatives. During any visit to the physician or in clinical trials, a patient is always asked for a medical history. Medical history is a prime example of such genetic information. Thus, almost every medical anamnesis is the collective contribution of many people. Likewise, it is of equal interest to all affected relatives. Moreover, such participation is likely to be scattered over time, since the process stretches over several generations. In practice, such collective participation is ignored, being limited exclusively to momentary physical participation – analysis, physical examination, filling out questionnaires. In fact, genetic privacy can be considered from the point of view of Réaume's concept of participatory goods, since in addition to the genetic information itself, collected from one or more relatives, belonging to a genetic group is already a certain good. The process of creating or, rather, deriving such information is associated with its consumption, which makes it possible to provide each member of the group with a higher level of protection against external intrusion, useful distribution of information within the group, more complete

[46] Khoury, M. J., Millikan, R., Little, J., & Gwinn, M. (2004). The Emergence of Epidemiology in the Genomics Age. *International Journal of Epidemiology*, *33*(5), 936–944, p. 940.
[47] Knoppers, B. M. (2005). Of Genomics and Public Health: Building Public "Goods"? *CMAJ: Canadian Medical Association journal = journal de l'Association medicale canadienne*, *173*(10), 1185–1186, p. 1185.

control over the entire volume of information concerning each member of the group, fair distribution of costs, and opportunity to make autonomous healthcare related decisions.

When treating genetic privacy as an individual good, the situation is exactly the same as with widespread surveillance, if not more serious, because genetic information can tell a lot, not only about a specific individual, or a patient who did a genetic analysis, but also about his/her family. The prevailing point of view, to a certain extent, contradicts the idea of genetic discrimination which is built on a group trait, such as belonging to a particular genetic group in relation to a particular disease, the same way racial discrimination is as a result of belonging to a particular race. However, in case of the right to privacy, belonging to a group is disregarded. Genetic privacy is reduced to a very primitive one-dimensional perception, which does not reflect the complexity of the object, as well as all concerned subjects, the circle of which we will define in the next chapter.

5.1.4. Relevance of genetics for identifying a genetic group

Legislating and regulating something as diverse and extensive as genetic information is a gargantuan challenge. Even when we take into consideration the fact that only 1% of our DNA directly dictates our appearance, bodily functions, and susceptibility to disease, understanding and managing information about such "coding DNA" is a science in itself.[48]

How then, can we begin to identify the genetic information that matter and are relevant to an individual? This question is a topic of ongoing research in human and animal gene science today. Heredity is the process of passing down traits from one generation to another.[49] As simple as it is to ponder, we inherit 50% each of our genetic material from each of our most immediate ancestor, our mother and father. In other words, we receive one copy or variant (the scientific term being "allele") of a certain gene from each of our parents, in the same way they received theirs from their parents, and so on. It must be specified, however, that this 50:50 inheritance pattern applies to

[48] Henninger, J. (2012, October 1). The 99 Percent…of the Human Genome. *Harvard University Graduate School of Arts and Sciences Website*. Retrieved February 14, 2021, from http://sitn.hms.harvard.edu/flash/2012/issue127a/
[49] Griffiths, A. J. F., Dobzhansky, T., & Robinson, A. (2019, October 11). *Heredity*. Encyclopedia Britannica. Retrieved February 14, 2021, from https://www.britannica.com/science/heredity-genetics/

what are called autosomal genes – genes that make up chromosomes that are not sex chromosomes.[50]

As visited earlier, our genomic make-up is structured through inheritance of 22 pairs of autosomes and a pair of sex chromosomes (X and Y). Aside from the inheritance of our autosomal genome, we inherit our sex chromosomes from each parent (XX for female offspring and XY for male offspring, with the Y chromosome coming exclusively patrilineally) and a portion of the DNA called the mitochondrial DNA, which is found in the energy compartment called the mitochondria of each and every cell in our body, coming exclusively matrilineally.[51] In other words, it is important to note that while majority of our genetic make-up come equally from each of our parents, some of them are passed down exclusively from one or the other.

In practice, however, the 50:50 inheritance pattern of autosomal genome is not as simple as it seems. While we certainly receive half of our genetic material from each of our parents, each parent does not always contribute the same 50%. Without going into depth, a process called genetic recombination or gene "shuffling" ensures that genetic materials are shuffled around randomly to create new combinations of traits that are not necessarily observed even in the parent generation. In this process, some new traits may be created, while others removed. This is a mechanism that nature has come up with in order to increase genetic diversity. According to this mechanism, we may, for example, inherit 45% and 55% of maternal genetic materials from our maternal grandfather and grandmother, respectively.[52] This is best demonstrated by the example of names, as shown below (Figure 3).[53]

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[50] Coop, G. (2013, November 12). *How much of your genome do you inherit from a particular ancestor?* The Coop Lab Population and Evolutionary Genetics, UC Davis. Retrieved February 14, 2021, from https://gcbias.org/2013/11/04/how-much-of-your-genome-do-you-inherit-from-a-particular-ancestor/

[51] Genetic Alliance, & The New York-Mid-Atlantic Consortium for Genetic and Newborn Screening Services. (2009). *Understanding Genetics: A New York, Mid-Atlantic Guide for Patients and Health Professionals* (Appendix E – Inheritance Patterns). Washington (DC): Genetic Alliance. Retrieved February 14, 2021, from https://www.ncbi.nlm.nih.gov/books/NBK115561/

[52] Coop, G. (2013, November 12). *Op. cit.*

[53] Ancestry. (2014, March 5). *Understanding Patterns of Inheritance: Where Did My DNA Come From? (And Why It Matters.)*. Retrieved February 14, 2021, from https://www.ancestry.com/corporate/blog/understanding-patterns-of-inheirtance-where-did-my-dna-come-from-and-why-it-matters/#:~:text=Your%20DNA%20contains%20a%20record,their%20parents%2C%20and%20so%20on/

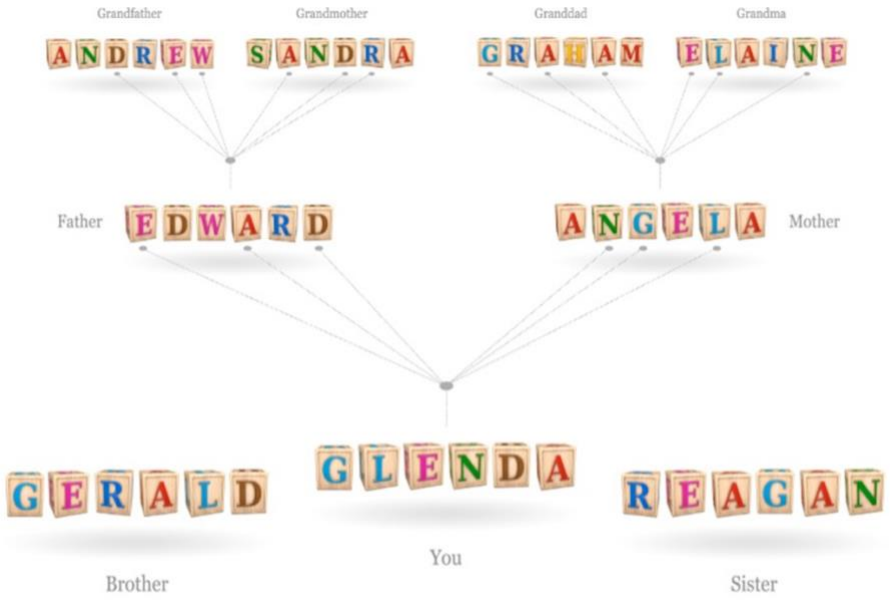

Figure 3. Gene recombination shows that inheritance is not simple mathematics.[54]

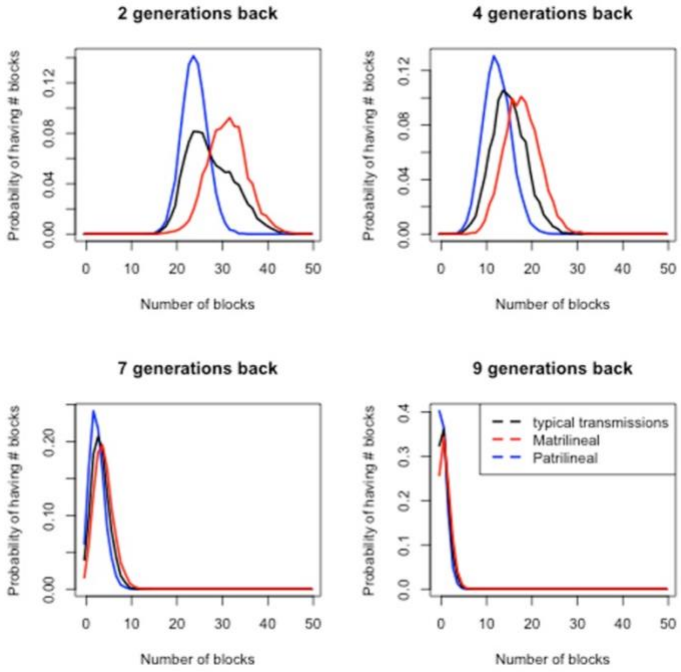

Figure 4. The limit of autosomal gene contribution.[55]

[54] *Ibid.*
[55] Coop, G. (2013, November 12). *Op. cit.*

Graham Coop of UC Davis argues that, if we follow the passage of "blocks" of genetic material back in time and extrapolate the observations far enough, there would be an ancestor that contributed zero autosomal genetic material to the present generation. The figures shown above (Figure 4) are the result of theoretical calculations performed by Coop et al. in trying to identify the limit of propagation of autosomal genetic material. It plots the probability of having a certain number of genetic blocks passed down, against the generation number. Indeed, the calculations suggest that we would only need to look far back as 9 generations to find one such ancestor having no contribution to our autosomal genome.[56]

Similarly, Coop et al. simulated inheritance patterns between cousins, who are individuals of the same generation that have common ancestors but are from different parents and found that it is unlikely for one to have any overlapping autosomal genetic material with 4th cousins and further.[57] Cooper's calculations concern autosomal genetic material in general, and do not follow any particular trait or ailment. Nonetheless, the results he obtained are important indicators that define the boundaries of autosomal genetic relevance, both in terms of generations back and extent of relatives of the same generation. Since looking beyond 9 generations and/or 4th cousins will only increase the likelihood of encountering individuals that have no autosomal genetic commonality with a particular person, it would be futile to examine the genetic information beyond these boundaries, let alone to look for defining traits or diseases.

In most situations, a visible trait, or a phenotype, is dictated by an individual's genetic information in relation to that trait, or genotype, as well as environmental factors.[58] Perhaps the most common example is cancer, where the likelihood of an individual developing cancer depends both on his/her genetic information and lifestyle-related factors. Be that as it may, the main focus of genetic counseling is an individual's genotype, as well as who else in their family share the same genotype. In medicine, tracking a certain genetic trait or mutation responsible for a disease across generations and a family map requires knowledge of the inheritance pattern of the trait. As discussed earlier,

[56] *Ibid.*
[57] Coop, G. (2013, December 2). *How many genomic blocks do you share with a cousin?* The Coop Lab Population and Evolutionary Genetics, UC Davis. Retrieved February 14, 2021, from https://gcbias.org/2013/12/02/how-many-genomic-blocks-do-you-share-with-a-cousin/
[58] National Human Genome Research Institute. (n.d.). Definition of Phenotype. In *Talking Glossary of Genetic Terms*. Retrieved February 14, 2021, from https://www.genome.gov/genetics-glossary/Phenotype/

many diseases are linked to the autosomal genes, while some are also linked to the X and Y sex chromosomes. Whether in autosomes or in sex chromosomes, a trait is described as either dominant or recessive. A dominant trait will be expressed even if only one of the alleles coming from the mother and father is dominant. On the other hand, a recessive trait requires both copies of the gene coming from the mother and father to carry the recessive trait. For this reason, autosomal dominant diseases are more likely to show up and thus appear in every generation, with each affected offspring having an affected parent. Conversely, an autosomal recessive disease does not appear in every generation, and the parents of an affected offspring tend to be carriers. A trait that is linked to the Y chromosome is never seen in a female offspring but is expressed in all male descendants of an affected male. This is because the Y chromosome can only be passed down from father to son. Like autosomal traits, X-linked traits too can be classified as dominant or recessive. X-linked dominant traits are expressed in all daughters and none of the sons of an affected male, and in both daughters and sons of an affected female. On the other hand, X-linked recessive traits are more commonly expressed in male offspring, as males have only a single X chromosome and a single trait-carrying chromosome is needed for it to be expressed.[59]

Indeed, many heritable diseases have been studied and classified accordingly, and based on the understanding of their classification of inheritance pattern, it is possible to determine the probabilities of ancestors, relatives and descendants being affected or expressing a particular trait.[60]

Thus, it is possible to determine a limited number of people who belong to each individual's genetic group. As we found earlier, any group, in order to be considered a potential right holder, must be built on common characteristics, and have a more or less constant composition, structure and unity. Taking into account all the abovementioned simulations, we can conclude that in theory, the genetic group of a given individual will be limited to nine generations "vertically" and four kinships "horizontally" on a family tree. In practice, depending on a disease of interest or available resources (at the moment it is simply impossible to gain access to genetic information of all 9 generations of ancestors), the number of relatives of concern will certainly be much smaller. For

[59] Genetic Alliance, & The New York-Mid-Atlantic Consortium for Genetic and Newborn Screening Services. (2009). *Op. cit.*

[60] Lubs, H. A. (1976). Privacy and Genetic Information. In J. M. Humber & R. F. Almeder (Eds.), *Biomedical Ethics and the Law* (pp. 399-413). New York: Plenum Press, pp. 404-405.

the purpose of genetic privacy, each relative should have his/her own genetic group. At the same time, he/she can simultaneously belong to several groups, the circle of members of which will either coincide or vary slightly. However, such variations cannot significantly affect the integrity and cohesion of the group, as the determining factor is the relevance of genetic information of each member.

5.1.5. Group rights and human rights: friends or foes?

Usually, the concept of collective rights is grounded to the normative moral standpoint of value-collectivism. Value-collectivism is based on the idea that collectives have their own value, regardless of their contribution to the well-being of individual members who constitute them.[61] This point of view is the opposite of the idea of value-individualism, which prioritizes, under any circumstances, the well-being of individuals. According to value-collectivism, an entity can be endowed with its own moral value, which permeates the very existence of such an organism. It is about the ontology of collectives and their value where most disputes about collective rights flare up.[62] These disagreements stem from the potential threat of the collective rights of communities allotted with moral agency to individual rights, especially human rights. We are inclined to believe that if we consider the right to genetic privacy as an extension or the next level of the individual right to privacy, we cannot consider the genetic group as an independent moral agent, separate from its participants, like a corporation. Genetic privacy is aimed primarily at complementing the individual rights of relatives, rather than opposing them. That is, its value ultimately depends on the well-being of each blood relative. It is wrong to expect, as formulated William Kymlicka in his earlier works, that "that individuals can legitimately be sacrificed to further the 'health' of something that is incapable of ever suffering or flourishing in a sense that raises claims of justice".[63] We will not delve further into this dispute, since our objective is not to prove or disclaim the theory of collective rights itself.

Supposably, moral right protects morally valuable goods that contribute to human well-being, which makes this person the only holder of said right.[64] But what if such a good contributes to the

[61] Jovanović, M. A. (2012). *Collective Rights: A Legal Theory*. Cambridge: Cambridge University Press, p. 6.
[62] Hartney, M. (1991). *Op. cit.*, p. 297.
[63] Kymlicka, W. (1989). *Liberalism, Community, and Culture*. Oxford: Oxford University Press, p. 242.
[64] Hartney, M. (1991). *Op. cit.*, p. 304.

well-being of more than one person? Can it be considered that a person has a moral right to it, and will this right protect the whole good? Most probably, not. Each individual has a moral right to a so-called "part" of such a good. If we are talking about a divisible material good, like a share in property or an apartment in a multi-story building, then the issue in both cases can be easily resolved through individual rights, with certain reservations. What is to be done if a good, or a value is completely indivisible? Genetic privacy is indivisible, just like genetic information. It is impossible to carve a border between generations to divide what part concerns whom. However, the current approach treats the moral right to have genetic information protected in a property-like manner: "my information – my right".

Continuing the analogy with private property, it is much more appropriate to compare genetic privacy with a house that was built by several family members, where one brought bricks, another – cement, third person – water, fourth – wood, the fifth took over all organizational issues, etc. While this may be a rough comparison, it reflects the fact that if an intruder wants to destroy this house, he/she has a moral obligation to refrain from it to all the people involved in building the house, and not just to one of them. It is logical that such a good would be protected by common efforts, by combining the moral rights of all interested parties to have the house protected, which ultimately gives rise to a right that is different from the rights of each participant. That is why it can be argued that this right is that of the entire group *qua* group, since individually each member of the group does not have exactly the same right. However, the group, in our case the genetic relatives, is not endowed with its own moral agency. Thus, behind this single legal subject there is a sum of moral agencies of all its participants combined. Therefore, despite the fact that the right the group has cannot be held separately by members of the group, it is indirectly vested in all its members.

Hence the question arises, whether a genetic group is simply the sum of its members, or it is a *persona ficta*, or something else. In addition to individuals and legal entities, various legal texts mention groups and collectives which are not formally organized, especially in labor law, competition law and international law. However, there are no established legal capacity of collectives or groups of individuals applicable to all branches of law. Similar issues of categorizing family as a legal institution have already been addressed by some scholars. Historically, the status of family was significantly different from that of individuals, that is, the family was considered

more like a corporation.[65] Naturally, this statement concerns a family that is formed as a result of marriage, and not a family that only consists of blood relatives of several generations. However, modern family bears little resemblance to a classic legal entity with its subordinations and order. Perhaps, unregistered groups or collectives can be considered the third type of subject of law in this classification, different from both individuals and legal entities. In previous chapters, we demonstrated that genetic family possesses qualities to be considered a single entity in the eyes of the law, nevertheless different from a conventional legal entity.

How can such a complex subject of law exercise its right? There are different opinions as to how closely the criterion of holding rights is related to its exercising. On the one hand, one can come across assertions that the ability to hold the right and the ability to exercise it "do go together".[66] Yet, exercising the right cannot be considered decisive in determining the right holder.[67] According to Miodrag A. Jovanović, this follows from the fact that just as individual rights do not cease to be individual, although they can be exercised in three different ways – individually, through a representative, or collectively (as we have already mentioned the right to strike or freedom of assembly), collective or group rights do not cease to be so, even if it is possible to exercise them both collectively and individually.[68] Jovanović illustrates this conclusion with Article 3 of the Framework Convention for the Protection of National Minorities and with the point of view expressed in the Explanatory Report.[69] This Framework Convention mentions that individuals who belong to national minorities "may exercise the rights and enjoy the freedoms […] individually as well as in community with others",[70] which "is distinct from the notion of collective rights".[71] Despite the fact that the Framework Convention focuses on individual rights, it is possible to draw a logical conclusion, which also applies to group rights, that the way in which the rights are exercised does not determine the type of the right holder. This means that, if individual

[65] Fax-Genovese, E. (1992). Legal Status of Families as Institutions. *Cornell Law Review*, *77*(5), 992–996, pp. 992-993.
[66] Morauta, J. (2002). Rights and Participatory Goods. *Oxford Journal of Legal Studies*, *22*(1), 91–113, p. 111.
[67] Jovanović, M. A. (2012). *Op. cit.*, p. 114.
[68] *Ibid.*
[69] *Ibid.*
[70] Council of Europe. (1995). Framework Convention for the Protection of National Minorities (ETS 157), Art. 3, para. 2
[71] Council of Europe. (1995). Explanatory Report to the Framework Convention for the Protection of National Minorities (ETS 157), para. 37.

rights can be exercised both individually and collectively, group rights can be exercised in the exact same ways.

In this regard, it is important to refer to the point of view of Allen Buchanan on different ways group rights can be wielded. The first possibility is that the right can be invoked, exercised or waived non-individually, and such rights are referred to as "non-individual group rights".[72] This possibility, in its turn, can be divided into two subcategories of ways to use group rights – either collectively, or through representative bodies or an agent.[73] A striking example of the first subcategory is the classic example of collective rights – the right of peoples to self-determination. Jovanović interprets the meaning of the right to self-determination as "collective decision-making procedure in which people *qua* people would communally exercise this right".[74] Nevertheless, this way of exercising rights is fraught with certain problems, such as possible non-participation in joint efforts needed to invoke the right, as well as certain costs and delays.[75] For this reason, in some cases, such an approach may not be the most optimal to exercise the right.

The second method of non-individual exercising of right involves the delegation of authority to a certain representative or a body of representatives. Most legal entities, in particular companies and corporations that have a hierarchical structure of representation, as well as the state, exercise their rights in this way. This possibility to exercise rights is still fraught with the negative side of hierarchy associated with the delegation of power, which automatically creates inequality within any collective or group. This can lead to representatives using their powers in their own interests, and not in the interests of rest of the members.[76] This precludes the use of such a way to exercise rights in relation to potential collective or group human rights. However, in both cases of non-individual exercising of rights, the basic idea is that no member of the group can use the right as an individual on behalf of himself/herself.[77]

[72] Buchanan, A. (1994). Liberalism and Group Rights. In J. L. Coleman & A. Buchanan (Eds.), *In Harm's Way – Essays in Honour of Joel Feinberg* (pp. 1-15). Cambridge: Cambridge University Press, p. 3.
[73] *Ibid.*
[74] Jovanović, M. A. (2012). *Op. cit.*, p. 115.
[75] Buchanan, A. (1994). *Op. cit.*, p. 12.
[76] *Ibid.*
[77] *Ibid.*, p. 3.

Buchanan's second way to exercise group rights concerns the so-called "dual standing rights", which implies that "any individual who is a member of the group can wield the right, either on his own behalf or on that of any other members of the group, or the right may be wielded non-individually by some collective mechanism or by some agent or agents on behalf of the group".[78] This means that the right can be exercised both separately by each member and jointly. It is in this category that we could include the previously mentioned rights of cultural minorities. The difference between such dual standing rights and individual rights is that any member of the group can claim protection of the right, regardless of whether he/she has suffered from interference or any other member of the group has.

In our opinion, Buchanan's concept of dual standing rights is the ideal model to show how the right to genetic privacy can be exercised. The possibility of an individual's exercising of such a right, combined with mutual rights and obligations within the group, would make it possible to fully protect the genetic information of interested persons without barring each of them from enjoying this right, as well as providing an opportunity to protect it directly, without the need to depend on the actions of others. There is an important difference when it comes to allowing the possibility of collective exercising and corporate exercising via a proxy. Collective exercising is theoretically possible, for example, with respect to certain issues related to genetic information, which can be resolved through informed consent forms by absolute or simple majority. From a practical point of view, such an approach would be associated with significant costs and redesigning of the healthcare system. However, we will take a closer look at this possibility in later chapters. In contrast, exercising this right through a proxy categorically contradicts the essence of this right for the aforementioned reasons.

Despite the fact that it is entirely possible to exercise the right to genetic privacy individually, we insist that such a right cannot be treated as an individual right, even as collectively exercised individual rights. First, by virtue of the subject of the right. Secondly, by virtue of the object of the right. The essence of the right to genetic privacy is beautifully conveyed through the meaning of Peter Jones' quote:

[78] *Ibid.*

> Participatory goods are not merely goods in which others may have interests as well as myself. Nor are they merely goods that will 'affect' the lives of others. They are goods in which the lives of others are necessarily involved. Thus, for me to have an individual right to a participatory good is for me to have a right over the lives of others, and that really is at odds with the idea of equal moral standing.[79]

Thus, the key points for distinguishing individual and collective, or group rights are the type of the object, or the category of goods, and the nature of the subject, or the right holder. Having analyzed the potential right to genetic privacy with regard to all these items, we have determined that it does not unconditionally fall under any concept but unites the features of some of them along with its own features. Since the terms "collective rights" and "group rights" are often used in various senses, it is better not to use them when defining genetic privacy. Therefore, the following definition of the right to genetic privacy is being proposed:

- the right of the genetic group to control the circulation of genetic information, including, but not limited to, having control over its collection, research, use, transfer;
- where the genetic group is understood as a group of blood relatives up to the 9th (ninth) generation and up to the 4th (fourth) degree of kinship, which at the same time are sources of this information and whose participation in the group is due to the relevance of genetic information;
- intended for guaranteeing the individual privacy of each member of the group, their autonomy in decision-making process with regard to genetic information, as well as to ensure the informational identity of the group; and
- which can be carried out separately by each member of the group or, in certain cases, jointly by the established majority;
- where the genetic information is understood as inherited genetic characteristics of an individual or his/her family member which give individual predictive information about the physiology or the health of that individual or his/her family member which result from genetic analysis of a biological sample of that individual or his/her family

[79] Jones, P. (2014). Collective Rights, Public Goods, and Participatory Goods. In G. Calder, M. Bessone & F. Zuolo (Eds.), *How Groups Matter: Challenges of Toleration in Pluralistic Societies* (pp. 52-72). London: Routledge, p. 61.

member, family medical history of that individual or the result from other scientific and medical examinations of that individual or his/her family member; and

- which does not affect the claims regarding individual genetic information, understood as the acquired genetic characteristics of an individual which provides an insight into the physiology or the health of that individual and which result from genetic analysis of a biological sample of that individual.

The important point to be made is that membership in a genetic family group is a matter of belonging to the family rather than some achievement. That is why, at first glance it may seem that the participation is based on non-voluntary criteria as well. However, genetic privacy is associated with the extraction of information. All family members share information in their genes, but this information has no practical value and does not need protection, unless it is extracted through tests, analysis, examinations, questionnaires about health and other tools and unless it is decoded or analyzed.

At the same time, no family member can be compelled to undergo any medical procedures in order to provide genetic information. For this reason, each member's participation can be regarded as absolutely voluntary, which is fair as genetic information, as a value, can be used only when produced. This concept excludes the free-rider problem, which is associated with pure public goods and is manifested in the fact that the consumer of the public good tries to evade payment of it. Each member of the genetic family can fully benefit from being part of the group when he/she sees a physician, thereby complementing their joint account of genetic information. However, the interference of genetic privacy with personal autonomy of blood relatives will be analyzed in the following chapters.

5.2. Respect for autonomy

5.2.1. Informational overload and duty to know

The consequences of the growing interest in genetics and the importance allotted to genetic information can be sometimes grave. In other words, this is when genetics diminishes a person exclusively down to his/her set of hereditary data. This paradigm is called biological, or genetic determinism. It emerged in the XX Century, presupposing that human behavior is directly

controlled by human genes, regardless of whether it is about embryonic development or education. As a result of this attempt to explain behavioral traits using genes, the diffusion and development of new technological developments affected social and cultural life in a way that transformed the understanding not only of physical health, but also of social significance of people. That is, genetics has changed the perception of human personality as whole.

With the concept of biological determinism is associated the idea of genetic reductionism, which reduces the cause of any human manifestation to genes. Thus, not only cardiovascular disease or Alzheimer's disease is associated with an individual's heredity, but also schizophrenia, alcoholism, manic-depressive illness, aggression, sexual orientation, and IQ.[80] Researchers have been trying for years to determine the genotype of criminals. Professor Jari Tiihonen, for instance, was the first to conduct the genetic background study of serious recurrent violent behavior.[81] Several decades earlier, some scientists stipulated that males with an extra Y chromosome (XYY genotype) were overly aggressive, lacking in empathy and prone to violent behavior. However, this discovery, which attracted an unprecedented amount of attention, was eventually refuted.[82] Biological determinism and genetic reductionism are not nearly as dangerous as genetic fatalism. This idea consists of the belief that any behavior is fixed and unchangeable if it is conditioned by genes and, therefore, called "genetic".[83]

Each bout of a new genetic determinism or fatalism is fraught with social upheavals, such as a gap in inequality in society, enmity, racial hostility, intolerance and, of course, discrimination. Knowledge of genetic traits influences attitudes towards oneself, towards one's own life, as well as affecting relationships within the family. Current legislation, the tendencies of which we have illustrated by the example of selected countries in earlier chapters, by and large, quite extensively restricts individuals from access to their genetic heritage. Individuals have access to only that part

[80] Alper, J. S, & Beckwith, J. (1993). Genetic Fatalism and Social Policy. The Implications of Behavior Genetics Research. *Yale Journal of Biology and Medicine*, 66, 511–524, p. 511.
[81] TIihonen, J., Rautiainen, M. R., Ollila, H. M., Repo-Tiihonen, E., Virkkunen, M., Palotie, A., Pietiläinen, O., Kristiansson, K., Joukamaa, M., Lauerma, H., Saarela, J., Tyni, S., Vartiainen, H., Paananen, J., Goldman, D., & Paunio, T. (2015). Genetic Background of Extreme Violent Behavior. *Molecular Psychiatry*, *20*(6), 2015, 786–92, p. 6.
[82] *E.g.*, Witkin, H. A., Mednick, S. A., Schulsinger, F., Bakkestrom, E., Christiansen, K. O., Goodenough, D. R., Hirschhorn, K., Lundsteen, C., Owen, D. R., Philip, J., Rubin, D. B., & Stocking, M. (1976). Criminality in XYY and XXY Men. *Science*, *193*(4253), 547–555.
[83] Alper, J. S, & Beckwith, J. (1993). *Op. cit.*, p. 511.

that becomes available to them if they undergo genetic testing themselves or their relatives voluntarily share their medical anamneses. The right to genetic privacy should remove this barrier by giving every member of the genetic group unlimited access to information related to their health.

Since we are considering the issue of patient rights and the rights of patient relatives regarding information important to the health, the issues associated with behavioral genetics, including the "killer gene", will mostly remain outside the scope of this study. However, the line between behavioral traits and hereditary diseases is difficult to draw. Genetic behavioral information is more sensitive, more associated with self-perception by constituting a large component of identity, and it has relevance over a larger period of time.[84] At the same time, the behavioral traits of a certain person affect not only himself/herself, but also his/her environment, and they are continuously distributed within the population and "some extreme of this distribution may have a pathological component".[85] Such behavioral extremes usually require medical treatment, thus, like anything that requires treatment, they can be considered medically significant.

Behavior is a more volatile category since it depends on well-established social norms. The requirements for behavior may differ from one degree to another depending on the era, the level of development of society, culture, and customs. As for the state of health, although it is also subject to changes, which are expressed in terms of life expectancy and the quality of life at different times, it is associated with more or less objective concepts such as the functioning of the body, pain, strength, and so on. It is much easier to distinguish behavioral traits from physical disabilities, but not from mental illnesses as the mind remains a mystery. Either way, the amount of information available to an individual about his/her existence is large. The same information, depending on its perception, can have a different effect on different people and lead to both positive and disastrous consequences. This potential duality results in problems associated with notifying individuals about their genetic predispositions.

With regard to the right to know, access to genetic information does not differ in any way from the scope of the current right to access a medical file. Legislation in the countries selected for

[84] Newson, A. (2004). The Nature and Significance of Behavioural Genetic Information. *Theoretical Medicine and Bioethics*, *25*(2), 89–111, pp. 95-96.
[85] *Ibid.*

analysis similarly regulates the right of patients to consult medical records, images and test results that relate to their treatment or diagnosis. Since genetic information is much more extensive than the information usually found in modern medical files, nevertheless, some adjustments will be required in how this right will be exercised. Changes may be necessary in relation to technical questions related to the way, place, and format of storage of information, which may affect the formal procedures of obtaining access. We will analyze in more detail the options for the acceptable storage of genetic information in subsequent chapters. Moreover, it is important to note that the format of the medical file will change as well. Given the peculiarity of genetic information, namely its group nature and depersonalized format, the medical dossier should be two-tier – a personal level, which resembles the medical records that are now being kept for the patient, and a group level, which contains all the genetic information that concerns the genetic group. Nevertheless, such a volume of data provided to an ordinary person will be useless, and it would be more logical to provide them in the form of a report, such as a family medical history.

Exercising the right to access medical information implies actions on the part of the right holder by sending a request, and it also implies the patient's desire to receive the records and the data contained in them. The right to access information about one's health is usually associated with obtaining benefits for oneself – control over treatment, seeking a second opinion, etc. Thus, it is an important tool for ensuring autonomy. In contrast, there are beliefs that the patient has a duty to know, not just a mere right.

First, there are claims that the duty to know is necessary in order for other family members to benefit from genetic information. Since genetics is a family matter, there are beliefs that there is also a family responsibility to be aware of their genetic information, even though, for the reasons listed above, access to such information may entail a serious psychological impact on a person.[86] In this case, the duty is directed towards relatives. However, it can lead to sacrificing an individual family member's integrity for the well-being of others, which is not acceptable under the human rights approach. For this reason, it is hard to agree with the idea of duty to know. Disclosure may be justifiable when absolutely necessary, but it should be regarded as an exception rather than a duty to know. At the same time, under the model of a joint account of genetic information, which

[86] Domaradzki, J. (2015). Patient Rights, Risk, and Responsibilities in the Genetic Era – A Right to Know, a Right Not to Know, or a Duty to Know? *The Annals of Agricultural and Environmental Medicine*, *22*(1), 156–162, p. 160.

is ensured by the right to genetic privacy, this problem is much easier to solve. In order for a family member to be able to receive information concerning his/her health to make autonomous decisions based on it, other relatives who are not interested in learning about their hereditary predispositions can still stay oblivious. Nevertheless, we will dwell on the peculiarities of mutual obligation within families, as well as responsibility to future generations in the next chapters.

Second, it is believed that most people would rather know what is wrong than remain in the dark, which also applies to genetic diseases.[87] In this case, the duty to know is viewed as an obligation to oneself. Thus, the obligation to receive one's own information is understood as a prerequisite for the realization of autonomy and component of the autonomous person's status, since the knowledge is a requirement for the possibility to choose. Therefore, everyone has a moral obligation to receive truthful information about herself/himself, on the basis of which he/she can rationally build his/her future life. For example, John Harris and Kirsty Keywood argue that discarding information is different from autonomously compromising autonomy, such as a decision to join the army or join the police, which will significantly limit the range of possible choices in the future.[88]

Prior to this, Rosamond Rhodes argued that the obligation to know, which includes awareness about one's own genetic heritage, stems from the Kantian idea of autonomy.[89] This idea expects that a truly autonomous person, free from irrational emotions and fear, has no right to remain ignorant when genetic information can influence his/her decisions and can be obtained with reasonable effort.[90] Nevertheless, it is difficult to agree with such a statement. On the one hand, such an interpretation of autonomy contradicts itself, depriving the individual of the freedom of choice. The concept of obligation to know does not take into account the fact that no matter how rational a choice is, if it is imposed from the outside, it cannot be autonomous. On the other hand, ignorance cannot always be automatically categorized as irrational.

[87] Takala, T. (2001). Genetic Ignorance and Reasonable Paternalism. *Theoretical Medicine and Bioethics*, *22*(5), 485–491, p. 487.
[88] Harris, J., & Keywood, K. (2001). Ignorance, Information and Autonomy. *Theoretical Medicine and Bioethics*, *22*(5), 415–436, p. 419.
[89] Rhodes, R. (1998). Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge. *The Journal of Medicine and Philosophy*, *23*(1), 10–30, pp. 17-18.
[90] *Ibid.*

The truth-telling in the context of healthcare is also associated with the value of truth. The concept of truth has always been the subject of philosophical reflection. Ever since Antiquity, when value was attached to truth, it was understood as a good, and a person who has cognized the truth was considered to have come into contact with eternal and unchanging being. Along with beauty, goodness and holiness, truth has been considered one of the key values, an absolute value in itself.[91] In this context, William Werkmeister wondered if truth was really a value. Trying to answer this question, he compared truth with other goods, namely, with beauty and holiness, in one row with which it was placed by philosophers. Beauty and holiness are categories intrinsic to the nature of certain objects, while truth is not such, but is a type of connection between propositions and facts.[92] Even though the truth does not have value in itself, according to Werkmeister, it has a binary relation to value.[93] First, when knowledge of truth satisfies the desire to know, this satisfaction is regarded as a value. Second, true propositions are considered valuable because of practical significance that they have. Werkmeister insists that it is true proposition that serves for something good, has "means-value", but not truth itself.[94] Similarly, Matthew H. Kramer in his essay challenging John Finnis's argument against skepticism notes that skeptical attitude towards truth being a good in itself contends that truth very often helps in achieving other goals.[95] However, when using the word "good" in its ordinary meaning, truth can be undesirable and harmful and knowing this kind of truth can be not valuable.[96]

Let us look at knowledge or ignorance of genetic information in terms of how it affects human life. All questions regarding the use of genetic information in medicine ultimately come down to a global dilemma about the quality and quantity of life. Of course, knowing the predisposition and diagnosis, one can promptly seek medical attention, receive treatment, and prolong life. In this case, knowing the truth is practical and valuable for the patient. At the same time, life can be "shortened" by darkening it with daily thoughts and suffering about an inevitable and incurable disease. This kind of truth does not serve for anything good. Moreover, it is important to note that information provided by physicians not always absolutely reflects the reality as sometimes there

[91] Werkmeister, W. (1970). Is Truth a Value? *The Southwestern Journal of Philosophy*, *1*(3), 45-49, p. 45.
[92] *Ibid*., pp. 48-49.
[93] *Ibid*., p. 49.
[94] *Ibid*.
[95] Kramer, M. H. (1992). What Good Is Truth? *The Canadian Journal of Law and Jurisprudence*, *5*(02), 309–319, p. 312.
[96] *Ibid*., p. 318.

can be a technical error, honest mistake, misinterpretation, or even worse – lack of experience and negligence. Otherwise, "second opinion" would not gain popularity in modern medicine. The right not to know does not prevent the patient to know the reality and does not promote lying. It is more about the right moment of learning about one's own – right now or later, or when the symptoms start to appear. Thus, the right not to know should not be associated with an ultimate choice between knowing or not knowing, but with a choice of how and when to know.

Life is the highest value. However, it is inextricably linked with concepts such as health, well-being, quality of life, which distinguish life from existence. The concept of quality of life combines subjective and objective features and implies "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns".[97] In modern health care, quality of life is seen as a key goal[98] in maintaining the health of population in general and in treating chronic illnesses[99] in particular. We will not argue about what is more important – life itself or its quality, but we insist that both values are objectively recognized and universal, so the choice in favor of either of them can be considered rational. Therefore, those who consciously choose ignorance to restrict the flow of information in order to improve their quality of life, rather than quantity, act as a completely autonomous individual. Another question is where the line between acceptable and unacceptable ignorance is.

5.2.2. The right not to know

In the context of patient rights, the right to know is mainly mentioned as one of the fundamental rights in the healthcare domain, as well as an ethical and legal principle.[100] Later, especially with the development of genetic technologies and their application in medicine, attention has shifted to the idea that the patient too has a right not to know. In the context of genetic testing, the right not to know means the ability to control what information the patient wants to receive regarding his/her

[97] World Health Organization. Division of Mental Health and Prevention of Substance Abuse. (1997). *WHOQOL: measuring quality of life*. Retrieved April 16, 2021, from https://apps.who.int/iris/handle/10665/63482/
[98] Skevington, S. M. (2007). Quality of Life. In G. Fink & A. Stepto (Eds.), *Encyclopedia of Stress* (pp. 317-319). Elsevier, p. 317.
[99] McGee, H. M. (2001). Chronic Illness: Quality of Life. In N. J. Smelser & P. B. Baltes (Eds.), *International Encyclopedia of the Social & Behavioral Sciences* (pp. 1779-1782). Pergamon, p. 1779.
[100] Andorno, R. (2004). The Right Not to Know: An Autonomy Based Approach. *Journal of medical ethics*, *30*(5), 435–440, p. 435.

inheritance, as well as respect for this desire.[101] The right not to know does not contradict with the right to know but is the exact opposite of the obligation to know, which excludes any choice about accepting or refusing information about one's health.

On the one hand, the right not to know is often linked to the principle of autonomy. All of the arguments given in the previous chapter against the obligation to know can be used to support the idea that the right not to know is in no way contrary to this bioethical principle. Thus, Roberto Andorno argued that the possibility of not knowing the results of genetic tests is an "enhancement of autonomy", since the decision belongs to the patient and not the physician, which is already a big challenge to excessive paternalism.[102] Against this background, there is a concern that such a choice of ignorance is impossible to perform due to the fact that the very process of asking would already reveal all the information.[103] That is, by promoting autonomous choice the state of ignorance can be compromised.[104] However, in order to express a desire to be kept in the dark, rather than waiving the informed consent,[105] it is enough to obtain knowledge about the nature of the choice, and not the detailed information which is normally required to consent to treatment and diagnostics.

On the other hand, a certain degree of ignorance is one of the components of informational privacy, which has also been discussed in earlier chapters. The concepts of autonomy and privacy overlap. However, the explanation of unwillingness to know any information in terms of autonomy loses its relevance if it was not possible to express in a timely manner one's desire or reluctance to receive information in the future.[106] In this context, Graeme Laurie asserted that the right not to know is based on a particular form of "spatial privacy", or "phycological separateness of others".[107] This link to privacy suggests *prima facie* respect for the private sphere even in the absence of

[101] Berkman, B. E., & Hull, S. C. (2014). The "Right Not to Know" in the Genomic Era: Time to Break from Tradition? *The American journal of bioethics: AJOB*, *14*(3), 28–31, p. 29.
[102] Andorno, R. (2004). *Op. cit.*, p. 436.
[103] Wertz, D. C., & Fletcher, J. C. (1991). Privacy and Disclosure in Medical Genetics Examined in an Ethics of Care. *Bioethics*, *5*(3), 212–232, p. 221.
[104] Laurie, G. (2014). Privacy and the Right Not to Know: A Plea for Conceptual Clarity. In R. Chadwick, M. Levitt & D. Shickle (Eds.), *The Right to Know and the Right Not to Know: Genetic Privacy and Responsibility* (Cambridge Bioethics and Law, pp. 38-52). Cambridge: Cambridge University Press, p. 40.
[105] Andorno, R. (2004). *Op. cit.*, p. 437.
[106] Laurie, G. (2014). Recognizing the Right Not to Know: Conceptual, Professional, and Legal Implications. *The Journal of law, medicine & ethics: a journal of the American Society of Law, Medicine & Ethics*, *42*(1), 53–63, p. 55.
[107] *Ibid.*, p. 58.

explicit choice, unless when there is a good cause to make an exception to the right to privacy.[108] Such presumption, not without reason, raised doubts that all patients who had not explicitly declared their propensity to ignorance actually do not want to exercise their right to know.[109]

The legislation on the right not to know is still quite stingy, and it remains a contested matter. However, some international legal documents have acknowledged this right. For example, the very first document that mentioned the right not to be informed was the Declaration on the Rights of the Patient adopted by WMA in 1981.[110] Afterwards, WHO proposed to respect the wish of individuals and family members not to know genetic information, nevertheless excluding testing of newborns and children for treatable conditions.[111] Besides these non-binding documents, there are international instruments that are enforcing this right.

Thus, the Council of Europe has "extended autonomy-based claims with respect to the right to know also to the right not to know"[112] in the Oviedo Convention on Human Rights and Biomedicine. Article 10 of the Oviedo Convention invokes to respect the wishes of an individual not to be informed about any information collected about his/her health.[113] Similarly, the UNESCO Universal Declaration on the Human Genome and Human Rights in its Article 5 provides that the "right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected".[114] In 2003, the same idea was reaffirmed in the International Declaration on Human Genetic Data.[115] Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes

[108] *Ibid.*, p. 59.
[109] Andorno, R. (2004). *Op. cit.*, p. 438.
[110] World Medical Association. (1981). Declaration of Lisbon on the Rights of the Patient [amended version of 2015], Art. 7 (d).
[111] WHO Meeting on Ethical Issues in Medical Genetics (1997: Geneva, Switzerland) & WHO Human Genetics Programme. (1998). *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services: Report of WHO Meeting on Ethical Issues in Medical Genetics*. Geneva, 15-16 December 1997, p. 10 (Table 7). Retrieved April 16, 2021, from https://apps.who.int/iris/handle/10665/63910/
[112] Laurie, G. (2014). Privacy and the right not to know. *Op. cit.*, p. 39.
[113] Council of Europe. (1997). Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS 164), Art. 10 (2).
[114] United Nations Educational, Scientific and Cultural Organization. (1997). Universal Declaration on the Human Genome and Human Rights, Art. 5 (c).
[115] United Nations Educational, Scientific and Cultural Organization. (2003). International Declaration on Human Genetic Data, Art. 10.

recognizes the wish not to be informed in the context of respect for private life.[116] All the aforementioned documents link the right not to know with an explicit choice, describing it using terms such as "wishes", "decision", "request".[117]

In the wake of its recognition by international law, some states incorporated the right not to know into their legislation as well. In the Spanish legal system, the right not to be informed was initially guaranteed by Ley básica 41/2002 with regard to healthcare rights in general.[118] Subsequently, this right was reaffirmed by Ley 14/2007, which ensured the right of an individual participating in biomedical research to decide not to receive genetic information obtained in the course of such research, except when, in the physician's opinion, it can cause damage to the health of the research participant or his/her biological relatives.[119] In Switzerland, the right to refuse to receive information about one's own genetic status is derived from the right to self-determination.[120] Likewise, the UK former Human Genetics Advisory Commission and then the Human Genetics Commission recommended in their reports in 1999 and in 2002, respectively, to uphold the individuals' right not to know their genetic constitution and genetic information about themselves.[121]

In the U.S., the right not to know is mentioned in the context of incidental and secondary findings. The American College of Medical Genetics (ACMG) provided guidance on the use of whole genome sequencing in the clinical context in 2012, where it was suggested to give patients the option of not receiving certain information.[122] One year later, a set of very influential ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing was published. In these recommendations, the ACMG advocated the routine evaluation of additional panel of genes, variants and conditions during the exome and genome sequencing and

[116] Council of Europe. (2008). Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Genetic Testing for Health Purposes (CETS 203), Art. 16 (3).
[117] Andorno, R. (2004). *Op. cit.*, p. 436.
[118] Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Boletín Oficial del Estado, 15 de noviembre de 2002, núm. 274, pp. 40126 a 40132, Art. 4 (1).
[119] Ley 14/2007, de 3 de julio 2007, de Investigación biomédica. Boletín Oficial del Estado, 4 de julio de 2007, núm. 159, pp. 28826 a 28848, Art. 4 (5).
[120] Loi fédérale sur l'analyse génétique humaine (LAGH) du 8 octobre 2004 (État le 1er janvier 2014), Art. 6.
[121] Cited in Andorno, R. (2004). *Op. cit.*, p. 436.
[122] Cited in Knoppers, B. (2014). From the Right to Know to the Right Not to Know. *Journal of Law, Medicine & Ethics*, *42*(1), 6-10, p. 8.

its reporting to the ordering physician to be included in the medical history of the patient and to notify the patient regardless of his/her preferences or age.[123] This proposal received criticism from the American Presidential Commission for the Study of Bioethical Issues (Bioethics Commission). The Bioethics Commission noted that this approach might entail additional health risks or psychological ramifications, overwhelm individuals with contradictory information and encourage medicalization and further testing.[124] Trying to mitigate concerns evoked by these recommendations, the ACMG issued an explanatory document that expects physicians to "contextualize these findings to the clinical circumstances" and to engage the patient in "a shared decision-making process regarding the return of results".[125] Thereafter, the ACMG Board of Directors claimed that the initial recommendations had been updated allowing patients to opt out of analysis of genes unrelated to the purpose of testing in advance.[126]

Incidental findings and secondary findings being variants in known disease genes are the results of genetic testing unrelated to the initial indication for such testing. Recently, the issue of communicating these findings to the patient has been widely debated.[127] Unsolved questions regarding incidental and secondary findings primarily enclose informed consent procedures, conflict with professional duty and patient autonomy. The ethics of managing incidental and secondary findings is very extensive and deserves separate attention. For this reason, we will not conduct a separate study of this topic but will return to it in the context of other related issues of genetic privacy in subsequent chapters. We believe that a new understanding of genetic

[123] Green, R. C., Berg, J. S., Grody, W. W., Kalia, S. S., Korf, B. R., Martin, C. L., McGuire, A. L., Nussbaum, R. L., O'Daniel, J. M., Ormond, K. E., Rehm, H. L., Watson, M. S., Williams, M. S., Biesecker, L. G., & American College of Medical Genetics and Genomics. (2013). ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing. *Genetics in medicine: official journal of the American College of Medical Genetics*, *15*(7), 565–574, p. 573.

[124] Presidential Commission for the Study of Bioethical Issues. (2013). *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*, p. 56. Retrieved April 13, 2021, from https://www.genome.gov/Pages/PolicyEthics/HealthIssues/Anticipate_Communicate.pdf/

[125] American College of Medical Genetics and Genomics. (2013). Incidental Findings in Clinical Genomics: A Clarification. *Genetics in medicine: official journal of the American College of Medical Genetics*, *15*(8), 664–666, p. 664.

[126] ACMG Board of Directors. (2015). ACMG Policy Statement: Updated Recommendations Regarding Analysis and Reporting of Secondary Findings in Clinical Genome-Scale Sequencing. *Genetics in medicine: official journal of the American College of Medical Genetics*, *17*(1), 68–69, p. 68.

[127] Saelaert, M., Mertes, H., De Baere, E., & Devisch, I. (2018). Incidental or Secondary Findings: An Integrative and Patient-Inclusive Approach to the Current Debate. *European journal of human genetics: EJHG*, *26*(10), 1424–1431, p. 1424.

information and genetic privacy can help resolve some of the problems associated with these types of findings. To determine the general principles of the right not to know in the context of genetic medicine, it is not necessary to distinguish incidental and secondary findings from the rest of genetic information.

Returning to the right not to know, the attitude among scholars on this matter is rather skeptical and some of them still support the idea of obligation to know and do not allow any refusal to hearing the unpleasant truth. Usually, in medicine, it is believed that this right belongs to terminally ill patients.[128] For example, statistical analysis of terminal cancer patients show that most patients prefer physicians to be realistic and to disclose the whole truth about their diagnosis, regardless of whether the prognosis is favorable or not.[129] Another study explored the interest in genetic testing for breast cancer and found that 58% of respondents were willing to undergo the tests.[130] However, this interest was inversely associated with having a family history of breast cancer.[131] It might be caused by elevated anxiety among those who have relatives affected by breast cancer, by them independently learning about BRCA1/2 genes, or preference towards other types of diagnostics.[132] Empirical data on predictive genetic testing for Huntington's disease (HD) show that 80% of adults with HD in their family anamnesis prefer not to undergo testing.[133] Clearly, the ratio between benefits and harm in the genetic testing for different diseases is not the same. A positive test result for HD at once increases at-risk individual's chance to develop symptoms from 50% to 100%,[134] when a confirmed genetic susceptibility to breast cancer is usually followed by prophylactic mastectomy which reduces the likelihood of getting sick by 90%.[135]

[128] Stahl, D., & Tomlinson, T. (2017). Is There a Right Not to Know? *Nature reviews. Clinical oncology*, *14*(5), 259–260, p. 259.
[129] Hagerty, R. G., Butow, P. N., Ellis, P. M., Lobb, E. A., Pendlebury, S. C., Leighl, N., MacLeod, C., & Tattersall, M. H. (2005). Communicating with Realism and Hope: Incurable Cancer Patients' Views on the Disclosure of Prognosis. *Journal of clinical oncology: official journal of the American Society of Clinical Oncology*, *23*(6), 1278–1288, p. 1280.
[130] Armstrong, K., Weber, B., Ubel, P. A., Guerra, C., & Schwartz, J. S. (2002). Interest in BRCA1/2 Testing in a Primary Care Population. *Preventive medicine*, *34*(6), 590–595, p. 592.
[131] *Ibid.*
[132] *Ibid.*, p. 593.
[133] Berkman, B. E., & Hull, S. C. (2014). *Op. cit.*, p. 29.
[134] *Ibid.*
[135] Hartmann, L. C., Schaid, D. J., Woods, J. E., Crotty, T. P., Myers, J. L., Arnold, P. G., Petty, P. M., Sellers, T. A., Johnson, J. L., McDonnell, S. K., Frost, M. H., & Jenkins, R. B. (1999). Efficacy of Bilateral Prophylactic Mastectomy in Women with a Family History of Breast Cancer. *The New England journal of medicine*, *340*(2), 77–84, p. 77.

Other studies show differences in physicians' opinions about when and how to give bad news to patients. An analysis of the reports of American oncologists conducted by Christopher K. Daugherty and Fay J. Hlubocky demonstrated that although most physicians consider it reasonable to respect the decisions of patients about whether they know about the terminal stage of the disease, about 40% of them still supported the point of view that patients should always know their prognosis.[136] The same study showed that 33% of physicians would ask their advanced cancer patients if they want to know the prognosis before discussing it, whereas 16% would give this kind of information to the patient only if he/she asked for it. At the same time, these figures vary depending on the country. Analogous studies among French oncologists showed that, unlike the 16% of American oncologists, almost 70% of French physicians said they would deliver unfavorable news when the patient explicitly requested such information.[137] The same response was given by the same percentage of French general practitioners and neurologists as well.[138]

It is fair to note that these are small-scale studies which were conducted involving a limited number of patients and physicians of a few specializations. However, they provide clear insights into trends in patient preferences and also provide some insight into physicians' attitudes toward the issue. Patients on the other hand can be divided into three large groups on the basis of such responses – those who already know their diagnosis (for example, terminal cancer), those who do not know or are not sure of the diagnosis but the disease is curable or allows maintaining a more or less normal quality of life with timely intervention (for example, predisposition to breast cancer) and those who do not know or are not sure of their diagnosis but the disease is not curable (for example, family history of HD). As far as physicians are concerned, the degree of paternalism in decision-making about delivering bad news to patients depends on the personal preferences of medical professionals, which in turn appear to depend on cultural differences. It is logical that the right not to know mainly concerns bad news, therefore, for the purposes of this chapter, we will mean by

[136] Daugherty, C. K., & Hlubocky, F. J. (2008). What Are Terminally Ill Cancer Patients Told About Their Expected Deaths? A Study of Cancer Physicians' Self-Reports of Prognosis Disclosure. *Journal of clinical oncology: official journal of the American Society of Clinical Oncology*, *26*(36), 5988–5993, p. 5990.
[137] Peretti-Watel, P., Bendiane, M. K., Obadia, Y., Lapiana, J. M., Galinier, A., Pegliasco, H., Favre, R., & Moatti, J. P. (2005). Disclosure of Prognosis to Terminally Ill Patients: Attitudes and Practices Among French Physicians. *Journal of palliative medicine*, *8*(2), 280–290, p. 283.
[138] *Ibid.*

bad news "any information likely to alter drastically a patient's view of his or her future (whether at the time of diagnosis or when facing the failure of curative intention)".[139]

Such discrepancy between patients' preferences and physicians' attitudes attests to the misunderstanding of the nature of the right not to know. This might lead to the violation of patient privacy and autonomy by imposing unwanted information, withholding wanted information or by denying choice, as well as to the obstruction of professional obligation to warn, duty to disclose and to act in the patient's best interests. Ignoring the right not to know can have both beneficial consequences in terms of lives saved and negative consequences in the form of spoiled lives, poorer levels of care provided, and result in increased medical malpractice lawsuits. The dilemma associated with the recognition and respect of the right not to know is probably impossible to solve using one single scheme for all people without exception and making a decision will often require a certain judgment. Andorno's autonomy-based approach and Laurie's approach based on privacy reveal this dilemma from different angles, but they are not necessarily opposite, if only because privacy and autonomy are inextricably linked. In the very first chapters, when illustrating historical evolution of patient rights, we could notice that long time ago, ancient physicians too were at the crossroads of the choice to tell or not to tell.

In search of practical compromise, we propose to draw the following borders to balance the aforementioned conflicting rights and obligations, by adapting existing criteria for delivering medical information to patients. First, it would be reasonable to exclude from the scope of the right not to know any information concerning conditions that have a cure available or supporting treatment to contain or delay symptoms and when early intervention can make a difference in the outcome. This kind of information should always be available to an individual regardless of his/her preferences. Ultimately, moderate paternalism is tolerable when it is about saving lives. Second, other types of information can be an object of the right not to know and, ideally, should be discussed with the patient beforehand during the informed consent process. Especially, it applies to those who do not know or are not sure if they have a condition for which there is no available cure or treatment. This category of information is the most complex to deal with. Without establishing an individual's preferences before testing or accessing a genetic database, there will

[139] Buckman, R. (1984). Breaking Bad News: Why Is It Still So Difficult? *British medical journal (Clinical research ed.), 288*(6430), 1597–1599, p. 1597.

always be a 50% change to violate either the right to know or right not to know. Importance and particularities of informed consent in the Era of Genetics will be covered in later chapters. The decisions about unfavorable prognosis can involve palliative care. For this reason, unless there is an explicit wish not to learn about the prognosis, the physician must communicate it to the patient. Finally, there can be a portion of information about conditions and predispositions of low probability, which should be by default covered by the right not to know unless there is an explicit desire to be informed.

However, there can be some exceptions from the right not to know that concern the second and the third blocs of data, in the form of therapeutic privilege discussed in the first chapters or to protect prevailing interests of third parties. The third parties can include, for example, children or unrelated individuals. As an example of the latter, the result of genetic test to detect predisposition for HD should be communicated to someone who works as a surgeon regardless his/her preferences about receiving such information as symptoms of movement disorder can one day affect his/her ability to perform an operation. This scheme can be applied to all sum of genetic information that concern a particular individual regardless of if it is received in the course of specific genetic testing or derived from a biological relative's anamnesis.

5.2.3. Is there a right to know of blood-unrelated family members?

As it has already been clarified, the concept of a family as a social unit and from the point of family law does not coincide with the concept of a genetic family. Since we have already established the rights of all members of the genetic family with respect to genetic information obtained from biological relatives, in this chapter we will focus on the rights of family members who are not part of the genetic family, namely children and spouses who are biologically unrelated, fully or partially.

The first category primarily involves adopted children. Often, the issues that are raised in the context of adoption and genetic testing and access to genetic information are limited to two main ones – the problem of testing children before, during or immediately after adoption in order to

identify hereditary, especially untreatable diseases,[140] as well as the risk of revealing family secrets,[141] including the fact that the child is adopted, especially by means of direct-to-consumer tests. In addition to adopted children, this group includes children whose paternity is unknown, children from donated gametes, as well as children from single-parent families in which the identity of one biological parent is unknown. These issues are very important; however, we would like to highlight another problem associated with the lack of access of adopted children to their genetic information, namely genetic information of their biological family.

Given how important genetic information of a fairly large number of biological relatives is for effective diagnosis and treatment of the index patient, the lack of access to such information in adopted children is an inequality that disadvantages them when receiving medical care, as well as fulfilling their right to health. Any knowledge of hereditary diseases or predispositions can influence decisions about future life, including choice of profession or planning a family.[142] The same applies to donor-conceived children.[143] Modern genetic technologies, especially next generation sequencing (NGS), offer the possibility to fill in this gap.[144] However, lack of access to genetic information impedes the ability to interpret some of the results of genetic tests as analysis of family history might be required. Moreover, the routine use of NGS instead of genetic information extracted from biological relatives with a very low probability reveals rare, but highly penetrant and pathogenic genetic diseases, indicating a predisposition to future diseases.[145] For

[140] *E.g.*, The American Society of Human Genetics Social Issues Committee and The American College of Medical Genetics Social, Ethical, and Legal Issues Committee (2000). Genetic testing in adoption. *American journal of human genetics*, *66*(3), 761–767; Schlee J. A. (2001). Genetic Testing: Technology That Is Changing the Adoption Process. *New York Law School journal of human rights*, *18*(1), 133–183; Erwin, D. J., Uhlmann, W., Freeark, K. & Yashar, B. M. (2018). Preadoption Genetic Testing: Social workers' decision-making process. *Adoption Quarterly*, *21*(3), 141–160.

[141] Pappas, S. (2018, June). Genetic Testing and Family Secrets. *Monitor on Psychology*, *49*(6). Retrieved April 17, 2021, from http://www.apa.org/monitor/2018/06/cover-genetic-testing/

[142] May, T. (2019). The Value of Genetic Testing for Family Health History of Adopted Persons. *Nature reviews. Genetics*, *20*(2), 65–66, p. 66.

[143] Ravitsky, V. (2016). Donor Conception and Lack of Access to Genetic Heritage. *The American Journal of Bioethics*, *16*(12), 45–46, p. 46.

[144] May, T., Strong, K. A., Zusevics, K. L., Jeruzal, J., Farrell, M. H., LaPean Kirschner, A., Derse, A. R., Evans, J. P., & Grotevant, H. D. (2016). Does Lack of "Genetic-Relative Family Health History" Represent a Potentially Avoidable Health Disparity for Adoptees? *The American Journal of Bioethics*, *16*(12), 33–38, p. 36.

[145] Fullerton, S. M. (2016). No Panacea: Next-Gen Sequencing Will Not Mitigate Adoptees' Lack of Genetic Family Health History. *The American Journal of Bioethics*, *16*(12), 41–43, p. 41.

this reason, the genetic test cannot substitute the access to family genetic history, or genetic information in the sense we propose in our research.

Another solution to this problem of access to family medical history is the practice of "open adoption", which has gained prominence in the U.S.[146] In the rest of analyzed countries – Spain, Switzerland and UK, the adoptees have the right to access adoption records and to find out the identity of their biological parents after they have turned 18. A relatively new form in the West, open adoption is a fairly traditional practice in Asian societies and is a form of adoption in which biological and adoptive families have access to varying degrees of each other's personal information and are able to communicate. In the U.S., for example, while some remain skeptical, this form of adoption became the norm.[147] There are supporters of application of openness beyond the adoption, even to donation of gametes.[148]

Even though open adoption is quite a feasible practice, except for the difficulties to maintain open process in international adoptions or when contacting biological parents is not advisable in terms of the best interests of the child, such as the parents being highly dysfunctional or dangerous, we cannot agree that the openness of donation is something that can be justified. Despite the fact that donor-conceived children should have access to their genetic information, it would be disproportional to violate the donor privacy in order to address the issue. That is why, the new approach to genetic information and genetic privacy can potentially restore the balance of interests. As genetic information in our sense does not contain any information based on which it could be possible to identify relatives, it can be made available to adopted or children from donated gametes for medical purposes without compromising rights and interests of a child or of his/her biological parent(s). The only problem with providing access to such information is the organization of its storage and the associated bureaucratic processes, which we will discuss in later chapters.

The second group of biologically unrelated third parties with interest in genetic information of a particular individual are his/her spouse and partners. In this case, the same rules apply as when

[146] May, T., Strong, K. A., Zusevics, K. L., Jeruzal, J., Farrell, M. H., LaPean Kirschner, A., Derse, A. R., Evans, J. P., & Grotevant, H. D. (2016). *Op. cit.*, p. 36.
[147] Siegel D. H. (2013). Open Adoption: Adoptive Parents' Reactions Two Decades Later. *Social work, 58*(1), 43–52, p. 43.
[148] Ravitsky, V. (2016). *Op. cit.*, p. 46.

providing individual health information to spouses – with the explicit consent of the patient himself/herself. Since the right to genetic privacy is stated as the right of a group against outsiders, the spouse *a priori* does not have the right to access such information without the consent of the other side. Since each member of the group can exercise this right to genetic privacy individually, then, of course, it is not necessary to obtain the consent of all members of the group in order to tell the future/present spouse about their genetic predispositions, as this would be impractical and unreasonable and would be contrary to family foundations and values. Moreover, the law should have its limits in the regulation of family relations, and there should be room within the family for mutual trust, rather than obedience to the norms of law. Attempts to establish mandatory pre-marriage testing, albeit not for genetic diseases, but for HIV, have either failed or sparked endless debate over ethical admissibility and human rights compatibility.[149] However, is it fair to assume that the access to the family genetic information can be, as an exception, granted to the spouse before or during pregnancy?

5.2.4. Reproductive autonomy and future generations

Unsurprisingly, with the constant advances in genetics and reproductive medicine, and taking into account that the right to genetic privacy can in practice significantly increase the amount of information available to each individual, the amount of information about the health of the future fetus and hereditary conditions in an unborn child will also increase. Nowadays, lawsuits regarding the lack of information during the performance of genetic diagnostics more often refer to wrongful life and wrongful birth[150] where the physician failed to notify about the availability of prenatal genetic testing to detect severe hereditary conditions.[151]

In general, wrongful life lawsuit is brought by a child born with hereditary condition through a legal guardian against a physician arguing that he/she would not have been born if not for the

[149] *E.g.*, McKillip, J. (1991). The Effect of Mandatory Premarital HIV Testing on Marriage: The Case of Illinois. *American journal of public health*, *81*(5), 650–653; Rennie, S., & Mupenda, B. (2008). Ethics of Mandatory Premarital HIV Testing in Africa: The Case of Goma, Democratic Republic of Congo. *Developing world bioethics*, *8*(2), 126–137; Ganczak, M. (2010). The Impact of Premarital HIV Testing: A Perspective from Selected Countries from the Arabian Peninsula. *AIDS care*, *22*(11), 1428–1433.
[150] Granata v. Fruiterman [668 S.E.2d 127] (Va. 2008); Breyne v. Potter [574 S.E.2d 916] (Ga. Ct. App. 2002); Schirmer v. Mt. Auburn Obstetrics and Gynecologic Associates, Inc. [802 NE. 2d 723] (Ohio 2003).
[151] Marchant, G. E., Campos-Outcalt, D. E., & Lindor, R. A. (2011). Physician Liability: The Next Big Thing for Personalized Medicine? *Personalized medicine*, *8*(4), 457–467, p. 461.

physician's negligence and that the non-existence is preferred over life with disabilities.[152] On the contrary, wrongful birth lawsuit is a type of medical malpractice case brought by a parent, primarily a mother of a disabled child against a physician arguing that if genetic consultation or appropriate prenatal diagnostics had been offered, the pregnancy would have been terminated and the child would not be born.[153] This type of medical malpractice action involves a choice to whether or not to give birth to a child with increased possibility of illness. The courts are usually more comfortable with the latter type of lawsuits.[154] For example, the Spanish legal system allows wrongful birth claims brought by mother, not by father, as the right to opt for abortion is a personal, non-transferable right inherent to mother, who accordingly is entitled to claim compensation for the damages associated with the birth of a sick child.[155] In the U.S., wrongful birth claims are recognized by majority of states.[156]

Interestingly, Ivo Giesen argues that both wrongful life and wrongful birth claims relate to the right to self-determination, a fundamental right exercised by both parents on their behalf or on behalf of their child that is breached by physicians' actions or inactions.[157] Thus, these lawsuits also involve personal autonomy and privacy. Under current understanding of genetic information and family history and its limited availability and accessibility to individuals, the claims are brought against the physicians who failed to inform future parents about genetic risks by either withholding information or not performing all possible tests to discover such information. For this reason, liable healthcare provider or the hospital are to compensate the damages associated with raising a gravely sick child.

As we transform how we understand genetic information and accept the right to genetic privacy, which would allow individuals to have access to a lot larger amount of information about their

[152] Caulfield, T. (2001). Liability in the Genetic Era: Wrongful Birth and Wrongful Life Lawsuits. *Journal SOGC*, *23*(2), 143–147, p. 144.
[153] *Ibid*., p. 145.
[154] *Ibid*.
[155] Macía Morillo, A. (2016). El tratamiento de las acciones de wrongful birth y wrongful life a la luz de la nueva ley sobre interrupción voluntaria del embarazo. *Revista Jurídica Universidad Autónoma De Madrid*, *23*(I), 83–98, p. 85. Retrieved April 18, 2021, from https://revistas.uam.es/revistajuridica/article/view/5993/
[156] Frati, P., Fineschi, V., Di Sanzo, M., La Russa, R., Scopetti, M., Severi, F. M., & Turillazzi, E. (2017). Preimplantation and Prenatal Diagnosis, Wrongful Birth and Wrongful Life: A Global View of Bioethical and Legal Controversies. *Human reproduction update*, *23*(3), 338–357, p. 344.
[157] Giesen, I. (2009). Of Wrongful Birth, Wrongful Life, Comparative Law and the Politics of Tort Law Systems. *Tydskrif vir Heedendaagse Romeins-Hollandse Reg (THRHR)*, *72*, 257-273, p. 268.

physical and mental health, the burden of responsibility for wrongful life and birth might shift as well – from the physician to one of the parents, or even both of them. By analogy with, although not so numerous but increasingly recognized and satisfied claims described above, claims against one of the parents who intentionally withhold from the other parent genetic information that could affect the reproductive decision, as well as claims of children born with serious degenerative diseases may well be satisfied in the future. Having established that the concept of genetic privacy can affect the right to be informed and personal privacy and autonomy of parties outside the circle of the genetic group, as well as future generations, it is necessary to determine who the responsibility of informing falls on – family members or physicians. This problem, together with reasonable limits for ensuring the best health for an unborn child, will be analyzed in later chapters.

5.2.5. Mutual responsibilities

Due to the fact that genetic privacy is a group good, and the right to genetic privacy belongs to the genetic group, accordingly, and not to its individual members, a concerted effort is needed to protect this good. Therefore, within the group, there must be mutual rights and obligations to guarantee genetic privacy at the group level. Since the informational integrity of the entire group, namely the rest of the biological relatives, depends on the actions of each member of the genetic group, it is necessary to outline the permissible and unacceptable actions, as well as the consequences and ways of protecting this right.

Charles Foster, Jonathan Herring and Magnus Boyd proposed a scenario to demonstrate issues related to the possibilities of resolving conflicting interests in relation to genetic information.[158] They gave the example of two identical twins – X and Y, both of whom are world famous celebrities and X, through a medical examination, found out about an inherited progressive degenerative disease, which means that Y has the same condition and prognosis. One of these hypothetical characters wants to disclose the information about the illness to the public, while the other one is against this. The situation of these twins is reminiscent of lawsuits that involve biographical details of celebrities when they resort to super-injunctions.[159] In English tort law, super-injunction means a type of order that prevents publication of certain information as well as

[158] Foster, C., Herring, J., & Boyd, M. (2015). *Op. cit.*, p. 379.
[159] *Ibid.*

the fact about the existence of such order.[160] Such an injunction is quite rare and is granted only when there is no justified exception to privacy, such as outweighing public interest in sharing information.[161]

However, the main question that Foster, Herring and Boyd ask is how this kind of conflict can be resolved if X and Y are just normal people without fame and publicity. They refer to the approach proposed by Roy Gilbar and Sivia Barnoy, which is based on communitarian and feminist approaches to patient autonomy that stress out moral responsibility of a patient when making decisions about genetic information towards those relatives who might be affected by such decisions.[162] Even though Gilbar and Barnoy resort to the concept of moral responsibility within the family to explain the mechanism of sharing genetic information between family members,[163] we can use this idea to justify mutual responsibilities of biological relatives concerning genetic privacy when interacting with "outsiders". When answering the question concerning X and Y as non-celebrities, Foster, Herring and Boyd look at the scenario through the lenses of Gilbar and Barnoy to conclude that there is a need to restrict disclosure in order to protect the confidentiality of Y.

The same argument can be applied to this case when solving it in the light of our concept of genetic privacy. We believe that biological relatives, or the members of a genetic family have mutual responsibility to preserve their genetic privacy and mutual right to expect this preservation. Moreover, by accepting the right to genetic privacy we acknowledge that this mutual right and obligation are not only moral, but also legal. This means that when there is no obvious preponderant reason to make information public, its disclosure should be avoided. Clearly, it does not apply to disclosure to family and friends of each member of the genetic group, to medical personnel, or even to employer or insurance companies when it is required by law. However, the withholding of information from biological relatives, sale, or transfer of genetic information to private or public organizations for profit or other reasons not related to improving health, unnecessary publications in social media regarding health and other actions regarding genetic

[160] Lowther, J. (2011). *Q&A Torts 2011-2012* (9th ed.). London: Routledge, p. 171.
[161] Foster, C., Herring, J., & Boyd, M. (2015). *Op. cit.*, p. 379.
[162] Gilbar, R., & Barnoy, S. (2012). Disclosure of Genetic Information to Relatives in Israel: Between Privacy and Familial Responsibility. *New Genetics and Society*, *31*(4), 391–407, p. 392.
[163] *Ibid.*

information that might jeopardize other members of the group should be considered illegal. Each member of the group who feels that their genetic privacy was violated by someone else, including another member, should be able to restore it in court. In general, no drastic changes in the law and courts are required to implement this difference in concept of privacy as the basic principles are the same. We believe that this model can and must work as only team effort can guarantee true privacy in the modern day.

5.3. Interim conclusion

Having studied privacy from the point of view of the classification of economic goods, we found that privacy in general and genetic privacy in particular differ significantly from many individual goods that are objects of individual rights. As a value, privacy has many similarities to public goods that require government support for fair production and distribution. Therefore, we agreed to consider genetic privacy in the light of individual goods (individual genetic information) and in the light of public goods (genetic privacy in general) in order to better reflect the multi-level structure and complexity of the concept.

On the one hand, genetic privacy as an individual good is very limited, as it is associated with the individual interests of a particular person in relation to his/her individual genetic information. Based on our definition of genetic information, a block of purely individual genetic information is negligible compared to a block of data that affects an individual's relatives as well. Thus, individual genetic information is an object of the individual right to privacy, namely the right to respect for medical confidentiality. On the other hand, information about the human genome is of great interest to all of humanity. Although, at first glance, such interests oppose one another, they are often complementary, since securing one is not possible without securing the other. Of course, this applies to real public goods from which the society can truly benefit, and not to those which represent a cover to justify somebody's individual political or economic interests.

Genetic information in the sense we have defined cannot be classified as either individual or public goods. It is of interest to a much larger circle of people than individual goods, but not as extensive as public goods, or common goods. Thus, genetic privacy practically and theoretically cannot be satisfied through individual requests. It also cannot be supported fully by the government. What is

more, in contrast to the claims regarding a global goal in decoding and using the human genome to improve the health of all people, genetic privacy is of interest for a strictly defined circle of people, sufficiently designated to act as a subject of law.

In seeking to find a balance between the individual rights of the patient and his/her family members in an evolving world of health care, the right to genetic privacy is of prime interest to our study, as it could act as a shield for the protection of all affected individuals, while at the same time providing a fair environment for each relative to exercise their autonomy. Nevertheless, the main problem in the way of recognizing collective and corporate, or group rights (the terms are vary significantly depending on the points of view as listed above) is their opposition to individual rights, in which one can fear that by having endowed groups rights the individual rights of group members cannot be guaranteed. For this reason, majority of scholars are skeptical about allocating human rights into the category of group rights. The catch lies in the perceived threat to individual human rights posed by group rights, or in the excessive bias from individualization to collectivization of the human rights system.

In defining the right to genetic privacy, it was necessary to determine who the subject is, what the right is aimed at, what its scope and limits are. We decided not to label it as collective or group rights due to the various ideas that are embedded in these concepts. However, from its essence it follows that it is quite different from individual rights.

Individual rights of members of a genetic group as well as the rights of third parties are closely tied to the right to genetic privacy. While there are great advantages in considering the right to genetic privacy in the light of a joint account, there are some concerns about respecting individual autonomy, namely respecting an individual's choice to know about his/her own predispositions. Also, denying the right not to know risks leading to individual privacy being breached. Since informational privacy implies not only the management of one's own information, but also protection against intrusion into personal space in order to feed unwanted information from outside, forcibly notifying a person about his/her health can be regarded as a violation of the right to privacy. Moreover, the positive and negative outcome of the notification differs from case to case, since it depends on the patient's personality, life position, and life philosophy.

If we assume that the right to genetic privacy exists and along with it the right to know and the right not to know, then in practice someone should have a counter obligation to disclose or conceal this information and/or notify all members of a genetic group and other interested parties, if any, about their access to genetic information and corresponding rights. At first sight, there are two suitable contenders for this role – physician or one of the relatives. However, to each there are advantages and disadvantages. On the one hand, relatives, especially close ones, better understand each other and their needs in order to appreciate the desire or reluctance to learn about genetic risks. On the other hand, ordinary people without medical education often do not fully understand the nature of the medical problem or the information revealed by genetic testing, and therefore can exacerbate the psychological burden. Also, relatives sometimes have a paternalistic attitude and decide that they can make decisions for a loved one to help him/her. The physician, on the other hand, is the more objective party and has sufficient knowledge and training to present such information. Nevertheless, based on the traditional model of therapeutic relationships, the physician is not bound by any relationship and, accordingly, obligations to family members of the patient. After all, might it be better to delegate this responsibility to someone else? Who can be a candidate to bear this responsibility? We will approach this dilemma in the chapters to come.

6. DUTY TO DISCLOSE

6.1. Intra-familial or intra-group obligation?

6.1.1. Nature of obligations in family

In any kind of relationship, whether a legal or moral one, duty or obligation – moral or legal, respectively, are considered the correlate of rights. This means that the right to genetic privacy correlates with a counter-obligation. Since the right to genetic privacy is quite extensive and combines more specific rights, the duty not to violate privacy consists of more specific obligations, such as obligation to not collect information without permission, to not change information, to not disclose. In general, the essence of these obligations is not much different from the essence of current obligations with regard to respecting the individual right to privacy. However, an expanded understanding of genetic information and the assumption that a wider range of data should be available to every individual also affects individual rights, such as the right to be informed, as well as the right to access medical records and receive information about one's own health. This raises the question of whether someone has a reciprocal obligation to inform a member of the genetic group about new information or the risk of disease, and to inform other interested third parties that we have mentioned in previous chapters.

Duty or obligation is perceived as something that "one ought or ought not to do".[1] On the one hand, the words "duty" and "obligation" are often used interchangeably. In casual discourse, the term "duty" is used in relation to those who have to take actions in virtue of holding certain official positions, such as police officers, politicians, or physicians. On the other hand, some philosophers, referring to the function of language in differentiating distinct concepts by using different terms, protested against this practice of mixing notions.[2] For example, Hart opposed duties and obligations by pointing out that the latter "may be voluntarily incurred or created" and "are owed to special persons (who have rights)".[3] Similarly, John Rawls distinguished "natural duties" from obligations on the basis of whether there is a previous performance of voluntary acts. Thus, natural duties apply to people unconditionally regardless of any institutional relationship, whereas

[1] Lake Shore & M. S. R. Co. v. Kurtz (1894) 10 Ind. App. 60, at 304, as cited in Hohfeld, W. (1913). Some Fundamental Legal Conceptions as Applied in Judicial Reasoning. *The Yale Law Journal*, *23*(1), 16-59, pp. 31-32.
[2] Brandt, R. B. (1964). The Concepts of Obligation and Duty. *Mind*, *73*(291), 374-393, p. 374.
[3] Hart, H. L. A. (1955). Are There Any Natural Rights? *The Philosophical Review*, *64*(2), 175-191, p. 179.

obligations are voluntarily generated and are grounded in the principles of fairness.[4] As examples of natural duties, Rawls mentioned the duty of mutual help in case of need or jeopardy, the duty not to harm or injure, the duty not to cause unnecessary suffering, and the duty of justice as a fundamental requirement for all individuals.[5]

These delimitation criteria of Hart and Rawls were followed by A. John Simmons, who summarized the features that distinguish the two concepts and characterized duties as "moral requirements which apply to all men irrespective of status or of acts performed" and which "are owed by all persons to all others and form the core of what used to be known as 'Natural Law'".[6] Thus, basic justification of such duties is the intrinsic nature of the obligee, which is sufficient to ground these duties.[7]

However, after having analyzed differences between "duty" and "obligation", Richard B. Brandt came to the conclusion that even though there are some distinct patterns in the use of these terms from the point of view of grammar and context of use, any generalizations about proper use would be complex and delicate.[8] When terms are used in a broader sense, it is permissible to use them as synonyms, and when in a narrower sense, the appropriate terms are usually intuitively used.[9] For the purposes of our study, there is no need to go deeper to distinguish the concepts of duty and obligation. Consequently, we will not emphasize the difference between "duty" and "obligation" when using them in broad sense. However, when it is required by the context, they will be distinguished.

Now, let us explore the nature and particularities of obligations within family. In contrast to natural duties, family obligations are also characterized as special obligations, as they arise from special relationships and are owed to a limited group of individuals.[10] Therefore, such obligations cannot be grounded in the intrinsic nature of individuals, whom they are owed to, and rather justified by

[4] Rawls, J. (1999). *A Theory of Justice (Revised edition)*. Oxford: Oxford University Press, pp. 98-99.
[5] *Ibid*.
[6] Simmons, A. J. (1979). *Moral Principles and Political Obligations*. Princeton, New Jersey: Princeton University Press, p. 13.
[7] Jeske, D. (2019). Special Obligations. In E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy*. Retrieved April 25, 2021, from https://plato.stanford.edu/archives/fall2019/entries/special-obligations/
[8] Brandt, R. (1964). *Op. cit*., p. 392.
[9] *Ibid*.
[10] Jeske, D. (1998). Families, Friends, and Special Obligations. *Canadian Journal of Philosophy*, *28*(4), 527–555, p. 528.

the nature of the relationships between the obligor and the obligee,[11] that is relationship of kinship between family members. However, from the point of view of voluntarism, obligations resulting from promise or even obligations resulting from friendship are not quite the same as family obligations. When we make friends with someone or promise to do something, we enter these relationships freely, otherwise it would be against autonomy and there should be no obligations.

When it comes to family, the voluntary act criterion is not entirely applicable to certain categories of relatives, by and large, to all of them apart from between spouses, as well as between parents in relation to children. For this reason, the claim that parents have obligations seems less controversial based on such claims. The issue of special obligations and voluntariness is even more acute in the context of relations between the closest relatives, namely regarding children in relation to their parents, as well as between siblings, as we do not choose our parents and siblings. Thus, we feel that in terms of common-sense morality, there should be certain obligations, but from the point of view of voluntarism, there is no ground for them.

In an attempt to solve the challenge posed by the too straightforward voluntarist approach to family obligations, Diane Jeske argued that friendship and family have much more in common than it seems at first glance.[12] Undoubtedly, friendship itself is voluntary. However, the process of befriending or being befriended is very complex and does not represent a mere single act of promise, which makes it impossible to determine from what exact moment the friendship begins, along with the ensuing obligations.[13] Individuals find themselves sharing different situations with other people, but not all situations and encounters lead to friendship, even with those with whom a lot of time is spent together, like colleagues or roommates. It is clear that friendship requires reciprocal actions, such as mutual revelations, trust, sharing of something personal, which results in a partial "merger" of private spheres. If someone learns personal information unilaterally from observation or interrogation, like a stalker or a detective, that would not make them friends. Thus, friendship requires genuine intimacy, and it is this intimacy that is supposed to be voluntary.[14] Just like friendships, family relationships are built on history of intimacy, which turns them to a mutual

[11] Jeske, D. (2019). *Op. cit.*
[12] Jeske, D. (1998). *Op. cit.*, p. 537.
[13] *Ibid*.
[14] *Ibid*., p. 538.

project, and which generates special obligations.[15] However, if relatives did not develop such intimate relations, a mere family relationship does not create any obligations.[16]

At the same time, we all have a large number of social roles on which our behavior depends. Social roles associated with the family, such as child, parent, sibling, grandparent, also require certain behavior. Nobody will deny that, depending on the social role performed, everyone is expected to have some obligations to other family members. Family obligations reflect a duty of mutual support and aid between relatives. Such obligations may be directly provided for by the law with the corresponding consequences for their failure, or they may also not be embodied into the law. The first type of obligations mainly concerns the relationship between parents and children, which includes parents providing their children with basic necessities, such as food, clothing, and shelter, as well as their education. It also includes some financial obligation between spouses. Thus, only a small part of family obligations is governed by the law, while the rest of family obligations is mostly regulated based on traditions and moral precepts. It is plausible to suppose that family obligations form, to some extent, a part of normative system of a particular society.

The abovementioned examples of the legislative assignment of certain obligations to certain family members testifies that the law distributes such duties on the basis of the family being a social institution, and each family member has his/her own rights and obligations based on the role he/she plays. However, the legislator does not usually stipulate the rights and obligations for all social roles within family. On the contrary, Michael O. Hardimon offers an account of "role obligations" – non-voluntary obligations that are applicable to all family members. The role obligation is defined as "moral requirement, which attaches to an institutional role, whose content is fixed by the function of the role, and whose normative force flows from the role".[17] These obligations are attached to certain social roles and apply to individuals who perform such roles.[18]

Despite the fact that Hardimon does not deny the lack of choice regarding social roles within the family, as a daughter or a sister, he refuses to accept that these roles are imposed such that as being

[15] *Ibid*., p. 540.
[16] *Ibid*., p. 543.
[17] Hardimon, M. O. (1994). Role Obligations. *The Journal of Philosophy*, *91*(7), 333–363, p. 334.
[18] *Ibid*., pp. 334-335.

born into a role does not mean the same as being impressed into a role.[19] Hardimon argues that if an unchosen social role is "reflectively acceptable", then the obligations associated with this role are morally binding.[20] A social role is reflectively acceptable if, upon reasonable consideration, one would accept it by judging it as "meaningful, rational, or good".[21] However, a simple reluctance to play a particular role is not an excuse from fulfilling correspondent obligations.[22] Thus, Hardimon's concept grounds family obligations in stereotypical content of different social roles that represent a kind of general guidelines for correct attitude towards relatives.

Ronald Dworkin proposes a similar idea of obligation identified by social practice when referring to "communal obligations" or "obligations of role". Such obligations, according to Dworkin, are not a matter of choice but are the special responsibilities that "social practice attaches to membership in some biological or social group, like the responsibilities of friends or family or neighbors".[23] He notes that only members of a true community who have sufficient psychological characteristics are bound by special responsibilities.[24] Unlike Hardimon's model, for Dworkin, social expectations alone do not suffice to create obligations between members of community.[25] Under this concept of special obligations, there is a risk to attribute some moral value to membership in communities that serve to non-moral or immoral purposes and participants of which might not deserve to be regarded as having special moral obligations to one another.[26]

The fact that the understanding of obligations between relatives that are not regulated by the law is rather broad, such as "children should take care of elderly parents", supports the view that these obligations have an element of negotiation that adapts generalized rule into a specific situation.[27] Moreover, the principle of reciprocity in family relationships suggests the same.[28] When analyzing kinship in British society, Janet Finch concludes that historical evidence proved that the

[19] *Ibid*., p. 347.
[20] *Ibid*., pp. 348-350.
[21] *Ibid*.
[22] *Ibid*.
[23] Dworkin, R. (1986). *Law's Empire*. Cambridge: The Belknap Press of Harvard University Press, p. 196.
[24] *Ibid*., pp. 199-201.
[25] Jeske, D. (2019). *Op. cit.*
[26] *Ibid.*
[27] Finch, J. (1987). Family Obligations and the Life Course. In A. Bryman, B. Bytheway, P. Allatt & T. Keil (Eds.), *Rethinking the Life Cycle* (pp. 155-169). London: Palgrave Macmillan, pp. 156-158.
[28] *Ibid*., p. 158.

relationship in the past were much more calculative.[29] This means that the nature of obligations that relatives have to each other partly result from the previous conduct of each individual who is currently requiring care or assistance.[30] Thus, whether obligation is incurred or not depends on emotional perception. This concept of negotiated obligations resonates with Jeske's account of intimate relations to the extent that intimacy is inextricably linked with emotionality. Since different types of behavior of an individual leave various emotional impressions on other relatives, which guides them by when making commitments, the obligations cannot be explained without reference to emotions.[31]

The idea that personal impact has moral value is affirmed by Michael J. Sandel, who advocates the claim that people are bound by special relationships that go beyond voluntary obligations and natural duties, with those who influenced their understanding of themselves and, therefore, partially determined who they are.[32] This special bond involves special obligations, or "constitutive commitments".[33] Such beliefs have served as the basis for the biological approach that goes even further than Hardimon's concept, beyond the essence of family relationships in attempts to justify obligations between relatives. Scientific theorists insist that biological ties are both intrinsically and instrumentally morally valuable.[34] When defending moral significance of ancestry, those who appeal to biology locate the identity of individuals in their genetic resemblance. According to them, genetic contribution, as the foundation of specific traits that are central to a personal identity, fully or partly ground familial obligations.[35] Thus, Raymond A. Belliotti suggests that "we have moral requirements of a special sort to those who contribute to and help nurture our identities, and those whose attachment is essential for our self-understanding".[36] According to Belliotti, adult children have *prima facie* obligations to their parents even if they have not developed a close relationship or if parents were not exemplary parents.[37]

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[29] *Ibid*.
[30] *Ibid*.
[31] *Ibid*., p. 159.
[32] Sandel, M. J. (1998). *Liberalism and the Limits of Justice* (2nd ed.). Cambridge University Press, p. 179.
[33] *Ibid.*
[34] Velleman, J. D. (2008). II. The Gift of Life. *Philosophy & Public Affairs*, *36*(3), 245–266, pp. 251-261.
[35] Monaghan, J. (2019). Biological Ties and Biological Accounts of Moral Status. *The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine*, *44*(3), 355–377, p. 356.
[36] Belliotti, R. A. (1986). Honor Thy Father and Thy Mother and To Thine Own Self Be True. *The Southern Journal of Philosophy*, *24*(2), 149 –162, p. 152.
[37] *Ibid*., p. 154.

Summarizing the ways of conceptualizing obligations between relatives discussed in this chapter, it became apparent that most of these options have clear disadvantages. The biological concept and the concept of social roles do not pay much attention to the value of the family. The first account runs the risk of reducing itself to biological or genetic determinism, and also fails to solve the problem of obligations between relatives unrelated by blood, such as adopted children and their adoptive parents as well as between spouses.[38] The second model is highly dependent on cultural and social differences, and the results from its application can vary greatly even within the same society. The concept of negotiation is linked to the possession of power and does not take into account the possible lack of equality in the family when assigning obligations.[39] The only concept that focuses on the warm feelings and caring, the basis on which a family is built, is the one that has been proposed by Jeske, which adapts to the voluntarism and defends personal autonomy.[40]

6.1.2. Moral and legal obligations

Since some of the obligations between relatives have been translated into legal ones, it is worth making a brief overview of the criteria to distinguish them. The most obvious difference that comes to mind is that legal obligations are enforced by the state and the failure to fulfill them entails legal liability and sanctions while failure to comply with purely moral obligations causes censure from society or remorse but does not involve any legal responsibility. However, there are different concepts of moral and legal obligations in the philosophy of law.

In the theory of John Austin, legal obligation is explained through the validity and coercive order of the law.[41] According to him, it is characterized by the presence of legal relations associated with the execution of the orders of the sovereign, which makes it impossible to distinguish between legitimate coercion and not. This interpretation of legal obligation in terms of sanctions has been attacked and received criticism. Some other criteria of differentiating moral and legal obligation that are often considered among philosophers were analyzed by Conrad D. Johnson in an attempt

[38] *E.g.*, Haslanger, S. (2009). Family, Ancestry and Self: What Is the Moral Significance of Biological Ties? *Adoption & Culture, 2*(1), 91-122.
[39] Finch, J. (1987). *Op. cit.*, pp. 160-161
[40] Jeske, D. (1998). *Op. cit.*, pp. 554-555.
[41] Austin, J. (1832). Lecture I. In W. Rumble (Ed.), *Austin: The Province of Jurisprudence Determined* (Cambridge Texts in the History of Political Thought, pp. 18-37). Cambridge: Cambridge University, 1995, p. 22.

to find out what that difference is. He was mostly concerned about promise-based obligation,[42] but his analysis demonstrated the main ways of reasoning.

The most typical criterion is the one about immunity from deliberate changes, which implies that, unlike moral requirements, legal requirements can be created, changed or eliminated by a deliberate act, will or decision of a person or a group of people.[43] The exact same idea can be found in Hart's doctrine.[44] While agreeing with this approach in terms of moral principles, Johnson argues, using the example of the parallel between the moral obligation to fulfill the promise and the corresponding legal principle that underlies contractual responsibility, that legal principles are not so easy to abolish. He states that in order to abolish such a principle, it is not enough for it to be outweighed by another principle or cease to be the basis for the field of law, but it needs to be "systematically excluded from having any weight in legal argument in any significant area of the law".[45]

The second differentiation criterion that distinguishes Johnson is the criterion of relativity to goals, purposes and policies which implies that legal requirements, and not moral requirements, are imposed depending on variety of goals and purposes.[46] In response, Johnson argues that moral obligations can also depend on policy when there is a reason not to decry someone who has violated the moral obligation, or if the community can change the rules of "punishment" for not adhering to them.

Finally, Johnson outlines another criterion of importance, which assumes that all moral rules and not all legal rules are of fundamental importance.[47] According to Hart, this feature is manifested, among other things, in that "moral standards are maintained against the drive of strong passions which they restrict, and at the cost of sacrificing considerable personal interest".[48] Furthermore, he adds that "if moral standards were not generally accepted, far-reaching and distasteful changes

[42] Johnson, C. D. (1975). Moral and Legal Obligation. *The Journal of Philosophy*, *72*(12), 315–333, p. 315.
[43] *Ibid.*, p. 321.
[44] Hart, H. L. A. (1961). Justice and Morality. In H. L. A. Hart, J. Raz & P. A. Bulloch (Eds.), *The Concept of Law* (3rd ed., pp. 79-99). Oxford: Oxford University Press, pp. 175-176.
[45] Johnson, C. D. (1975). *Op. cit.*, p. 324.
[46] *Ibid.*, p. 326.
[47] *Ibid.*, p. 329.
[48] Hart, H. L. A. (1961). *Op. cit.*, pp. 173-174.

in the life of individuals would occur".[49] In this context, Johnson illustrates the obligation between family members to refill the tank upon emptying it, to ignore which would not be morally correct, but such an obligation does not coincide with the requirement of importance in the sense of Hart's explanation, especially when it comes to "strong passions" and "far-reaching and distasteful change" in the life of a family.[50]

The idea Johnson conveys in his argument is that there is no such a sharp line drawn between morality and law. Based on his analysis, Johnson offers his own version of conceptualizing the relationship between legal and moral obligations, according to which "[to] be under a legal obligation is to be under a requirement that is […] a moral obligation".[51] Thus, a legal obligation can be considered an enforceable administration of morality. In the example of an obligation based on promise to do something, a moral obligation to execute the promise exists alongside a correspondent legal contractual obligation. He notes that an individual who lives under a reasonably just regime may find moral underpinnings of legal obligations. Despite this, an individual who is under moral obligations imposed by the legislature is not necessarily obliged to comply as disobedience can be morally justified as well.[52]

6.1.3. Obligation to disclose genetic information

In regulating the question of notifying a patient's relatives of important genetic information, international and national legal instruments, the content of which we have reviewed in earlier chapters, mainly reflect the position that the obligation to notify at-risk family members rests primarily on the shoulders of the patient. The ability of the physician to raise the issue with the ethics committee about direct notification of relatives is secondary, which means that the physician can resort to this option only if the patient refuses to disclose the information by himself/herself. The review of guidelines and legislation suggested that individuals have moral obligation to communicate genetic information to their family members which follows from the nature of family

[49] *Ibid.*
[50] Johnson, C. D. (1975). *Op. cit.*, p. 330.
[51] *Ibid.*, p. 332.
[52] *Ibid.*, p. 333.

ties and the presumed desire to protect loved ones from harm.[53] At the same time, healthcare professional are advised to encourage and assist their patients in such communication process.[54] Nevertheless, the case law that we have also reviewed in previous chapters shows that dissatisfied relatives who have not been informed about genetic risks sue the physician, and not their family member who was the primary source of the medical information.

Shifting the duty to inform onto the patient is a limited approach to handling genetic information, which historically has been information ascribed exclusively to the patient.[55] However, some scholars who are promoting a family account of genetic information also believe that the patient should take an active part in the process of disclosing risks to his/her relatives. The main argument is that the patient represents an indispensable link in such communication due to the importance of the family factor. No one can understand better than the patient himself/herself whether his/her relatives want to know about any predispositions or conditions or not, how bad the news might affect their mental state and further decisions about their course of life, in what form it is better to convey information, etc.[56] Thus, Gilbar is convinced that the solution to the tension over genetic information is to appeal to family ethics "which is mainly based on care, commitment, intimacy, solidarity and mutual responsibility" between those who are emotionally close.[57]

The same opinion is shared by Rhodes, who links moral obligations with intimacy, dependence, and history of interaction, and not with genetic ties.[58] She notes that people do not feel morally responsible to mice although they are genetically similar.[59] This approach is very similar to the concept of Jeske on family obligations mentioned above, which emphasizes social bond between relatives. Moreover, according to research findings that Gilbar cites as an example, patients often base their decisions to disclose information to family members on the quality and nature of the

[53] Forrest, L. E., Delatycki, M. B., Skene, L., & Aitken, M. (2007). Communicating Genetic Information in Families – A Review of Guidelines and Position Papers. *European journal of human genetics: EJHG*, *15*(6), 612–618, pp. 614-615.
[54] *Ibid*.
[55] Grill, K., & Rosen, A. (2020). Healthcare Professionals' Responsibility for Informing Relatives at Risk of Hereditary Disease. *Journal of Medical Ethics*, p. 2. Published Online First: 27 November 2020. https://doi.org/10.1136/medethics-2020-106236/
[56] Gilbar, R. (2007). Communicating Genetic Information in the Family: The Familial Relationship as the Forgotten Factor. *Journal of medical ethics*, *33*(7), 390–393, pp. 390-391.
[57] *Ibid*.
[58] Rhodes, R. (1998). Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge. *The Journal of Medicine and Philosophy*, *23*(1), 10–30, p. 21.
[59] *Ibid*.

relationship with them.[60] This demonstrates that patients themselves intuitively rely on the same criterion of intimacy when justifying their moral obligations towards family members. Yet, another study shows that the majority of respondents believed that initially only relatives of the first degree of kinship should be notified of genetic risks, according to the principle of cascade screening approach.[61]

Some scholars have proposed the so-called concept of "familial comity", emphasizing the importance of solidarity and altruism.[62] The principle of comity is intended to justify further the disclosure of genetic information to relatives of a patient in the event of the patient's refusal. It thus ensures the social responsibility that stems from the hereditary nature of the genetic information. Familial comity strikes a balance between individual autonomy and the needs of genetic relatives.[63] According to this concept, obligations arise from the hereditary nature of genetic information, that is, from its scientific characteristic. Therefore, solidarity and altruism are based rather on biological ties, and not on intimate relationship between relatives. Likewise, Charles Weijer emits that siblings, because they are siblings, "owe each other a duty to respect and care", which would be violated if genetic information is not communicated by one of them to another.[64] Moreover, he concludes that since relatives are not strangers, it is odd to apply the terms of privacy rights to them.

Given that the genetic family, in the sense that it was defined as in order to ensure the right to genetic privacy, does not coincide with the concept of a family in a social sense used in family law, the question is whether any of those accounts is suitable to justify a hypothetical obligation between relatives to share genetic information. In health care, the individual right to access information about one's own health is one of the fundamental rights, since, together with informed

[60] *E.g.*, McGivern, B., Everett, J., Yager, G. G., Baumiller, R. C., Hafertepen, A., & Saal, H. M. (2004). Family Communication About Positive BRCA1 and BRCA2 Genetic Test Results. *Genetics in medicine: official journal of the American College of Medical Genetics*, *6*(6), 503–509; Kenen, R., Arden-Jones, A., & Eeles, R. (2004). Healthy Women from Suspected Hereditary Breast and Ovarian Cancer Families: The Significant Others in Their Lives. *European journal of cancer care*, *13*(2), 169–179.
[61] Marleen van den Heuvel, L., Stemkens, D., Zelst-Stams, W. A. G., Willeboordse, F., & Christiaans, I. (2020). How to Inform At-Risk Relatives? Attitudes of 1379 Dutch Patients, Relatives, and Members of the General Population. *Journal of Genetic Counseling*, *29*, 786–799, p. 789.
[62] Davey, A., Newson, A., & O'Leary, P. (2006). Communication of Genetic Information within Families: The Case for Familial Comity. *Journal of Bioethical Inquiry*, *3*(3), 161–166, p. 164.
[63] *Ibid*.
[64] Weijer C. (2001). Family Duty Is More Important Than Rights. *Western Journal of Medicine*, *174*(5), 342–343, p. 343.

consent, it ensures the principle of autonomy. In general, the importance of the right to access information is due to it being a mechanism for securing other rights, both within and outside of health care. Therefore, such a right should be provided to all members of the genetic group without exception. However, it seems that all models have flaws that make it impossible to guarantee this right by intra-familial obligations.

With regard to intimacy as a way to justify the obligation to notify relatives of health-related risks, most relationships between members of a genetic group extend beyond intimate relationships, because the genetic group includes larger number of people than the intimate circle. It turns out that the access that each member of the group has to information about their health depends both on personal relationships with the patient, who is the direct source of a certain "piece" of genetic information, and on the remoteness of kinship, which is, after all, one of the conditions for establishing close ties. Using such a model, no member of the genetic family will have a complete picture of medically relevant information, while having in disposal only pieces of the whole puzzle. With more distant kinship, the sense of obligation diminishes, which is natural in relation to the obligation of caring. However, it does not seem right when quality of relationship with someone else decides whether an individual can access his/her own information.

It is logical that a person has moral familial obligations, such as support and care, to his/her parents much stronger than to his/her parents' second cousins, because people normally share more history and intimacy with parents rather than with the second cousins of their parents. Nonetheless, when genetic information is at stake, such a statement risks to contradict one of the criteria we have outlined for the relevance of genetic information, namely its pertinence up to fourth degree of kinship "horizontally" on a family tree. In addition to significantly reducing the circle of family members who are owed to, the intimacy approach also has serious consequences for adopted children and children with one unknown parent, as it leaves them practically cut off from access to their information for lack of intimacy with one or both biological sides.

It seems that the biological account would provide some capacity to avoid all the problems listed above. But is it? Indeed, genetic similarity leaves an imprint on the personality of an individual and serves as a good reason to assign persons connected by such biological ties into a group to be, for example, a right holder. However, there is nothing morally relevant or sufficient in biological

similarity itself to generate moral obligations between "species" of their own kind. Earlier, we discussed group identity and how it acts as an argument for group privacy. Therefore, if we are to look for the origins of special obligations between genetic relatives, then it is necessary to switch from biological proximity to group membership as a ground of these obligations.

On the one hand, we could turn to Dworkin's conception of communal obligations, or, by comparing a genetic group to a nation, we could refer to the associative model of political obligations. The adherents of the latter, like supporters of the biological account of special obligations, echo Sandel's idea of constitutive commitments, believing that membership in a certain polity state generates special obligations, since identity is conditioned by the fact that people are part of a particular political community. According to John Horton, some institutional obligations do not need an external justification, as they may be justificatory themselves due to the deep-rooted connection with participants' identity.[65] Usually, people are born into a certain political system, but in the end, it leaves an imprint on who they become. Thus, this conception takes character of special obligations that are owed to particular individuals and of natural duties that are owed non-voluntarily to everyone.[66]

On the other hand, participation in a genetic group is voluntary. Even though everybody is born to a family, thereby sharing genetic similarities without a choice, what is more important is that everybody has a choice whether to actually participate in the genetic group, namely in the production of group goods – genetic information and genetic privacy. Therefore, the associative account of special relationships in its pure form, as well as the voluntaristic promise-based approach are not quite applicable to our idea of a group. Similar to Jeske's model of family responsibilities, members of the genetic group voluntarily go to a physician who collects their medical information. However, their participation in producing their shared good does not end there – it is an ongoing collaborative effort to contribute to the quantity and quality of health-related genetic information and to ensure both their personal privacy and that of the group. The shared history of producing and protecting the good justifies mutual commitments of blood relatives that we have already mentioned in the previous chapters, regarding the purpose of

[65] Horton, J. (1992). *Political Obligation*. Issues in Political Theory. London: Palgrave, p. 157.
[66] Horton, J., & Windeknecht, R. G. (2014). Is There a Distinctively Associative Account of Political Obligation? *Political Studies*, *63*(4), 903–918, p. 916.

establishing the group. According to this approach, if it can be called a participatory-group-good-special-obligation approach, the fact that the members constitute a mechanism for producing their common good and for protecting their common right to privacy from within the group justifies the obligations associated with their participation in this process. However, the duty to inform, and even more the duty to warn about the risks, goes beyond the general mutual obligations that are grounded in group membership.

Regardless of the grounds of obligations between genetic relatives, the main problem with shifting the obligation to the patient to disclose information to his/her relatives is the unwillingness to see genetic information as being common to all biological relatives. While assigning a new person responsible for the disclosure of new information obtained by medical examination or testing, our society continues to break genetic information down into parts by incorrectly confirming that each of these parts "belongs" to the patient, during whose medical consultation these parts were retrieved. To illustrate this issue with an example, we follow Parker's and Lucassen's analogy with a bank account – if one of the account holders puts money in the account, the rest will find out about this through the bank when accessing transaction history or even through a notification via an online banking application, and not directly from the person who deposited the money into the account. Now, let us imagine that the bank shifts this obligation to each account holder and does not display the total amount for the rest of the holders until the one who performed the transaction allows the bank to notify or actively notifies the others. Does this look like a joint account? Rather, it looks like a sum of individual bank accounts, each with multiple cards attached.

Furthermore, the fulfillment of such an obligation is essentially impossible or unbearable. First of all, from the point of view of the relevance of genetic information in time, it is in no way possible in practice to personally notify descendants in the ninth generation. Even relatives of the same generation may simply not know about or not be able to contact each other. For this reason, the circle of recipients of information will be unfairly reduced, albeit for objective reasons. Moreover, the question of children with one or both biological parents not known to them will remain open. In all cases, except for open adoption, children will not be able to access complete information about their health.

In addition, this established approach creates several unnecessary conflicts of interest. One is the conflict between the right not to know of the patient being tested and the right to know of other relatives. Such a conflict of equally important rights cannot be resolved fairly, regardless of the number of exceptions the legislator may ascribe to them. The burden of notifying other relatives forces each member of the group to give up his/her own interests for the sake of the rest of the group, which in no case should be allowed. Another example of a conflict of interest is that of intrafamilial responsibilities arising from intimate relationships within the family. Thus, most likely, the duty to notify the children of the siblings of a patient, who is regarded as the source of new hereditary information, will be carried out through the patient's siblings, the parents of the children, and not directly by the patient, not to usurp parental authority.[67] Even though one can consider that group responsibilities do not extend beyond the perimeters of the nuclear family,[68] it is unlikely in this case that we will still be considering obligations within a group, and not within a family.

Finally, the idea of a relative's obligation to notify the rest of the genetic group completely contradicts the position of most countries regarding the "ownership" of medical information. We have already mentioned that most countries choose not to specify who exactly is the owner of genetic information. However, based on the procedures and requirements that a patient faces in order to obtain a copy of medical records, medical institutions have more property rights in relation to such documents than the patient himself/herself. Of course, the intangible content of documents, that is, information, differs from the material registration of medical records, but in order to notify relatives of all new information and risks, the results of the analytical activities of physicians that are set out in medical records are required. This makes it illogical to put this burden on someone who does not fully possess the asset that needs to be shared.

For all of the above reasons, it is not certain that there are prerequisites for imposing the obligation to notify all members of the group on one individual who is the source of new genetic data. It is possible that such data may indirectly act as the object of special obligations in family between

[67] Keenan, K. F., Simpson, S. A., Wilson, B. J., Van Teijlingen, E. R., Mckee, L., Haites, N., & Matthews, E. (2005). "It's Their Blood Not Mine": Who's Responsible for (Not) Telling Relatives About Genetic Risk? *Health, Risk & Society*, *7*(3), 209–226, p. 216.
[68] Nycum, G., Knoppers, B. M., & Avard, D. (2009). Intra-familial Obligations to Communicate Genetic Risk Information: What Foundations? What Forms? *McGill Journal of Law and Health*, *3*(1), 21–48, p. 32.

close relatives out of intimacy, such as care shown in the form of advice to go to the hospital for perceived genetic risks, mutual disclosure of genetic predispositions in family planning, psychological or financial support of a family member who suffers from a genetic condition. However, such obligations are not directly related to the right to genetic privacy and to the right to access one's own medical information. Due to voluntary participation in a genetic group, blood relatives have special obligations that take the form of collaborative efforts to ensure genetic privacy. Special moral obligations, such as the obligation to refrain from preventing other group members from accessing their common health information, must find support as well from the legal system to ensure that the right to privacy is properly protected. Imposing the obligation to notify all biological family members on the shoulders of each of them is unjustified, unbearable, and ineffective in guaranteeing their autonomy and individual rights.

6.1.4. Patients who are young

In the communication process, special attention should be paid to the issue of informing children about hereditary diseases and predispositions. As we have already mentioned, talking about such topics usually lies within the framework of parental authority and is a rather difficult task for parents. We have also found that the obligation to disclose all information about medically significant genetic heritage, including reporting genetic risks, goes beyond the mutual obligations of members of the genetic group. Therefore, this responsibility must be assigned to someone outside of the group to ensure that the right of each individual to access genetic information is fully guaranteed. Therefore, adults who are raising a child – biological or adoptive parents or guardians – being an intermediary in informing children, may face some difficulties. Parents are faced with the dilemma of what and when to tell their children about inherited diseases, while taking into account the desire to protect them from unnecessary anxiety, the child's self-identity, and the consequences for future generations.[69] Therefore, it is necessary to take into account situations where a lack or an overabundance of care for children of any age under 18 may lead to an infringement of their rights with regard to medical information. Foremost, this applies to

[69] Metcalfe, A., Coad, J., Plumridge, G. M., Gill, P., & Farndon, P. (2008). Family Communication Between Children and Their Parents About Inherited Genetic Conditions: A Meta-Synthesis of the Research. *European Journal of Human Genetics*, *16*(10), 1193–1200, p. 1194.

asymptomatic children with adult-onset diseases in the family, treatment for which need not be started during childhood.

On the one hand, some studies have shown that sometimes more distant relatives, like aunts and uncles, feel resentment that the children of their siblings do not know enough about the hereditary disease than they should.[70] Parents who hide important genetic information from their children have power over them by preventing their children from making informed choices about their future.[71] Harboring relevant information that could affect the future of children can do more harm than good.[72] According to some statistics, children from whom parents have successfully hidden genetic predispositions, growing up, are prone to feelings of indignation, because they believe that parents should have told them about such important issues.[73] The same research shows that regardless of whether the respondents knew about their genetic heritage during childhood, they agree such information is very important in order to accept in a timely manner and draw conclusions from.[74] For this reason, it is necessary to take into account the child's opinion and involve him/her in all processes that are associated with genetic information.

As children's ability to comprehend develops, their participation in decision-making deserves greater respect.[75] In 1989, the UN adopted the Convention on the Right of the Child (UNCRC) that set out in its Article 12 the right of children to be heard and to participate in the decisions made concerning them.[76] From the moment children are able to communicate and make any decisions about themselves, they should not be excluded from the discussion of their health and heredity. Full implementation of Article 12 UNCRC requires a range of different approaches and methods of verbal and non-verbal communication, including through play and art, to fulfill the duty of adults to listen to the children.[77] Given the broadness of the scope of Article 12 UNCRC,

[70] Forrest, K., Simpson, S., Wilson, B., Van Teijlingen, E., McKee, L., Haites, N., & Matthews, E. (2003). To Tell or Not to Tell: Barriers and Facilitators in Family Communication About Genetic Risk. *Clinical Genetics*, *64*(4), 317–326, p. 321.
[71] Skirton, H. (1999). Telling the Children. In A. Clarke (Ed.), *The Genetic Testing of Children* (pp. 103-111). Oxford: BIOS Scientific Publishers, p. 110.
[72] Malpas, P. J. (2006). Why Tell Asymptomatic Children of the Risk of an Adult-Onset Disease in the Family but Not Test Them for It? *Journal of Medical Ethics*, *32*(11), 639–642, p. 640.
[73] Metcalfe, A., Coad, J., Plumridge, G. M., Gill, P., & Farndon, P. (2008). *Op. cit.*, p. 1197.
[74] *Ibid.*
[75] Clayton, E. W. (1997). Genetic Testing in Children. *Journal of Medicine and Philosophy*, *22*(3), 233–251, p. 244.
[76] United Nations. (1989). Convention on the Rights of the Child. *Treaty Series*, *1577*, 3, Art. 12.
[77] Donnelly, M., & Kilkelly, U. (2006). *The Child's Right to Be Heard in the Healthcare Setting: Perspectives of Children, Parents and Health Professionals*. Dublin: Stationery Office, p. 17.

its provisions apply to all areas in which there can be any matters affecting a child.[78] In comparison, a pediatric clinical trial protocol usually requires consent from potential participants starting at about four to five years of age, adding more detail and information about the study for each subsequent age group of children until they are asked to re-sign the informed consent form upon reaching maturity. For the disclosure of genetic information to be effective and contribute to the formation of their self-identity and promote their autonomous decisions, it is necessary to deliver children the idea in understandable form.[79] The right to be heard is reinforced by other provisions of the UNCRC that guarantee the enjoyment of the rights to all children without discrimination (Article 2) and recognize the right of children to the freedom of expression (Article 13).

On the other hand, there is another heated debate related to the issue of disclosure of hereditary information to children. The question of predictive genetic testing in asymptomatic minors generates a lot of controversy.[80] The decisions in this case are made by the parents based on the best interests of the child, in the same way as with any other medical procedure involving minors.[81] This principle is formulated in Article 3 UNCRC, which requires that in all decisions taken over children, the child's best interests must be a primary consideration. Both numerous guidelines on predictive genetic testing and position of geneticists have suggested that predictive genetic testing should be deferred until adulthood, except for diseases for which preventive measures may be initiated earlier.[82] Therefore, Phillipa J. Malpas raises the question of why testing in childhood is not worthwhile, although the disclosure of genetic information without testing is recognized as being essential for children in order to make a decision about their own predictive testing in adulthood.[83] She believes that predictive testing that follows communicating a family history to a child is, in some cases, an extension of the disclosure process and is in the best interests of the child.[84] Genetic testing represents a natural step in case of well-to-do families where the children

[78] *Ibid.*
[79] Malpas, P. J. (2006). *Op. cit.*, p. 641.
[80] Clarke, A. J., & Wallgren-Pettersson, C. (2019). Ethics in Genetic Counselling. *Journal of community genetics*, *10*(1), 3–33, p 11.
[81] Borry, P., Evers-Kiebooms, G., Cornel, M. C., Clarke, A., Dierickx, K., & Public and Professional Policy Committee (PPPC) of the European Society of Human Genetics (ESHG) (2009). Genetic Testing in Asymptomatic Minors: Background Considerations Towards ESHG Recommendations. *European journal of human genetics: EJHG*, *17*(6), 711–719, p. 712.
[82] *Ibid.*, p. 714.
[83] Malpas, P. J. (2006). *Op. cit.*, pp. 641-642.
[84] *Ibid.*

are surrounded by a supportive environment, while it can be inexpedient in dysfunctional families.[85] In such cases, when the parents do not or cannot act in the best interests of the child, it is important to understand who has the responsibility to inform the children, so that the issue is not about whether to notify or not, but about when and under what conditions. Moreover, it is necessary that the child understands that such an option of predictive testing or access to information is available to them. This is crucial if in the future genetic testing will become part of routine clinical practice.

6.1.5. Obligation to future generation

Another matter that needs to be highlighted in the light of the discussion of family obligations is responsibilities to future generations. Since the future generation cannot be viewed as the subject of the right to be informed or the obligee to inform, it seems that the future generations are "left out" of all family relationships, including rights and obligations. We will not delve into the debate about the legal capacity of a fetus, as for the purposes of this chapter there is no practical interest in determining the status of the fetus and the following reflections will equally apply to all unborn children, planned, unplanned, conceived or not. Therefore, from a legal point of view, there should be no special questions about any rights or obligations since future generations are not considered subjects of the law. On the contrary, from a moral point of view, not everything is so simple.

Expanded access to genetic information, to which members of the genetic group should have the right, aims not only to protect their privacy, but also to provide them an opportunity of the most autonomous choice in decision-making, including medical ones. Nowadays, most hereditary diseases in children are considered a lottery played by nature, since no one is immune from the manifestation of certain mutations in a particular generation. On the contrary, it can be viewed as a result of people not being adequately informed about themselves. The case law that we reviewed in earlier chapters indicates that medical negligence claims in relation to genetic information often concern not only the violation of the plaintiffs' individual right to privacy and their autonomy, but also to some extent the issues of newborns or small children, including wrongful life and wrongful birth lawsuits.

[85] *Ibid.*

This is understandable, since many, if not all, will agree that it is a normal and natural desire, or wish, to bring a healthy child into this world to have a better life than the parents. People who have already been born with some conditions adapt over time if they survive, but hardly anyone deliberately plans for the child to suffer after being born. Surely, in this context, it is very important to understand what disability is. There are two main models that define disability – the medical model and the social mode. In broad terms, the medical model focuses on impairment as deviation from normal human functioning, and the social model, by contrast, regards the harm from having impairment through the social injustice. The latter model is more preferred when talking about disabilities. Thus, the United Nations Convention on the Rights of Persons with Disabilities opts for the social model, defining disability as "long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others".[86] However, it is not always easy to classify a condition as disability. For example, there is a long-standing dispute about deafness not being a disability, but rather a participation in a cultural and linguistic minority. This argument was used among others by Sharon Duchesneau and Candy McCullough, a deaf lesbian couple living in Washington D.C., who intentionally decided to have a deaf baby, by artificial insemination through a donor – a friend they knew to have come from five generations of inherited deafness.[87] Dissatisfied with the existing approaches to disability, Julian Savulescu and Guy Kahane offer original conception of disability that closely ties impairment with an individual's well-being relative to some given context.[88] Without intending to discriminate against people with disabilities in any way, we simply want to consider what possible obligations come with increased access to genetic information as a result of a truly joint account of genetic information.

Genetic technologies now provide us the possibility to override the outcome of this genetic lottery. There are currently few options of reproductive technologies available that aim to eliminate embryos that carry some genetic abnormalities, including sex preselection, prenatal genetic screening, *in vitro* fertilization, and preimplantation genetic diagnosis. The widely discussed gene editing technologies may one day be applied to the prenatal diagnosis.[89] For the time being, the

[86] United Nations. (2006). Convention on the Rights of Persons with Disabilities. *Treaty Series, 2515*, 3, Art. 1.
[87] Mundy, L. (2002, March 31). A World of Their Own. *The Washington Post.*
[88] Savulescu, J., & Kahane, G. (2011). Disability: A Welfarist Approach. *Clinical Ethics*, *6*(1), 45–51, p. 47.
[89] Wells, D., Vermeesch, J. R., & Simpson, J. L. (2019). Current Controversies in Prenatal Diagnosis 3: Gene Editing Should Replace Embryo Selection Following PGD. *Prenatal diagnosis*, *39*(5), 344–350, p. 344.

most commonly used organism for embryonic editing remains the mouse, and CRISPR technology is increasingly employed with high efficiency in other animals as well.[90] Scientists have already performed prenatal gene editing to prevent a lethal metabolic disorder in mice, demonstrating that prenatal treatment using CRISPR-Cas9 gene-editing tool can potentially open a door to human congenital disease prevention before birth.[91] However, editing of the human genome is largely banned by laws or regulations, even in those countries where human embryonic stem cell research is legal. In 2016, the Opinion Group of the Bioethics and Law Observatory of the University of Barcelona published the Document on Bioethics and Gene Editing in Humans, focusing on this genome modification technique.[92] In the wake of the launching of the document of the Bioethics and Law Observatory, European and American institutions also presented their recommendations regarding the use of human gene-editing technologies.[93] In 2018, the "Chinese CRISPR babies" scandal was followed by criminal charges against the research group, sending shock waves around the world.[94] This news provoked new discussions on humane gene editing and resulted in a temporary moratorium for it.[95] Scientists and ethicists expounded their concern about application of this technology in humans, stressing out the lack of safety and efficacy and exigency to prohibit any form of genetic enhancement.[96] Nevertheless, in 2019, the same year when the moratorium was called for, Russian researchers announced that they have started *in vitro* experiments to repair a gene that causes deafness using CRISPR.[97]

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[90] Alves-Bezerra, M., Furey, N., Johnson, C. G., & Bissig, K. D. (2019). Using CRISPR/Cas9 to Model Human Liver Disease. *JHEP reports: innovation in hepatology*, *1*(5), 392–402, p. 392.

[91] Rossidis, A. C., Stratigis, J. D., Chadwick, A. C., Hartman, H. A., Ahn, N. J., Li, H., Singh, K., Coons, B. E., Li, L., Lv, W., Zoltick, P. W., Alapati, D., Zacharias, W., Jain, R., Morrisey, E. E., Musunuru, K., & Peranteau, W. H. (2018). In Utero CRISPR-Mediated Therapeutic Editing of Metabolic Genes. *Nature medicine*, *24*(10), 1513–1518, p. 1513.

[92] Casado, M., & Santaló, J. (2016). *Document on bioethics and gene editing in humans.* Edicions de la Universitat de Barcelona. Retrieved May 9, 2021, from http://hdl.handle.net/2445/105022/

[93] de Lecuona, I., Casado, M., Marfany, G., Lopez Baroni, M., & Escarrabill, M. (2017). Gene Editing in Humans: Towards a Global and Inclusive Debate for Responsible Research. *The Yale journal of biology and medicine*, *90*(4), 673–681, p. 676.

[94] Cyranoski, D. (2020). What CRISPR-baby Prison Sentences Mean for Research. *Nature*, *577*(7789), 154–155, p. 155.

[95] Knoppers, B. M., & Kleiderman, E. (2019). Heritable Genome Editing: Who Speaks for "Future" Children? *The CRISPR Journal*, *2*(5), 285–292, p. 285.

[96] Lander, E. S., Baylis, F., Zhang, F., Charpentier, E., Berg, P., Bourgain, C., Friedrich, B., Joung, J. K., Li, J., Liu, D., Naldini, L., Nie, J. B., Qiu, R., Schoene-Seifert, B., Shao, F., Terry, S., Wei, W., & Winnacker, E. L. (2019). Adopt a Moratorium on Heritable Genome Editing. *Nature*, *567*(7747), 165–168, pp. 166-167.

[97] Cyranoski, D. (2019). Russian 'CRISPR-baby' Scientist Has Started Editing Genes in Human Eggs with Goal of Altering Deaf Gene. *Nature*, *574*(7779), 465–466, p. 465.

The ethical issues surrounding the application of gene-altering technology in humans are beyond the scope of our study. Regardless of whether it will be permitted, and most likely it will be if it really represents a solution to cure diseases that cause families to suffer for several generations, there are already available methods of prenatal intervention in the health of unborn children that require parenting decisions about the future generation.

In spite of the intuitive desire of parents to provide all the best for their children, children are at the same time perceived as a gift. Thus, Sandel emphasizes that parental love does not depend on the talents and qualities of the child, and parents do not choose their children, but value them for who they are, that is "not as objects of our design or products of our will or instruments of our ambition".[98] However, he acknowledges that to appreciate children as a gift does not mean "to be passive in the face of illness or disease".[99] Contrary to this idea, Savulescu and Kahane propose the principle of procreative beneficence (PB), according to which parents, who "decided to have a child, and selection is possible, […] have a significant moral reason to select the child, of the possible children they could have, whose life can be expected, in light of the relevant available information, to go best or at least not worse than any of the others".[100] At the same time, this principle is not absolute, but does not represent a mere permission to choose an advanced child. According to the PB principle, parents have a moral obligation to select the most advantageous child they could have, by not just promoting their health, but, if possible, by selecting more intelligent and more empathetic offspring. Rather than health alone, memory, sense of humor, temperament, patience and other qualities affect people's lives and should be manipulated on biological basis to give the child an opportunity for a better life.[101] However, this does not imply that the child is supposed to be perfect or superior to other people.[102] Savulescu chooses an instrumental approach to the value of health as a resource to maximize well-being,[103] the concept of which is based on nothing philosophically distinct but on ranking of goodness of life that people

[98] Sandel, M. J. (2007). *The Case Against Perfection: Ethics in the Age of Genetic Engineering*. Cambridge: Harvard University Press, p. 45.
[99] *Ibid.*, p. 46.
[100] Savulescu, J., & Kahane, G. (2009). The Moral Obligation to Create Children with the Best Chance of the Best Life. *Bioethics*, *23*(5), 274–290, p. 274.
[101] Savulescu, J. (2005). New Breeds of Humans: The Moral Obligation to Enhance. *Ethics, Law and Moral Philosophy of Reproductive Biomedicine*, *1*(1), 36–39, pp. 37-38.
[102] Savulescu, J., & Kahane, G. (2009). *Op. cit.*, p. 275.
[103] Savulescu, J. (2005). *Op. cit.*, p. 37.

employ in everyday context.[104] This way of thinking about health, argues Sandel, blurs the boundaries between healing a sick child and enhancing a healthy one.[105]

While the PB principle received some criticism due its possible implications for the ethics of reproductive choice,[106] the dilemma about special obligations to the future children can be analyzed in light of the rights of the child. The UNCRC recognizes the right of children to enjoy "the highest attainable standard of health" both before and after birth.[107] The guarantee of prenatal medical care, however, concerns more the future mothers than the unborn children themselves. The International Covenant on Economic, Social and Cultural Rights (ICESCR) sets out the steps to be taken in order to realize this right to "the highest attainable standard of health", including "the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child".[108] While the UNCRC is silent about biomedical research, the wording of Article 12 ICESCR implies that the standard of health will evolve over time in response to scientific and medical progress.[109] Thus, the right to health in general, and the right to health of the child is closely connected to the right to science, both the freedom of scientific research and the right to access its benefits.[110] The right to science was first recognized in the UDHR,[111] followed by the ICESCR[112] and, subsequently, by some other international statements and recommendations.[113] Interestingly, Bartha M. Knoppers and Erika Kleiderman pay attention to the fact that while the non-discriminatory nature of access to scientific achievements is emphasized, children are not mentioned in any of those relevant documents, even in relation to the progress directed to their health and welfare.[114]

[104] Savulescu, J., & Kahane, G. (2009). *Op. cit.*, p. 279.
[105] Sandel, M. J. (2007). *Op. cit.*, pp. 47-48.
[106] *E.g*., Parker, M. (2007). The Best Possible Child. *Journal of medical ethics*, *33*(5), 279–283.
[107] United Nations. (1989). Convention on the Rights of the Child. *Treaty Series*, *1577*, 3, Art. 24.
[108] United Nations General Assembly. (1966). International Covenant on Economic, Social, and Cultural Rights. *Treaty Series*, *993*, 3, Art. 12.
[109] Yamin, A. E. (2005). The Right to Health Under International Law and Its Relevance to the United States. *American Journal of Public Health*, *95*(7), 1156–1161, p. 1156.
[110] Knoppers, B. M., & Kleiderman, E. (2019). *Op. cit.*, p. 286.
[111] United Nations General Assembly. (1948). Universal declaration of human rights (217 [III] A), Art. 27(1).
[112] United Nations General Assembly. (1966). International Covenant on Economic, Social, and Cultural Rights. *Treaty Series*, *993*, 3, Art. 15(1).
[113] Knoppers, B. M., & Kleiderman, E. (2019). *Op. cit.*, p. 287.
[114] *Ibid.*

Typically, future generations and the rights of future generations are referred to in the context of two broad categories – environmental rights (sustainable development) and bioethical rights (protection of the human condition). The Oviedo Convention, in its preamble, affirms that "progress in biology and medicine should be used for the benefit of present and future generations".[115] The notion of protecting future generations was also embodied in the UNESCO Declaration on the Responsibility of the Present Generations Towards Future Generations[116] and the Universal Declaration on Bioethics and Human Rights.[117] However, granting rights to unborn children is associated with some practical and theoretical issues.

Addressing these problems, Axel Gosseries identifies four main challenges that the concept of future generation rights may face.[118] The first one is a non-existence challenge, that questions the possibility to ascribe rights to potential right holders who are not yet "present". Nevertheless, Gosseries admits that this challenge can be disposed of by defending the idea of future rights.[119] The second challenge is the non-identity problem, which is well-illustrated by wrongful life cases and which refers to the actions that affect the token-identity of who ends up being born.[120] This problem is quite serious and extends to available technologies of selection to eliminate postnatal suffering and sex preselection mentioned above.[121] However, prenatal therapy aiming to eliminate or correct defective genes to improve health can affect type-identity if the child is born healthy instead of sick, rather than token-identity. Thus, the non-identity issue does not concern all intergenerational relationships in health care. The two other challenges, namely the judicial actionability of future rights and the challenge of self-sanction, are more practical. The actionability in court have significant meaning for enforceability of rights and it can still be provided in case of overlapping generations, while both violator and victim coexist.[122] Finally, the

[115] Council of Europe. (1997). Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS 164), Preamble.
[116] United Nations Educational, Scientific and Cultural Organization. (1997). Declaration on the Responsibility of the Present Generations Towards Future Generations, Art. 1.
[117] United Nations Educational, Scientific and Cultural Organization. (2005). Universal Declaration on Bioethics and Human Rights, Art. 16.
[118] Gosseries, A. (2008). On Future Generations' Future Rights. *Journal of Political Philosophy*, *16*(4), 446–474, pp. 449-450.
[119] *Ibid.*, pp. 455-457.
[120] *Ibid.*, pp. 458-459.
[121] *Ibid.*, p. 460.
[122] *Ibid.*, pp. 464-465.

challenge of self-sanction arises from intergenerational dependency, when by sanctioning one generation the losses can burden the other one.[123]

Hence, the question of children's rights before birth raises many questions and certainly deserves a separate study. As human rights start with birth, the law protects interests of individuals who are already born. It is not surprising why, amid the growing acceptance of wrongful birth lawsuits, wrongful life lawsuits are still practically banned. Nevertheless, the law allows children, once they are born, to have their right that accrue *in utero* protected, such as inheritance or medical malpractice.[124] With regard to the latter, the courts rely on principle of fairness when recognizing the postnatal right "to begin life with a sound mind and body"[125] for persons who allege prenatal injuries.[126] Here, we can also recall the tragedy associated with Thalidomide, when the surviving victims received compensation for congenital malformations caused by the use of the drug in pregnant women. Yet, there is no right to be born healthy or without preventable or foreseeable genetic conditions.[127] That is, it is possible to file a claim against the physician or medical institution regarding harm the born child experiences, caused by negligent actions or omissions before birth, but at the same time there are absolutely no tools to protect against harm from intentional actions or omissions on the part of the parents.

Discarding the question of enhancement and focusing exclusively on prenatal gene therapy, provided that it is safe for both the mother and the child, and the process is able to get rid of the disease, it seems that the child is automatically deprived of the right to health, since if such diseases can be treated only before birth, then once the child is born the chance is lost forever. It can be inconsistent with the idea of a joint account of genetic information, which is promoted not only to better protect privacy, but also to maximize its use for health-related decisions for all blood relatives. If the knowledge about heredity cannot help to prevent and eliminate certain problems at least for the future generations, then, especially with the progress of science, the importance of genetic information will diminish. Each subsequent generation will be able to benefit from it to

[123] *Ibid.*, p. 469.
[124] Knoppers, B. M., & Kleiderman, E. (2019). *Op. cit.*, p. 289.
[125] Smith v. Brennan [31 N.J. 353, 364. 157 A.2d 497] (N.J. Sup. Ct. 1960).
[126] Capron, A. M. (1976). Legal Rights and Moral Rights. In J. M. Humber & R. F. Almeder (Eds.), *Biomedical Ethics and the Law* (pp. 375-397). New York: Plenum Press, p. 390.
[127] Knoppers, B. M., & Kleiderman, E. (2019). *Op. cit.*, p. 289.

the exact same extent as the previous one did, without any additional advantages, which contradicts the meaning of progress.

Although an unborn child is considered part of the mother, society, for example, condemns smoking and drinking during pregnancy not for reasons of how it may affect the woman herself, but for how it will affect the child inside her. Moreover, in some cases after birth, such behavior during pregnancy can even serve as an argument in the process of deprivation of parental rights. If it is morally wrong to worsen the condition of an unborn child, then doing nothing to improve it, given a realistic opportunity, is wrong as well. Considering that by the time of birth, the formation of the body is completed, it is inappropriate to measure birth as a starting point for the purposes of health care. Expanding access to genetic information aims to involve patients, including future parents, in the healthcare process and provide them with control over their health and the health of future children, shifting it away slightly from healthcare providers.

Since it is impossible to involve unborn children, like newborns and very small children, into the process of medical decision-making, we can assume that children possess "anticipatory autonomy rights" that are held in trust by their parents for them.[128] These rights are violated if a child is left with limited opportunities in life.[129] Joel Feinberg writes that "not all interests of the newborn child should or can qualify for prenatal legal protection" as government cannot spare everybody from bad luck, however "to be dealt severe mental retardation, congenital syphilis, blindness, deafness, advanced heroin addiction, permanent paralysis or incontinence, guaranteed malnutrition, and economic deprivation so far below a reasonable minimum as to be inescapably degrading and sordid", is not the same as to be unlucky.[130] According to Feinberg, parents who are aware of possible disabilities and who bring the child to the world anyway, would have morally harmed their child.[131]

[128] Feinberg, J. (1980). The Child's Right to an Open Future. In W. Aiken & H. LaFollette (Eds.), *Whose Child? Children's Rights, Parental Authority, and State Power* (pp. 124-153). Totowa, NJ: Rowman and Littlefield, pp. 124-126, as cited in Smolensky, K. R. (2008). Creating Children with Disabilities: Parental Tort Liability for Preimplantation Genetic Interventions. *Hastings Law Journal*, *60*(2), 299-345, p. 309.
[129] *Ibid.*
[130] Feinberg, J. (1984). *Harm to Others: The Moral Limits of The Criminal Law*. Oxford: Oxford University Press, p. 99.
[131] *Ibid.*, pp. 98-100.

The basis for legal claims of children against a parent is even more meager than for claims of wrongful life against physicians, and even the idea of such a claim seems, to some extent, strange and inappropriate. Yet, as far as it concerns the health, in terms of traditional and moral values, parents have an obligation to take into account the best interests of an unborn child as much as possible, including striving to ensure the highest attainable standard of health starting from before birth by making decisions based on the complete genetic information and prenatal diagnosis at their disposal. If a decision to have or not to have a child is made based on the principle of reproductive autonomy, the choice to have a sick or a healthy child goes far beyond that.

In this context, John A. Robertson has developed a potential framework for defining harm. According to his idea, there would be no interference with the parents' procreative liberty, if they are stopped from having a less than healthy child given the possibility of a healthy child, unless it is proven that "children born to such parents are in fact better off if they share the parents' disability".[132] This definition is relative, since it depends on the concept of health, which, like the concept of disability, is rather vague and unstable. In this context, it is more logical to make decisions based on medical concepts, rather than link these concepts to the participation in society, since the medical element of health can be easily measured for newborns, and the social element, like well-being, can only be established as time passes.

In any case, the long-standing debate over the rights of future generations, including in the context of biomedicine, shows that this issue is truly significant and requires solutions, especially in light of the incorporation of genetic technologies and diagnostics into medical practices. Cutting off future generations from the benefit of progress limits both their rights and the progress itself.

6.2. Professional duty

6.2.1. Open-ended duty of care

As the analysis of intra-familial obligations has shown, there are no convincing prerequisites for assigning the responsibility to disclose genetic information, including informing about genetic risks, to each of the members of the genetic group. While the legislations of the countries examined

[132] Robertson, J. A. (1994). *Children of Choice: Freedom and the New Reproductive Technologies.* Princeton: Princeton University Press, p. 171.

hesitate to specify who should be entrusted with the responsibility of informing at-risk relatives of the index patient, case law has been gradually determining the candidate for this mission by expanding the physician's duty, which was illustrated in the earlier chapters. According to the letter of the law, the main party responsible for informing family members is the patient himself/herself, but in practice the physician shoulders most of the trouble. However, the extension of the physician's obligation towards family members is unclear. The law occupies a so-called intermediate position, choosing respect for patient confidentiality as a general rule, in rare and special circumstances allowing the physician to ignore this indication, but does not impose a legal obligation on the physician, instead imposing an ethical one. Even if we accept this position that the patient is morally obliged to inform the family, which can take place in a circle of close relatives based on their intimate relations, it is very unlikely that the physician, among his other professional duties, has a duty to guarantee the patient's behavior to comply with moral standards.[133]

Earlier, considering the essence of medical malpractice, we also mentioned that one of the main elements for holding any healthcare worker liable is, depending on the jurisdiction, either existing contractual relationships or a violation of the duty of care, which does not greatly affect the structure of responsibility in health care. The duties that the physician's duty of care imposes under the law of tort are comparable to the duties that the physician must fulfill in relation to the patient under contract law. These responsibilities derive from an established standard of care that reflects the level of medical practice. Higher the level of medical technologies available in health care, the more people come to expect from physicians.[134] With a possibility to use genetics in diagnosis and treatment, people expect physicians to provide more precise treatments and diagnosis. The relatives of patients more often sue physicians in the U.S. and the UK, and the courts in these countries, considering the impact of genetic technologies on standard of care, are gradually extending the duty of care beyond the patient to his/her family. Thus, duty of care is constantly facing rising expectations not just in quality, but also in quantity.

With genetic testing and diagnostics becoming increasingly available as a part of standard medical practice, the courts have already included other addressees, aside from the patient, of physician's

[133] Grill, K., & Rosen, A. (2020). *Op. cit.*, p. 2.
[134] Howarth, D. (2006). Many Duties of Care – Or A Duty of Care? Notes from the Underground. *Oxford Journal of Legal Studies*, *26*(3), 449–472, p. 454.

professional duty. As it was manifested in case law, the courts also refer to the duty to warn the relatives of the patient justifying the breach of patient's confidentiality. As we have discussed, the duty to warn was first formulated in the *Tarasoff* case.[135] Duty to warn the patient about all material risks, alternative treatments, and all other information related to the process of treatment is one of the aspects of the duty of care. In Switzerland and Spain, legal documents advise physicians to convince patients to disclose genetic information to their affected relatives based on the principle of beneficence and non-maleficence wherein is rooted the duty to warn and, accordingly, the duty of care. Should the patient refuse to communicate information about possible serious damage, the law opts for an "interventionist" approach[136] that instructs physicians to inform a party of concern. However, this imposed duty is rather relative because the notion of serious damage is different for every person.

Generally, the duty of care and the duty to warn are assessed by courts in an attempt to balance the conflicting duties of the physician – the obligation of confidentiality towards the patient, and the duty of care to others. Nevertheless, keeping in mind our extended concept of genetic information, the question of conflicting obligations should not be at stake any more as the physician should no longer have any obligation of confidentiality to the patient alone regarding genetic information.

According to the traditional model of relations in health care, the rights and obligations of both the physician and the patient regarding each other follow from seeking medical care and providing it, that is, when the physician is in charge of the patient. When referring to what the physician owes to the patient, the term "duty" is usually used instead of "obligation", unlike when referring to special obligations between family members. That is because physician's duty is associated with the performance of tasks related to a specific occupation. However, when analyzing the differences between duty and obligations, the duty of care, in a legal sense, is a special obligation based on the physician's promise, manifested with oath, to care for the sick. Such a special obligation results from a promise and is directed towards a patient with whom the physician has a patient-physician relationship. From this point of view, the duty of care does not extend beyond the performance of professional duties. For example, if a physician or a nurse is at the scene of an accident and helps

[135] Tarasoff v. Regents of University of California [17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14] (Cal. 1976).
[136] Knoppers, B. M., & Kekesi-Lafrance, K. (2020). The Genetic Family as Patient? *The American Journal of Bioethics*, *20*(6), 77–80, pp. 77-78.

a victim, they always have an ethical and professional duty to assist[137] and, in some cases, might have a legal duty to rescue someone who needs help, but the duty of care does not arise in such a situation. For this reason, the legal duty of care has always been addressed to a specific existing patient.[138] The duty of care usually includes responsibilities of a treating physician towards the patients concerning medical process, such as monitoring, diagnosing, referring, treating, and instructing the patient.[139]

In addition to its legal definition, the duty of care can still be interpreted in a broader sense in terms of ethics, according to which physicians owe this duty to all people who can benefit from their professional skills. In this case, we are talking about duty in the same sense as it was defined by Hart, that is, what an individual owes to an indefinite circle of persons due to his/her abilities. In its broadest sense, the duty of care concerns every person living in society, imposing on him/her the obligation to act in relation to others with the vigilance, attention, caution, and discretion that a reasonable person would do in similar circumstances. In this case, it implies that individuals have a moral duty towards others.

The legal principle of duty of care was first established in 1932, when in the case of *Donoghue v. Stevenson*, a landmark decision for the modern law of negligence, Lord Atkin identified that there was a general duty to take reasonable care to avoid foreseeable injury to a neighbor.[140] A neighbor was defined as someone who may be reasonably contemplated as closely and directly affected by an act or an omission in question.[141] In *Donoghue v. Stevenson*, a woman drank a ginger beer that a friend of hers bought for her at a bar from a bottle until she found a decomposing snail at the bottom, causing her to become ill. Subsequently, she sued the manufacturer of this ginger beer. As a result, the manufacturer was found having breached a duty of care to her which it owed due to the reasonable foreseeability that failure to ensure the product's safety would lead to harm to consumers. It was reasonable to assume that anyone who drank the ginger beer would suffer the

[137] Dowie, I. (2017). Legal, Ethical and Professional Aspects of Duty of Care for Nurses. *Nursing Standard*, *32*(16-19), 47–52, p. 49.
[138] Torda, A. (2005). How Far Does a Doctor's "Duty of Care" Go? *Internal Medicine Journal*, 35(5), 295–296, p. 295.
[139] Davies, C. E., & Shaul, R. Z. (2009). Physicians' Legal Duty of Care and Legal Right to Refuse to Work During a Pandemic. *Canadian Medical Association Journal*, *182(*2), 167–170, p. 167.
[140] Donoghue v. Stevenson [1932] AC 562.
[141] *Ibid.*

same consequences, and therefore the case could be treated according to the "neighbor" principle. Moreover, the relationship between consumers and product manufacturers was declared sufficiently proximate. Thus, duty of care is not exclusive to medicine or health care and constitutes a part of a functioning society, as a lot of everyday activities such as driving a car or riding a bike require individuals engaging in these activities to ensure safety of others.

Comparing legal duty of care that has been established in healthcare practice and the duty of care from the abovementioned case, it is evident that the physician has a much narrower circle of individuals to whom the duty is owed, traditionally limited only by the patient. However, the case law shows a tendency towards expanding the scope of this duty. Starting to establish a duty of care or a duty to warn towards patient's relatives eventually can lead to creating an open-ended duty to any non-patient.[142] Obviously, a legal duty as such would be extremely disproportional and impossible to meet. However, nowadays there are more and more talks about implementing a family-centered approach into medical care. Adopting this approach might justify expansion of existing duty of care but within valid limits. If it is admissible, the issue is to analyze if the duty of care, including the duty to warn, can be legally extended based on the criteria set out in *Caparo Industries PLC v. Dickman* – reasonable foreseeability of harm, relational proximity between the physicians and each member of genetic family, and whether it would be fair, just, and reasonable to impose the liability.[143]

6.2.2. Family as a single patient

The concept of family-centered approach to medical practice is not new. The oldest example is the family doctor who practices family medicine and who is devoted to ensuring comprehensive and continuing health care for individuals and their close relatives. Usually, family doctors provide their services at the place of residence of family members, regardless of their age, gender, and type of the disease. Starting from the second half of XIX Century, the general practice was already predominant in both Europe and the U.S., and the particularly valuable aspect of that practice was the concept of house-visiting family doctors.[144] Even if we look back hundreds of years in the

[142] Parker, M., & Lucassen, A. (2018). Using a Genetic Test Result in the Care of Family Members: How Does the Duty of Confidentiality Apply? *European Journal of Human Genetics*, *26*(7), 955–959, p. 957.
[143] Caparo Industries PLC v. Dickman [1990] 2 AC 605.
[144] Loudon, I. (1984). The Concept of The Family Doctor. *Bulletin of the History of Medicine, 58*(3), 347-362, p. 347.

history of medicine, home-visiting physicians was a prototype of the modern healthcare system. Modern version of family medicine was reestablished in the U.S. and Europe in the second half of XX Century as a distinct form of general practice requiring special postgraduate training.[145]

However, the concept of family medicine is quite often confused with the idea of general medicine. The work of a family doctor is distinguished from the work of a general practitioner by such features as having a family-oriented approach, focusing on disease prevention and lifestyle, continuity of observation, and being in charge of a wider scope of medical care. As family doctors know their patients all their lives and follow up with them, this type of practice may be the most holistic.[146] Cooperation with family is an important element of family practice. As a rule, family doctors know family anamnesis, chronic diseases, peculiarities of their clinical course, medication history of every family member, and other information about illnesses. This knowledge helps to diagnose new health problems faster and to prescribe more personalized treatments. In this case, the family is not defined solely by blood relation, but coincide more with the social concept of family.

Similar to family doctors, geneticists, due to their specialization, have a close relationship with the index patient's family members. Even though relatives can accompany the patient to the physicians of other specializations, consultation with a geneticist may have direct relevance for relatives of the patient as well. For this reason, geneticists also tend to involve family members into consultations by explaining to the index patient the importance of their participation. Unlike family doctors, geneticists are more focused on biological relations between family members. However, patients can define who they regard as family members based on their wishes, ties, and background.[147] Participation of patient's relatives in the medical decision-making in genetic counselling is important not only because it may reveal health information about the relatives as well, but also because just like family medicine, genetic counselling aims to provide care for a

[145] Arya, N., Gibson, C., Ponka, D., Haq, C., Hansel, S., Dahlman, B., & Rouleau, K. (2017). Family Medicine Around the World: Overview by Region: The Besrour Papers: A Series on the State of Family Medicine in the World. *Canadian family physician Medecin de famille canadien*, *63*(6), 436–441, pp. 437-438.
[146] López-Roig, S., Pastor, M. Á., & Rodríguez, C. (2010). The Reputation and Professional Identity of Family Medicine Practice According to Medical Students: A Spanish Case Study. *Atención Primaria*, *42*(12), 591–601, p. 595.
[147] Gilbar, R., & Barnoy, S. (2018). Companions or Patients? The Impact of Family Presence in Genetic Consultations for Inherited Breast Cancer: Relational Autonomy in Practice. *Bioethics*, *32*(6), 378–387, p. 379.

patient within the context of family's support. Given the important role of the family, geneticists as well as other healthcare practitioners feel morally responsible towards their patients' relatives.[148]

Thus, family-centered model of health care is a health planning built on partnership in medical decision-making process between physician, patient, and patient's family,[149] where there is respect for strengths of each party and belief that optimal results can be achieved through physiological and social support. Potentially, treating family as a unit when providing medical care could even improve clinical outcomes and reduce costs.[150] When considering family as a whole in decision-making and treatment plans, it indirectly benefits the patient as well as the family getting necessary support as well.[151] This approach requires family members to participate in targeting the patient's needs and treatments as well as to address their own concerns and emotions about the disease. This model is based on appreciating family values, environment, culture, resources and what is important for a particular family.[152] Very often, the idea of family-centered care is mixed with patient-centered care.[153] The latter, in contrast to the paternalistic approach, focuses on individual autonomy of the patient in relation to any decision to be made and appeal to the quality of interaction between physician and patient.[154] The focus on family, on the contrary, moves beyond this two-way interaction by recognizing all family members as care recipients.[155]

Of all the medical areas, family-centered care is most associated with pediatric care. The main principles of family-centered healthcare are open, objective, and unbiased exchange of information, respect and honoring for diversity, including care preferences, collaboration of all involved parties,

[148] Dheensa, S., Fenwick, A., Shkedi-Rafid, S., Crawford, G., & Lucassen, A. (2015). *Op.* cit., p. 296.
[149] Kuo, D. Z., Houtrow, A. J., Arango, P., Kuhlthau, K. A., Simmons, J. M., & Neff, J. M. (2011). Family-Centered Care: Current Applications and Future Directions in Pediatric Health Care. *Maternal and Child Health Journal*, *16*(2), 297–305, p. 297.
[150] DiGioia, A. M., & Greenhouse, P. K. (2016). Creating Value with the Patient- and Family-Centered Care Methodology and Practice: What Trainees Need to Know, Why, and Strategies for Medical Education. *AMA journal of ethics*, *18*(1), 33–39, p. 34.
[151] Wittenberg, E., & Prosser, L. A. (2016). Health as a Family Affair. *New England Journal of Medicine*, *374*(19), 1804–1806, p. 1804.
[152] Selber, K., Hernandez, V. R., & Tijerina, M. (2006). Developing Family-Centered Models of Genetic Services. *Journal of Social Work in Disability & Rehabilitation*, *4*(4), 15–38, pp. 17-18.
[153] Kuo, D. Z., Houtrow, A. J., Arango, P., Kuhlthau, K. A., Simmons, J. M., & Neff, J. M. (2011). *Op. cit.*, p. 298.
[154] Epstein, R. M., Fiscella, K., Lesser, C. S., & Stange, K. C. (2010). Why The Nation Needs a Policy Push on Patient-Centered Health Care. *Health Affairs*, *29*(8), 1489–1495, p. 1489.
[155] Shields, L., Pratt, J., & Hunter, J. (2006). Family Centred Care: A Review of Qualitative Studie. *Journal of Clinical Nursing*, *15*(10), 1317–1323, p. 1317.

negotiation, reflection of the pediatric patient in the context of family, school, activities, and quality of life within the community.[156] In pediatrics, it is easier to adopt the idea that the family is the main resource of support for the sick child. However, this approach can be applicable to adult patients as well, especially in case of severe and life-threatening diseases, like cancer.[157] For cancer patients, the use of the Family Systems Illness (FSI) model has been proposed to understand the complex interactions between the patient and the family, emphasizing individual and family development and facilitating research about illness within the family.[158] This model addresses three dimensions – psychosocial category of the illness, time phases of the development of illness, and key family system variables.[159]

Family-centered care models are used in pediatrics and oncology and may also be applied in other diagnostic departments. Hereditary diseases unite a family not only emotionally, but physically as well, as another family member can be affected with the patient's diagnosed condition. The only difference is that in cases where patients are affected by conditions that are not due to genetics, the illness usually affects only the nuclear family.[160] Yet, in cases where patients are diagnosed with inherited diseases, it affects a larger circle of blood relatives. However, the existing similarities were sufficient for attempting to adapt FSI into the context of genetics.[161] Eventually, John S. Rolland and Janet K. Williams presented the Family Systems Genetic Illness (FSGI) to organize communication of genetic information within the family and to anticipate challenges that genetic family members might face.[162] According to this model, genetic conditions are categorized based on the likelihood of the condition to develop, the overall clinical severity, the timing of clinical onset in the life cycle, and the availability of effective therapeutic interventions to alter clinical onset or progression.[163]

[156] Kuo, D. Z., Houtrow, A. J., Arango, P., Kuhlthau, K. A., Simmons, J. M., & Neff, J. M. (2011). *Op. cit.*, p. 298.
[157] Daly, M. B. (2015). A Family-Centered Model for Sharing Genetic Risk. *The Journal of law, medicine & ethics: a journal of the American Society of Law, Medicine & Ethics*, *43*(3), 545–551, p. 545.
[158] *Ibid.*, p. 547.
[159] Rolland, J. S., & Williams, J. K. (2005). Toward a Biopsychosocial Model for 21st-Century Genetics. *Family Process*, *44*(1), 3–24, pp. 3-4.
[160] Daly, M. B. (2015). *Op. cit.*, p. 547.
[161] *Ibid.*
[162] Rolland, J. S., & Williams, J. K. (2005). *Op. cit.*, pp. 3-4.
[163] *Ibid.*, p. 7.

Now let us return once again to the current regulations governing the disclosure of genetic information to family relatives. In sum, the following options are available for the physician on how to communicate about genetic risks – the legal public health approach, the physician's own discretion, the approach depending on patient preference, and the approach based on the decision of ethics committee. The law does not mention any other duties toward the patient's biological relatives, other than to inform. Hence, the duty to warn can be satisfied once a relative of concern becomes aware about the hereditary nature of the disease. Both legislation and case law make the duty of care and the duty to warn coexist without crossing each other, reinforcing patient-centered approach, where, under special circumstances, the breach of patient's autonomy can be justified by another overweighing duty. This is, despite the prolonged efforts to bring together the patient and the family when dealing with genetic conditions, until recently, there were no attempts to take a step closer to family-centered care.

In the case of *ABC v. St. George's Healthcare NHS Trust* mentioned earlier, the judge adopted a relational approach to autonomy, which was developed by feminist and communitarian scholars.[164] According to this approach, an individual is perceived as a social being, who influences his/her significant ones and is influenced by them as well.[165] Catriona Mackenzie and Natalie Stoljar explain that "[relational] autonomy perspectives are premised on a shared conviction, the conviction that persons are socially embedded and that agents' identities are formed within the context of social relationships and shaped by a complex of intersecting social determinants, such as race, class, gender, and ethnicity".[166] The relational model presumes that a person's identity, interests, goals, and beliefs dynamically and continuously shape and reshape as a result of "dialogic process" with other people, history and traditions.[167] As long as an individual retains the

[164] Gilbar, R., & Foster, C. (2017). It's Arrived! Relational Autonomy Comes to Court: ABC v ST George's Healthcare NHS Trust [2017] EWCA 336. *Medical Law Review*, *26*(1), 125–133, p. 132.
[165] Donchin, A. (2000). Autonomy and Interdependence: Quandaries in Genetic Decision Making. In C. Mackenzie & N. Stoljar (Eds.), *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* (pp. 236–258). New York: Oxford University Press, p. 240.
[166] Mackenzie, C., & Stoljar, N. (2000). Introduction. In C. Mackenzie & N. Stoljar (Eds.), *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* (pp. 3–31). New York: Oxford University Press, p. 4.
[167] Walter, J. K., & Ross, L. F. (2014). Relational Autonomy: Moving Beyond the Limits of Isolated Individualism. *Pediatrics*, *133*(Suppl), S16–S23, p. S19.

ability to adequately reflect conditions that underline the decision, accept them, and believe that there are no obstacle to decide otherwise, this individual can be considered autonomous.[168]

The *ABC* case endorsed the relational aspect of autonomy with regards to genetic testing, because it acknowledges that when a person decides to undergo genetic testing, this decision has implications for his/her family as a unit.[169] However, the court applied this argument only to genetic medicine, unreasonably leaving aside all other healthcare domains.[170] Nevertheless, by replacing the existing definition of genetic information by the extended concept proposed in this study, the relation approach, following the *ABC* court, can be applicable to the majority of cases. The idea of relational autonomy is compatible with the model of family-centered health care, which, in some cases, is a lot more advantageous.

6.2.3. Impact on patient-physician relationship

Incorporation of family-centered approach into the medical system, regardless its advantages, is not an easy task and is associated with some challenges from the part of the physicians and from the part of the patient and the family. Primarily, the former is associated with the lack of organizational preparation, especially in terms of medical education. Medical education is not very eager to embrace the philosophy of family-centered health care, as evidenced by the relatively little attention paid to how physicians "can best meet the health care needs, goals, priorities, and preferences of patients and their families".[171] Medical training does not fully take into account the social environment of the patient as well as how the disease affects his/her daily life and financial well-being.[172]

In order to fill in this gap between reality and theory, it is important to change the culture of medical education to better integrate science into the patient care, in order to address the perspectives of the patient and his/her family.[173] As a result, lack of training can lead to barriers such as having an

[168] Christman, J. (2004). Relational Autonomy, Liberal Individualism, and the Social Constitution of Selves. *Philosophical Studies*, *117*(1/2), 143–164, p. 155.
[169] ABC v. St. George's Healthcare NHS Trust [2017] EWCA 336.
[170] Gilbar, R., & Foster, C. (2017). *Op. cit.*, p. 132.
[171] Weinberger, S. E., Johnson, B. H., & Ness, D. L. (2014). Patient- and Family-Centered Medical Education: The Next Revolution in Medical Education? *Annals of Internal Medicine*, *161*(1), 73-75, p. 73.
[172] *Ibid.*
[173] *Ibid.*, p. 74.

inappropriate work environment, lack of role models at workplaces and lack of guidelines and policies on family-centered care.[174] There can also be individual barriers for healthcare professionals to adhere to this model of medical care, among which stands out the lack of motivation and time, as well as absence of holistic view on care.[175]

To address the ethical challenges in health care that both patients and family members may face and to compensate for the shortage in literature about these issues, Hae Lin Cho et al. have conducted a few surveys in hospitals wherein patients and their relatives gave responses to open-ended questions about their experience with an ethical concern.[176] As the researchers note, most situations that raised concern in participants were associated with their family members, rather than with themselves.[177] Many individuals involved in this study had family-related tensions and disagreements in the process of making decisions either about their own treatment options, or in relation to another relative.[178]

Usually, patients bring their family members to consultation to have informational and emotional support, but in some cases it can turn out to be disadvantageous for the index patient as there can be "the imbalance of power in the patient–relative relationship where the relative is the dominant party in the consultation".[179] Moreover, there can be situations depending on the nature of intra-familial relationship, when patients are under substantial pressure and do not feel independent and autonomous.[180] Some patients were able to make decisions against their family members' wishes, but some respondents had to change their decisions about important procedures to accommodate relatives.[181] Aside from this issue within the family, there were other concerns, including those that were related to communication with the healthcare provider, access to healthcare, reproductive decisions, and genetic testing, etc.[182]

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[174] Kiwanuka, F., Shayan, S. J., & Tolulope, A. A. (2019). Barriers to Patient and Family-Centred Care in Adult Intensive Care Units: A Systematic Review. *Nursing open*, *6*(3), 676–684, p. 679.
[175] *Ibid.*
[176] Cho, H. L., Grady, C., Tarzian, A., Povar, G., Mangal, J., & Danis, M. (2020). Patient and Family Descriptions of Ethical Concerns. *The American journal of bioethics: AJOB*, *20*(6), 52–64, p. 52.
[177] *Ibid.*, p. 55.
[178] *Ibid.*
[179] Gilbar, R., & Barnoy, S. (2018). *Op. cit.*, p. 382.
[180] *Ibid.*
[181] Cho, H. L., Grady, C., Tarzian, A., Povar, G., Mangal, J., & Danis, M. (2020). *Op. cit.*, p. 55.
[182] *Ibid.*, pp. 57-61.

Another issue that deserves attention is that increased interaction between the physician and the family of the patient will involve asymptomatic or unaffected relatives being disclosed their unknown predispositions or even the possibility of a predisposition for their future children. This will change the current dichotomous social role of being sick, according to which people are categorized into two groups – sick or healthy.[183] With more knowledge about the hereditary picture of the family, it will be nearly impossible to characterize somebody as healthy, because red flags can be found in any family history. On the one hand, it might place more psychological burden on the recipient of the information, unless the physician helps this recipient to comprehend and process this kind of information. On the other hand, it could solve many problems of health status discrimination due to a large diversity of health statuses.

Patients are usually influenced to make correct decision through relational identity and being part of complex familial and other interpersonal relationships.[184] However, since there are a lot of unresolved problems within the patient-family-physicians triad, it is clear that "more work remains to be done to implement supportive, and respectful family-centered care in clinical practice and clinical ethics consultation".[185] Adopting the family-centered approach requires joint effort and education of physicians through the medical education system and patients through the process of informed consent. It is not enough to simply notify the relatives or to tell the patient. As the use of genetic information is incorporated into health care more, the relative will be expected to participate by hospital or home visits, which is justified from the point of view of genetic privacy.

When looking at genetic information in the sense we propose, not only genetic testing or genetic counselling, but a lot of other specializations of medical practice will have this aspect of "composite patient". It is necessary to shift the approach to the extent that it correctly engages patient's relatives into the process to better distribute medical services using genetic technologies. Family solidarity is more important than ever for preserving dignity and autonomy in health care.[186] Even though this approach might challenge the conventional bioethical patient-centered

[183] Parsons, T. (1951). Illness and the Role of the Physician: A Sociological Perspective. *American Journal of Orthopsychiatry*, *21*(3), 452–460, pp. 455-456.
[184] Cho, H. L., Grady, C., Tarzian, A., Povar, G., Mangal, J., & Danis, M. (2020). *Op. cit.*, p. 62.
[185] *Ibid.*
[186] Ho, A. (2008). Relational Autonomy or Undue Pressure? Family's Role in Medical Decision-Making. Scandinavian *Journal of Caring Sciences*, *22*(1), 128–135, p. 134.

perspective, it is no longer possible to consider only one individual as a patient.[187] Moreover, this approach would not be innovative if it is looked at in the historical context. Without changing the healthcare system from the inside, there is no practical benefit of the courts and the law imposing new duties on physicians.

6.2.4. Limits of professional liability

As we have demonstrated, it is plausible that the definition of patient can alter depending on the number of people in the physician's office or patient's house. We believe that the extension of duty of care, including the duty to warn, is possible only when there is a progress in incorporating family-centered care in medical practice. Otherwise, the duty has a rudimentary character and seems to be too burdensome or too uncertain for the physician in some cases.

According to the three-step test for legal duty mentioned above, the first element is the foreseeability, which aims to determine whether it was reasonable for an idealized agent to foresee that his/her actions or inactions would have caused negative repercussions for others.[188] In case of disclosing medical information, it concerns harmful ramifications of not informing. Under the family-centered approach, it is undoubtedly reasonable to expect the physician to take actions toward each family member participating in the treatment planning. With the two-way patient-physician relationship, the same model of accessing information that we used in relation to the right not to know can be used in such situations as well. That is, when it is a question of life and death or when a treatment is available to reduce or prevent a negative clinical outcome, it is reasonable to assume that the physician can envisage the harm. However, in other situations where the knowledge of genetic information can be crucial for one person and disruptive for another, does the physician always know enough about a person to understand whether knowing or not knowing will cause any harm? Probably, not.

The second element is proximity, which involves evaluating any previous or existing connections between a physician and a patient's relative.[189] When exercising the proximity test, the court must

[187] Gilbar, R., & Barnoy, S. (2018). *Op. cit.*, p. 385.
[188] Witting, C. (2005). Duty of Care: An Analytical Approach. *Oxford Journal of Legal Studies, 25*(1), 33-63, p. 36.
[189] *Ibid.*, p. 37.

find out whether the parties were close enough to be regarded as being in a legal relation.[190] In family-centered care, patient's relatives are in close contact with the physician. On the contrary, in the conventional patient-physician relationship, depending on the level of intimacy within the family, a lot of relatives can be out of the physician's reach and knowledge. If the same physician used to treat or is consulting any family member, the proximity is satisfied. However, in all other cases the test of proximity will probably fail.

Finally, the third element is how fair, just, and reasonable it would be to impose such a legal duty on the physician. Here, courts retain a lot of discretion in whether to recognize a duty as such, given the presence of two previous elements.[191] As for the relationship in family-centered care, in all cases this duty should be recognized. Nonetheless, when it comes to imposing duty of care to a physician towards the relatives of a patient with whom he had no previous patient-physician relationship independent from the relations with the index patient, in a lot of cases revelation of medical information that might concern them can cause more harm than benefit. Besides the fact that it might impede the physician's normal job performance, warning relatives without providing them other components of duty of care can put them in distress.

It is important to note that the family-centered approach is applicable if the patient and his/her family members are willing to participate together, and for this reason will be pertinent only when the patient agrees to involve family members, when family members want to be involved, when there are no drastic conflicts and disagreements on account of values, and most importantly, when the patient and the family are physically reachable in terms of time and distance. Even though we advocate for unlimited sharing of genetic information between blood relatives of concern, we emphasize the depersonalized nature of medically relevant genetic information, as it should contain only physical traits of interest without mentioning data about hair or eye color, and it should be depersonalized to be an object of genetic privacy. Family-centered approach will not be able to guarantee the second condition, as when family members are treated as a unit, there is not a lot of room for secrets. For this reason, generally close relatives, be it nuclear family or two, maximum three direct generations, would be willing to partake in joint health planning. This means that the rest of the genetic family are not, for obvious reason of absent intimacy relationship,

[190] *Ibid.*
[191] *Ibid.*

involved in planning and, as a result, are not guaranteed to have their right to access to health information respected.

It is unrealistic to demand the physician to reach out to a patient's relative of second and greater degrees of kinship. The physician's duty to warn is owed to a strictly limited circle of a patient's relatives – those who participate in joint care. Therefore, family-centered care can be regarded as a better format of healthcare in genetic diagnostics for those, who would notify the family or accompany them to the consultation in any case. It does not provide a universal all-purpose solution on how to share genetic information and how to secure the rights of distant biological relatives.

6.2.5. Duty to recontact: realistic or not?

Before providing our alternative model for informing the genetic family, we would like to highlight another question related to the disclosure of genetic information and relevant professional duties. With the development of technologies that are used in medicine, especially genetic diagnostics, there is a possibility that old results will be interpreted in another light.[192] For this reason, in literature, there is debate on whether the physician has a duty to recontact previous patients and their relatives. This potential duty is associated with issues such as what type of new information justifies recontacting, whether it is beneficial or not, what the views of the physician and patient are about it, to whom this duty to establish contact belongs, how to find a balance between conflicting obligations, what the practical instruments to exercise this duty are, and whether there should be liability, etc.[193] Given that the number of policies that address the question of recontacting is very limited and there is no professional consensus, these issues remain open.

In the U.S., the first document that mentioned the duty to recontact was the ACMG Policy Statement *"Duty to re-contact"* issued in 1999, which emphasized the responsibility of patients

[192] Giesbertz, N., van Harten, W. H., & Bredenoord, A. L. (2019). A Duty to Recontact in Genetics: Context Matters. *Nature reviews. Genetics*, *20*(7), 371–372, p. 371.
[193] Otten, E., Plantinga, M., Birnie, E., Verkerk, M. A., Lucassen, A. M., Ranchor, A. V., & Van Langen, I. M. (2014). Is There a Duty to Recontact in Light of New Genetic Technologies? A Systematic Review of the Literature. *Genetics in Medicine*, *17*(8), 668–678, p. 668.

and primary care physicians to re-establish contact with clinical genetics departments.[194] Two decades later, the ACMG underlined the necessity to delineate all aspect of recontacting in the process of informed consent procedure and stated that recontacting "is fundamentally a shared responsibility among the ordering health-care provider, the clinical testing laboratory, and the patient".[195] In Europe, the first guidelines appeared in 2015, wherein EuroGentest and the European Society of Human Genetics emitted that the laboratories should share responsibility for initialization of recontact, if over time reinterpretation of variants occurs.[196] Both American and European guidelines admit that there is a need to elaborate databases and mechanisms, that would allow laboratories to update changes and identify affected patients.[197]

Both healthcare professionals and patients recognize the importance of recontacting.[198] From the patient's perspective, some patients prefer to be updated albeit the cost of this not being addressed, while others prefer not to learn anything new about their past problems.[199] Support for patient's interest to be recontacted can be found in human rights instruments and bioethics.[200] The right to privacy, especially informational privacy and right to self-determination, the principles of autonomy and beneficence form a solid basis for this duty. At the same time, informational privacy, which covers the right not to know, and the principle of non-maleficence prevent healthcare professionals from re-initiating communication with the patient.[201] According to a data analysis, most physicians who participated in a survey on recontacting of patients considered "recontacting

[194] Hirschhorn, K., Fleisher, L. D., Godmilow, L., Howell, R. R., Lebel, R. R., McCabe, E. R., McGinniss, M. J., Milunsky, A., Pelias, M. Z., Pyeritz, R. E., Sujansky, E., Thompson, B. H., & Zinberg, R. E. (1999). Duty to Re-Contact. *Genetics in medicine: official journal of the American College of Medical Genetics*, *1*(4), 171–172, p. 171.
[195] David, K. L., Best, R. G., Brenman, L. M., Bush, L., Deignan, J. L., Flannery, D., Hoffman, J. D., Holm, I., Miller, D. T., O'Leary, J., Pyeritz, R. E., & ACMG Social Ethical Legal Issues Committee (2019). Patient Re-contact After Revision of Genomic Test Results: Points to Consider – A Statement of the American College of Medical Genetics and Genomics (ACMG). *Genetics in medicine: official journal of the American College of Medical Genetics*, *21*(4), 769–771, p. 769.
[196] Matthijs, G., Souche, E., Alders, M., Corveleyn, A., Eck, S., Feenstra, I., Race, V., Sistermans, E., Sturm, M., Weiss, M., Yntema, H., Bakker, E., Scheffer, H., Bauer, P., EuroGentest, & European Society of Human Genetics (2016). Guidelines for Diagnostic Next-Generation Sequencing. *European journal of human genetics: EJHG*, *24*(1), 2–5, p. 5.
[197] Ploem, C., Mitchell, C., van Harten, W., & Gevers, S. (2018). A Duty to Recontact in the Context of Genetics: Futuristic or Realistic? *European Journal of Health Law*, *25*(5), 537-553, pp. 543-544.
[198] Otten, E., Plantinga, M., Birnie, E., Verkerk, M. A., Lucassen, A. M., Ranchor, A. V., & Van Langen, I. M. (2014). *Op. cit.*, p. 677.
[199] Pyeritz, R. E. (2011). The Coming Explosion in Genetic Testing — Is There a Duty to Recontact? *New England Journal of Medicine*, *365*(15), 1367–1369, p. 1368.
[200] Ploem, C., Mitchell, C., van Harten, W., & Gevers, S. (2018). *Op. cit.*, pp. 544-546.
[201] Giesbertz, N., van Harten, W. H., & Bredenoord, A. L. (2019). *Op. cit.*, p. 371.

patients an ethically desirable, but not feasible, goal".[202] Some scholars propose to consider the duty to recontact "a *prima facie* moral duty rather than an absolute one".[203] With prevailing uncertainty of any possible liability for not recontacting, there is no ground to impose a legal duty on physicians, who do not, at least for now, possess sufficient resources to fulfill this duty. With rethinking genetic privacy, the idea of duty to recontact can enter a new stage of development due to the different status of genetic information. For this reason, we will analyze this duty together with the duty of care and duty to warn in light of our alternative proposal in the next chapter.

6.3. Interim conclusion

Over time, legislation and jurisprudence have established a kind of dualistic approach to the obligation to inform relatives about genetic information that are at risk. On the one hand, this is sometimes seen as a moral obligation of the patient towards his/her family. On the other hand, the legal norms and the court's decision ascribe the physicians with a moral or legal obligation, respectively, to warn the patient's relatives. Having considered the grounds for inter-familial and professional obligations, it is fair to conclude that none of these models fully meet the needs of biological relatives, who, in our opinion, have the right to access the full extent of information about their health.

Undoubtedly, relatives have both moral and legal obligations towards each other. The bulk of the relationship between relatives is governed by moral norms and is based on the nature of the interaction between them. Thus, intimacy is seen as a justifying factor for the existence of moral obligations between relatives, including the obligation to notify about the health risks. However, such close relationships usually develop between a limited number of relatives compared to the whole circle of relevant genetic relatives. Therefore, this approach leaves most of the genetic relatives without any prospect of receiving any information. If we consider genetic relatives as a group, and not as a family, then their voluntary participation in the production of the common good also generates certain rights and obligations between participants. However, such rights and obligations relate specifically to the process of producing and protecting their joint good – genetic

[202] Fitzpatrick, J. L., Hahn, C., Costa, T., & Huggins, M. J. (1999). The Duty to Recontact: Attitudes of Genetics Service Providers. *American journal of human genetics*, *64*(3), 852–860, p. 852.
[203] Giesbertz, N., van Harten, W. H., & Bredenoord, A. L. (2019). *Op. cit.*, p. 372.

information and genetic privacy. At the same time, the right to access health information is an individual right that goes beyond group privacy. For this reason, the approach where the patient is tasked with notifying relatives of interest is not a universal solution to guarantee the right to access genetic information.

As far as professional responsibility is concerned, attempts to expand the duty of care also turned out to face some serious challenge. This extended duty is more practical for a healthcare system that is designed for the family rather than for a single patient. Certainly, a departure from the established approach will entail some changes to the relationship between physicians and patients. It also can affect who should be considered a patient. For more effective implementation, it is necessary to change the approach to care through medical education and the informed consent process. Although, in most other cases, imposing an extended duty of care on the physician will be either ineffective or unbearable. Therefore, in order to maximize the guarantee of the patient rights of the rights of his/her family, we believe that a third approach is needed.

7. SOLUTIONS AND QUESTIONS

7.1. Alternative approach

7.1.1. Disclosure system model

What might be an alternative model to balance and protect the interests of patients, families, and physicians in terms of circulation of health-related genetic information? The ideal scheme should be able to make available familial genetic information to all members of a genetic group. The creators of the joint account model of genetic information, Parker and Lucassen, have mentioned that their preferred model would be the one where "familial genetic information was available for the care of family members in situations where it has a significant potential for health benefit".[1] According to the model they propose, the information about an index patient's health status should be kept confidential while clinically useful information about hereditary predisposition obtained through genetic testing should be available to healthcare professionals for use in diagnosis and treatment of the index patient's family members.[2] In the context of disclosing information, they have introduced a "response mode" approach "in which familial genetic information would be available for use by professionals in situations where family members have approached health services because of a concern about an inherited condition".[3]

Parker and Lucassen show how the model would work by using an example of a patient who, knowing vaguely about her family history of early-onset breast cancer in distant relatives, was worried about developing this condition.[4] The patient also knows that to receive an accurate result from testing, it is necessary to determine the particular predisposing mutation that run in the patient's family. Thus, the patient consulted the physician who happened to provide care to patient's family members and was aware of the disease-predisposition mutation in this patient's family. This information was found from the patient's aunt who was a patient of the same physician and who did not want to share her genetic information with the rest of the family. When applying the "response mode" approach to the physician's professional dilemma of whether to communicate the details of the mutation to the patient or preserve confidence of patient's aunt, Parker and

[1] Parker, M., & Lucassen, A. (2018). *Op. cit*., p. 957.
[2] *Ibid.*
[3] *Ibid*., p. 958.
[4] *Ibid.*, p. 955.

Lucassen propose that the physician could offer the patient a predictive genetic test without disclosing to the patient the identity of her aunt, what would fulfill the physician's duty toward at-risk relatives.[5] This means that there is no further duty to seek out other family members of the patient who might be interested in such information.[6]

The idea to put familial genetic information at the disposal of healthcare professionals seems to be the most logical approach to the balanced use of shared information. The research on patient's views on confidentiality and sharing of genetic information suggests that while healthcare professionals have certain difficulties with sharing genetic information, patients would want it to be available to health services and be shared as part of standard practice.[7] This approach can guarantee that the confidentiality of each family member is respected, and at the same time, the relatives can have access to their familial health information. Alluding once again to the analogy with the bank, such a system provides that the responsibilities of the bank are assigned to the healthcare system. The physicians, who appear to be like employees of a bank branch or even ATMs, take on the responsibility of disclosing relevant genetic information to their patient's at-risk family members. Based on the idea of a "response mode" approach, the relatives themselves should take actions to request any information at the disposal of physicians that could be of interest to them. Thus, the healthcare system in general and healthcare professionals in particular are a kind of filter that outlines the boundaries where individual privacy ends and group privacy begins in the context of genetics and health care.

However, Parker and Lucassen have not discussed practical ways of implementing their approach[8] to facilitate the exchange of genetic information between members of a biological family. Their example illustrates the situation where the physician had patient-physicians relationship with both relatives – the index patient, who appeared to be a source of important familial genetic information, and the relative who could benefit from that information. As we have accentuated before, most issues of sharing genetic information are associated with those situations where family members

[5] *Ibid*., p. 958.
[6] *Ibid.*
[7] Dheensa, S., Fenwick, A., & Lucassen, A. (2016). "Is This Knowledge Mine and Nobody Else's? I Don't Feel That." Patient Views About Consent, Confidentiality and Information-Sharing in Genetic Medicine. *Journal of Medical Ethics*, *42*(3), 174–179, pp. 177-178.
[8] Parker, M., & Lucassen, A. (2018). *Op. cit*., p. 958.

are seen by different healthcare professionals who do not know about other family members or normally do not have access to the medical charts of those family members. For example, what would happen if Parker's and Lucassen's patient went to another physician who had not known her aunt and, therefore, could not have known about the details of the predisposing mutation?

Considering that our concept of genetic privacy is slightly more extensive than the joint account model, we propose our so-called "open-access-family-history model". The term "open" means that genetic information is unlocked to each member of a certain genetic group and to all healthcare professionals who provide them medical services. This approach is to address all cases of sharing genetic information, including those where family medicine or extended duty of care cannot provide answers. The model intertwines with the abovementioned idea of Parker and Lucassen to the extent where health-related genetic information should be accessible for physicians for use to provide care to all relatives. Nevertheless, the communication of genetic information should not entirely depend on the initiatives of an individual, unlike it is suggested in the "response mode" approach. In our opinion, access to genetic information gives a unique opportunity to elevate patients' participation and cooperation in health care as well as to engage them in the decision-making process about their own health, which does not mean to reduce physicians' involvement in the process of care.

Our definition of genetic information refers to what physicians of all specializations call family medical history or family anamnesis. Family medical history is a record of relationships between family members along with their medical history, which includes current and past illnesses and draws a picture of patterns of certain illnesses in the family.[9] Collecting medical history is considered an essential and mandatory part of the primary care appointment. For a very long time in the history of medicine, especially in absence of modern diagnostic tests, it was the most important source of information about a patient.

[9] National Cancer Institute. (n.d.). *NCI Dictionary of Cancer Terms:* family medical history. Retrieved May 28, 2021, from https://www.cancer.gov/publications/dictionaries/cancer-terms/def/family-medical-history/

Referring to ancient times, the Ebers Papyrus, a compilation of Egyptian medical texts dating back to ca. 1500 B.C., mentioned family history to be a helpful diagnostic tool.[10] Much later, in 1842, the surgeon Henry Ancell mentioned the importance of family history when first describing multiple cylindroma – a tumorous condition of the skin that can be passed down in a hereditary manner.[11] Sometimes, for those diseases that are not known to be inheritable, physicians can notice a pattern in family history. Thus, idiopathic scoliosis (IS), the most common type of scoliosis, the definite cause of which is still unknown, has always been considered independent from genetic predispositions until the attempt to identify the genes responsible for the development of IS became the prerogative of last decades. Since the hereditary factors in the etiology of IS were reported in 1934,[12] a vast amount of relevant genetic studies was conducted.[13] This testifies to the fact that a lot more conditions run in family. Therefore, a complete anamnesis of a whole genetic family backed up with the results of genetic testing can potentially represent the most powerful tool in providing more accurate diagnosis and treatment.

Interestingly, patients are always told to collect family anamnesis themselves before coming to their appointments with healthcare practitioners. People are usually advised to speak to close relatives of up to three generations and three degrees of kinship, to ask questions about their previous or ongoing conditions, symptoms, and the age when the condition was initially diagnosed, to record this information, including through web-based tools,[14] and to bring the gathered details with them to the medical appointment, even if incomplete.[15] Some clinics publish guidelines for patients on how to collect family medical history, including sample questions such as sex, date of birth, ethnicity, mental health conditions, including alcoholism and substance abuse, pregnancy complications, including miscarriage, stillbirth, birth defects or infertility, lifestyle habits,

[10] Tiffon Nonis, B.-N. (2009). El informe pericial psicopatológico. En B.-N. Tiffon Nonis (Ed.), *Manual de actuación profesional en psicopatología clínica, criminal y forense: Una dimensión jurídico-legal* (pp. 49–67). Barcelona: J.M. Bosch Editor, p. 50.
[11] Ancell, H. (1842). History of a Remarkable Case of Tumours, Developed on the Head and Face; Accompanied With a Similar Disease in the Abdomen. *Medico-chirurgical transactions*, *25*, 227–246, 306-9-306-11, p. 230.
[12] Garland, H. G. (1934). Hereditary Scoliosis. *British medical journal*, *1*(3816), 328-328, p. 328.
[13] Grauers, A., Einarsdottir, E., & Gerdhem, P. (2016). Genetics and Pathogenesis of Idiopathic Scoliosis. *Scoliosis and spinal disorders*, *11*(1), 45, pp. 2-5. https://doi.org/10.1186/s13013-016-0105-8/
[14] Centers for Disease Control and Prevention. (2020). *My Family Health Portrait: A tool from the Surgeon General*. Retrieved May 28, 2021, from https://phgkb.cdc.gov/FHH/html/index.html/
[15] Centers for Disease Control and Prevention. (2020). *Knowing is not enough – Act on your family health history*. Retrieved May 28, 2021, from https://www.cdc.gov/genomics/famhistory/knowing_not_enough.htm/

including diet, exercise and tobacco use, etc.[16] They also give some tips on how and where to find health-related information, such as old books and public records, and strategies on how to communicate with relatives if the patient encounters reluctance from the family, like face-to-face conversations and short questions that go straight to the point.[17] It is also possible to find templates to use to fill in the details about health information obtained from family members and to return them to the physician before the next visit.[18]

Comparing this approach with the current approach to patient privacy and the autonomy of patient's family members with regard to genetic information, it follows that there is a certain discrepancy in appreciating privacy and autonomy within the walls of the hospital and outside of them, especially in the U.S. The impression is that the advice to patients to collect family history before a medical appointment has greater weight, particularly when it is suggested to access family archives that belong to the whole family and not only to the patient himself/herself, than the recommendations to share newly discovered genetic information with the rest of the family. Some of the details an individual brings to the hospital as part of family health history might be available to his/her knowledge not because the affected members had a choice to tell or not about their conditions, but since it is more difficult to keep the secrets at home.

Despite the importance of family anamnesis, it seems that the approach unanimously chosen by healthcare systems, where it is up to the patient to retrieve the family anamnesis, does not ensure the correct use of familial information. Practically, this approach has the same weaknesses as the idea of obliging the index patient to notify his/her relatives about possible genetic risks.

First, it is the lack of choice and the conflict between the unwillingness of relatives to reveal the details of their personal health and the desire to help their loved ones to receive better medical care. When conversations about health occur within the family, it is not possible to divide health information into personal and familial as there is no capacity to eliminate personal identifiers. In some families having a warm and intimate relationship, there might be no problem. However,

[16] *E.g.*, Mayo Clinic. (2019). *Medical history: Compiling your medical family tree*. Retrieved May 28, 2021, from https://www.mayoclinic.org/healthy-lifestyle/adult-health/in-depth/medical-history/art-20044961/
[17] *Ibid.*
[18] American Medical Association. (2018). *Adult Family History Form* (PDF). Retrieved May 28, 2021, from https://www.ama-assn.org/system/files/2018-10/adult_history.pdf/

some people consider being sick shameful or a manifestation of weakness, and regardless of the quality of the relationship with the rest of the family, they might also prefer not to go into details or might still proceed at the cost of personal suffering. For example, men are less willing to seek medical help and are less likely to discuss their health problems with friends, family, or medical professionals.[19] It is even more difficult to collect acceptable family anamnesis when it concerns more distant relatives. Second, neither family members who provide an account of family history, nor the patient of interest possess an adequate level of medical knowledge to convey or receive and record, respectively, the information. Misunderstanding, personal judgment or even medical errors in their past treatments and diagnosis, threaten the veracity of compiled data. Thus, the process of collecting family medical history is more likely to resemble the "Chinese whispers" or "Telephone" game, since the information that reaches the physician of a certain patient may no longer coincide with the real health status of the patient's relative. Third, aside from psychological difficulties associated with sharing personal information, time between generations and distance may prove to be obstacles that complicate or make impossible the access to family history. Finally, cases of adoption or donor insemination can jeopardize the integrity and relevance of familial information.

As we can see, collecting family anamnesis and sharing genetic information between relatives face the exact same issues. However, these two processes are still divided in theory and practice. For this reason, we believe that creating a shared medical database of familial genetic information, which would also represent a possibility to access the most complete and correct family medical history record for every patient, would be a solution. This open-access-family-history model can resolve the existing practical, ethical, and potential legal problems associated with the conflicting rights and obligations of patients, their relatives, and physicians.

To incorporate this model to the healthcare system, it would be necessary to build an electronic network that connects all medical institutions, public or private, in a designated area – be it a city, region, country, and, ideally, worldwide. The database accessible through the network should be two-tiered, where the first level is a database of personal records, which can include patient's personal data, and the second level is a database of family records, wherein the information should

[19] Banks, I. (2001). No Man's Land: Men, Illness, and the NHS. *British Medical Journal (Clinical Research Edition)*, *323*(7320), 1058–1060, pp. 1058-1059.

be depersonalized. Depersonalization should be exercised in such a way that it prevents the identity of relatives from being disclosed without impeding the interpretation and evaluation of familial genetic information for the needs of other relatives. This kind of database requires constant update of the information and of the register of the patient, which is not difficult to maintain as majority of people see a healthcare professional at least once in their lives, be it in childhood or older age.

In the context of data protection, it is important to distinguish two processes – anonymization and pseudonymization of information. Anonymization is an irreversible data sanitization technique which eliminates personal identifiers so that the subjects can no longer be identified by those who work with the information. For example, the GDPR mentions among such identifiers name, identification number, and one or more factors specific to the physical, physiological, genetic, mental, or social identity of a person, etc.[20] According to Recital 26 of the GDPR, anonymized data does not fall under protection of personal information.[21] Pseudonymization replaces personal identifiers with nonidentifying references or keys such that those who work with or use the information cannot connect it with its source without these references and keys. This can be achieved by using identifying references or keys. The GDPR specifies that personal information that underwent pseudonymization and can be attributed to a person with help of additional information is still considered "information on an identifiable natural person".[22] Therefore, pseudonymized information falls under the GDPR's coverage. The GDPR does not draw a line between personal information and genetic information, for this reason it is not entirely suitable for protection of genetic privacy. Special attention to possibly required changes to regulations to provide adequate level of protection will be discussed in the next chapters.

The information in family records should not contain personal identifiers, however, it cannot be irreversibly anonymized as it might jeopardize the quality and accuracy of family history for the rest of family members. For practical reasons of delimiting the volume of relevant genetic information for a particular individual, it might be important to understand in which generation a disease or a mutation was detected. Otherwise, it will be impossible to filter the data based on

[20] Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), Art. 4 (1).
[21] *Ibid.*, Recital 26.
[22] *Ibid.*

generational relevance which will lead to overloading the family record. Thus, pseudonymization would be more suitable for protecting personal privacy in the context of genetics. However, healthcare professionals and patients should not be able to identify the index patient who is the source of a certain piece of information. This function should be embedded in the program algorithm for automated generation of family history record for each new patient. Possibly, if there is an urgent need and should the family record be insufficient, in order to gain access to a personal record of one of the members of the genetic family to provide medical care necessary to another family member, the conflict of interest can be resolved according to the existing approach that justifies the breach of one's individual right in the presence of a prevailing right of another person. This kind of access can be granted in such situation only to the treating physician without providing the patient with personal information of his/her family members.

The open-access-family-history model would require that both tiers of medical records, personal and family, are created for everyone starting from birth. The idea of lifelong personal health records (PHR) is not new.[23] Unlike EHR, PHR are intended for storing all medical information, which is related to a particular person and collected throughout life, independently of healthcare providers who created the document.[24] Thus, traditional EHR are institution-specific documents that each healthcare provider keeps for itself. It means that any given patient has records, as many as the number of hospitals or clinics he/she ever visited. The main point of the PHR system is to generate one record per patient, regardless of the number of different medical facilities he/she might visit. While EHR are limited to the time frame of patient-physician relationship, PHR last for life.[25] Developing a PHR system on a national level is an important instrument for implementation of our model. In the context of genetic information, these records will acquire the nine generations-long character. Nowadays, PHR used in Europe and the U.S. are examples of systems developed by medical facilities, by companies specialized in health information and

[23] van der Westhuizen, & E., Pottas, D. (2010) Towards Characteristics of Lifelong Health Records. In H. Takeda (Ed.), *E-Health. E-Health 2010* (pp. 61-70). IFIP Advances in Information and Communication Technology, vol. 335. Berlin: Springer.
[24] Barbarito, F., Pinciroli, F., Barone, A., Pizzo, F., Ranza, R., Mason, J., Mazzola, L., Bonacina, S., & Marceglia, S. (2015). Implementing the Lifelong Personal Health Record in a Regionalised Health Information System: The Case of Lombardy, Italy. *Computers in biology and medicine*, *59*, 164–174, p. 164.
[25] *Ibid.*

communication technologies, by governments, as well as by large companies such as Google and Microsoft.[26] Nevertheless, most countries have not switched fully to this kind of system.

Such two-tier records should be also available for adopted children and for children born from donors. For the latter, the records can be made available by linking the donated gametes with a reference key code to personal and familial health records. In this way, personal privacy of the donor remains protected while the child can enjoy the access to genetic information. In case of adoption, for those children who are born in medical facilities, it should not be complicated to create health records based on the mother as reference, even if the father is absent or unknown. This will provide at least half of the family records. Should both parents be unknown, it might be more difficult to connect the child to the family health records. An alternative would be to use the DNA ancestry search within the healthcare database. Earlier, we mentioned the direct-to-consumer test services that private companies provide to clients who want to know more about themselves and map out their family pedigree. In the public sector, DNA databases are widely used for forensic identification purposes to find correspondence between samples, to individualize the suspect, or to establish kinship.[27] For example, cooperation in exchange of DNA profiles between the EU countries that started in 2005 allowed Spain to generate more than nine thousand coincidences of crimes from other countries and identified more than eight thousand profiles linked with unsolved crimes in internal searches.[28] Unlike DTC-GT companies, forensic databases are limited to a lower number of markers, that reduces power of tracing to close relatives.[29] Besides these ways of genetic identification, some countries are already discussing the possibility of implementing genetic passports for citizens.[30] Genetic passport database is supposed to operate only with non-coding DNA to identify a specific person, without physiological, morphological, hereditary characteristics.[31] Thus, it can possibly supplement the health record system, providing a possibility

[26] *Ibid.*, p. 165.
[27] Crespillo-Márquez, M., López-Reyes, E., & Alonso-Alonso, A. (2020). Organization and Operation of the Spanish DNA Database. *Spanish Journal of Legal Medicine*, *46*(2), 45–48, p. 45.
[28] *Ibid.*, p. 46.
[29] Clayton, E. W., Evans, B. J., Hazel, J. W., & Rothstein, M. A. (2019). The Law of Genetic Privacy: Applications, Implications, and Limitations. *Journal of law and the biosciences*, *6*(1), 1–36, p. 28.
[30] *E.g.*, Kornienko, I., Faleeva, T., Rakuts, V., Ivanov, I., & Sidorenko, U. S. (2018). Prospects of Genetic Passport System in the Russian Federation. In A. Troitsky & L. Rusin (Eds.), *Molecular Phylogenetics: Contributions to the 5th Moscow International Conference "Molecular Phylogenetics and Biodiversity Biobanking" (Moscow, Russia, August 25—28, 2018)* (pp. 77-78). Moscow: TORUS PRESS.
[31] Rassolov, I. M, Chubukova, S. G., & Shagieva, R. V. (2020). Legal Problems of Forming Genetic Information Banks in Russia. *Eurasian Journal of Biosciences*, *14*(2), 3427-3432, p. 3428.

for each person to have a full access to his/her health information, regardless of whether the biological family is known or not. Yet, this topic is beyond the scope of our research and deserves a separate and extensive study.

Returning to the structure of the health record, both tiers of health records can be accessible from any registered national, or even foreign medical institutions. Clearly, it is a lot easier to build such a structure within the same legal system. To make it work worldwide might be impossible, however, it is quite feasible to achieve some positive results through bilateral and multilateral international agreements, or regional cooperation, especially in the European Union. The access to the first level can be granted to all physicians who are treating the same patient, whereas the second level can be accessible by any healthcare professional who is proving services to any member of a particular genetic group. This could help reduce the scattering of medical records of a given patient as different physicians in different medical institutions access it. At the same time, unified family records could allow use of relevant familial genetic information not only for diagnosis, but at every step of medical treatment for each family member. Thus, while family records would be used to provide care for each member of the genetic family, it is automatically updated by all those physicians who are treating or just assessing the state of health of biological relatives during routine check-ups. This mechanism ensures joint participation in producing the group's good and distribution of related benefits between members of the group that we have discussed in previous chapters.

The same two-tier scheme can be applied to the patients themselves – in case an individual decides to exercise the right to access his/her healthcare information, there should be two records available, one of which should contain the information which is normally found in medical records under current regulations, and the other one should represent a complete family anamnesis without personal data of biological relatives, who are members of the genetic group. The connection between PHRs and family records can be made by means of identifying references and keys. To improve the organization and control of the healthcare system at least within one country, all certified healthcare facilities should participate in electronic registry of medical records. Regardless of pervasive digitalization, paper medical records have not yet been completely lost in annals of history. On top of that, the practice of EHR being shared between hospitals has always

been poor.[32] For example, in the U.S., only 30% of hospitals achieved interoperability and only 19% regularly use information from external providers.[33] Further organizational problems and obstacle that this idea might face will be discussed subsequently.

7.1.2. Advantages of the model

Most importantly, the open-access-family-history model can resolve in practice the conflict between patient privacy and the autonomy of patient's family members. Whilst patient privacy is protected, the rest of the family can enjoy benefits of having a complete familial medical record. Making depersonalized familial genetic information available to every member of the genetic group can finally put an end to the redundant discussion of what is a serious genetic condition and what is not serious enough to justify the breach of confidentiality. This approach is meant to provide the opportunity for everyone to decide which health condition or predisposition is serious enough to deserve their attention and actions. At the same time, the right not to know can be observed as well, when the patient receives an explanation about the cases, such as predisposition to untreatable diseases and low probability of developing the condition, or terminal stage of an existing disease that can be kept secret from him/her if he/she wishes so.

This kind of wish can be documented in a dedicated part of the informed consent form which, owing to the electronic medical records being shared, does not need to be re-signed before every medical appointment. It can be done once at the pediatric stage, when most people see their first physician, respecting all the recommendations about involvement of children into the process of medical care. Then, the informed consent can be re-signed once the patient comes of age. It is also important to make it clear to the patient that he/she has a possibility to change this decision any time by asking the healthcare professional to update the informed consent form. Existence of such a section in the medical records could help every medical professional participating in the treatment process to understand how to act in order to respect patient privacy and autonomy, as well as to have an idea about the limits of admissible paternalism, and what kind of actions can potentially breach patient rights and lead to lawsuits. However, with greater scientific

[32] Rapaport, L. (2017, October 3). Few U.S. hospitals can fully share electronic medical records. *Thomson Reuters Healthcare & Pharmaceuticals*. Retrieved May 31, 2021, from https://www.reuters.com/article/us-health-medicalrecords-sharing-idUSKCN1C72UV/
[33] *Ibid.*

advancements, the more possible it will become to prevent, treat, or manage diseases that are currently untreatable, including before birth, which will inevitably defy the rationality of the right not to know.

This model also solves the confusion that physicians currently have regarding their duty to inform family members. This approach opts to release the physicians from obligation to look for their patient's relatives with whom they have no existing or previous patient-physician relationship to communicate them their possible health risks. This should be the responsibility of those medical professionals who provide medical services to the respective relatives. This distribution of obligations does not contradict with the concept of family medicine mentioned earlier, the implementation of which would have a positive effect on the functioning of any healthcare system as a whole. Provided with such a database, family doctors would be able to use a more complete family anamnesis of their patients and share it when their patients need a referral to secondary care physicians, who specialize on a particular organ/area of the body or diseases and command expertise over them. As family doctors oversee a wider scope of medical complaints, majority of health issues can be resolved by them, and when having to refer a patient, they can still follow-up with the updated health records.

In case family medicine is not an option, the obligation to check the updates in patients' family records and analyze them in the context of patients' personal records might be attributed to general practitioners (GP). Like family doctors, GPs are considered primary care practitioners (PCP). Most EU countries have adopted a gatekeeping system, whereby GPs control access to secondary care by being the entry point to the healthcare services.[34] Of the analyzed countries, the gatekeeping system is seen in the UK and Spanish public healthcare systems, as well as in social health insurance system in Switzerland.[35] In some EU countries with a possibility of a direct access to the secondary care, financial incentives in the form of lower cost sharing are used to motivate patients to obtain PCP's referral.[36] At the same time, majority of EU countries do not require mandatory registration with the PCP as such a registration system is seen as a limitation of patient

[34] OECD. (2016). Strengthening Primary Care Systems. In *Health at a Glance: Europe 2016: State of Health in the EU Cycle* (pp. 37-53). Paris: OECD Publishing, p. 39. https://doi.org/10.1787/health_glance_eur-2016-5-en
[35] Garrido, M. V., Zentner, A., & Busse, R. (2010). The Effects of Gatekeeping: A Systematic Review of the Literature. *Scandinavian Journal of Primary Health Care*, *29*(1), 28–38, p. 28.
[36] OECD (2016). *Op. cit.*, p. 39.

freedom.[37] For example, an individual can lose his/her possibility to register with a particular physician if he/she lives outside the area that the practice covers. Gatekeeping system is common in the U.S. as well.[38] The organization of primary care affects the level of quality healthcare services that are available to the population. While a gatekeeping system might be the best option for coordination of preventive actions and treatments to more efficiently allocate limited medical resources, there are certain concerns about PCPs authorizing access to specialty care. Thus, there is evidence that long waiting lists for initial diagnosis within gatekeeping systems used to lead to lower survival rate in cancer patients regardless of the availability of high-quality treatments.[39]

Patient engagement in the healthcare processes is not limited to gathering information and making decisions, but also includes an active behavior of a patient towards maintaining his/her own health and choosing suitable medical services instead of being a passive recipient of designed treatments. There is a lot of information in medical brochures and on the Internet about importance of regular check-ups. The starting age to have annual medical check-ups with the PCP may vary depending on the source of information. Nevertheless, the idea is that it is recommended to visit a family doctor or a GP once per year for preventive measures even though there are no perceptible health problems. The open-access-family-history model can contribute to preventive health care. A more complete family history can offer enough information about an individual to undertake necessary anticipatory actions. With the correct use of genetic information from family records, which will be available starting from birth, this can reduce mortality from chronic conditions, to improve quality of life and lifespan, to understand the etiology of diseases and to provide effective treatment for those illnesses that could not have been prevented. Given the connection between level of public health and socio-economic indicators, eventually, sharing genetic information for healthcare purposes will positively affect the development of a country.

7.1.3. Physician-patient communication

In the context of updating genetic information relevant for each member of a particular genetic group, there is not much difference between gatekeeping and self-referring systems. As every

[37] *Ibid.*
[38] Garrido, M. V., Zentner, A., & Busse, R. (2010). *Op. cit.*, p. 28.
[39] Vedsted, P., & Olesen, F. (2011). Are the Serious Problems in Cancer Survival Partly Rooted in Gatekeeper Principles? An Ecologic Study. *British Journal of General Practice*, *61*(589), e508–e512, p. e508-e509.

treating physician will have to organize new information in the two-tier record, the available data should be always updated. Moreover, with more available data there will be greater guarantee that an individual is aware of predispositions from a younger age. In contrast to all scenarios of the legal cases discussed, where at-risk relatives of patients whose physicians failed to notify them about hereditary conditions, implementation of a centralized system should see fewer such surprises. To maximize the benefits of sharing genetic information and to provide better communication and discussion of information contained in shared healthcare records, it is important to improve the organization of primary care. Due to the complexity of medical information, patients still need PCP to guide them through their health data and explain what exactly it means for them at every stage of their lives.

However, there are two types of occasions that would require some information to be reported to individuals more frequently than during their preventive visits or medical procedures. The first situation is for recontacting patients in case of new treatments becoming available or there being changes to existing treatment options, as well as to inform about the results of new studies on lifestyle and health risks, etc. Electronic system of healthcare records can make such notifications easier through directly communicating the information to all individuals who have the same health condition.[40] This can be done automatically from, for example, information centers or similar entities, based on personal preferences of patients expressed on a special informed consent section of the health records. In the same section, it should be possible to for patients to specify their preferred means to receive such news. For example, notifications can be sent through a mobile application, similar to what is currently proposed by the NHS for online use of health and prescription services.[41] Nevertheless, it would be unproductive and unreasonably expensive to send out alerts on insignificant news that people will ignore like spam and advertisement.[42] For this reason, Mark A. Rothstein insists that such communication should be restricted to "truly

[40] Rothstein, M. A. (2018). Reconsidering the Duty to Warn Genetically At-Risk Relatives. *Genetics in medicine: official journal of the American College of Medical Genetics*, *20*(3), 285–290, p. 289.
[41] National Health Service. (2019). *Online health and prescription services*. Retrieved June 2, 2021, from https://www.nhs.uk/nhs-services/gps/online-health-and-prescription-services/
[42] Rothstein, M. A. (2018). *Op. cit.*, p. 289.

exceptional, crucial updates"[43] limited in time depending on nature and stage of a disease, age of a patient, and period of time elapsed since the last medical consultation.

The second situation is directly related to genetic testing and is important to be analyzed in the context of revising the duty to recontact. As we described in previous chapters, genetic tests are conducted to find changes, called mutations or variants, in the DNA. A particular genetic test can be ordered based on a patient's family history and personal anamnesis. The results of genetic tests can be of the following three types – 1) negative, which means that the test did not find any disease-causing mutations in the genes that were tested, 2) positive, which means that the mutation was found, and 3) unclear, which means that the test found a variant of uncertain significance (VUS), the knowledge of which is so limited that it is not possible to give an exact diagnosis based on it. Hight rates of VUS are common not only for clinical genetic sequencing for hereditary cancer, representing a particular issue for ethnic and racial minorities due to the limited genetic data available.[44]

Even though in most cases, VUS are reclassified by downgrading to "likely benign" or "benign" status,[45] an upgrade to "likely pathogenic" or "pathogenic" can also occur, which may have more of an impact on the course of a previously designed treatment plan for a patient.[46] Some scholars suggest that a duty to recontact, the limited regulation of which we discussed in the earlier chapters, is "merely the final stage of a more complex set of obligations that we subsume under the rubric of a "duty to reinterpret".[47] The duty to reinterpret is thought to include four elements – data storage, initiation of reinterpretation, reinterpretation of the data and recontacting the patient.[48] From the point of view of ethics, this duty is supported by the principles if beneficence and non-maleficence, as well as by the respect for autonomy of the patient,[49] provided that the patient's

[43] *Ibid.*
[44] Appelbaum, P. S., Parens, E., Berger, S. M., Chung, W. K., & Burke, W. (2020). Is there a Duty to Reinterpret Genetic Data? The Ethical Dimensions. *Genetics in medicine: official journal of the American College of Medical Genetics*, *22*(3), 633–639, p. 633-634.
[45] Mersch, J., Brown, N., Pirzadeh-Miller, S., Mundt, E., Cox, H. C., Brown, K., Aston, M., Esterling, L., Manley, S., & Ross, T. (2018). Prevalence of Variant Reclassification Following Hereditary Cancer Genetic Testing. *JAMA*, *320*(12), 1266–1274, p. 1267.
[46] Halverson, C., Connors, L. M., Wessinger, B. C., Clayton, E. W., & Wiesner, G. L. (2020). Patient Perspectives on Variant Reclassification After Cancer Susceptibility Testing. *Molecular genetics & genomic medicine*, *8*(7), e1275, p. 2 of 8.
[47] Appelbaum, P. S., Parens, E., Berger, S. M., Chung, W. K., & Burke, W. (2020). *Op. cit.*, p. 634.
[48] *Ibid.*
[49] *Ibid.*, pp. 634-635.

preferences to not know updated information are taken into account as well. The unclear results introduce uncertainty into the treatment process both for the physicians who ordered the test and for the patient who was tested, and they do not actually serve the initial purpose of testing – to confirm or to rule out the diagnosis.

Unlike other types of medical testing, genetic information of a patient regarding the variant remains stable throughout the patient's life, while the knowledge about genetics changes constantly. Therefore, by ordering the test and knowing that the results that cannot be interpreted today may be interpreted in future, the healthcare system assumes the responsibility of providing a definitive result when available.[50]

Assuming the existence of ethical grounds, Paul S. Appelbaum et al., using the same four-element scheme, have analyzed who might be able to execute this duty most effectively and least burdensomely. They argue that the laboratory is the most apt to store the data from the initial analysis. With the increasing volume of test results, storage of results can become too expensive for the laboratory, requiring the patient to share the burden by downloading the results, which, however, can be risky and unreliable.[51] Possibility to keep test results in electronic records, limited access to which can be granted to laboratories, can resolve this issue. The laboratory would be the first to become aware of new data on variant reinterpretation to trigger the reinterpretation, though, in some circumstances the patient and the specialist physician who ordered the test could also request for reinterpretation.[52] Hence, the laboratory, aside from other third-party interpretation services, is best placed to repeat the analysis and to reinterpret it.[53] Surely, there are a lot of practical challenges related to the implementation of these three steps of the reinterpretation process, especially with respect to costs and resources. Nevertheless, these issues can be overcome with automatization of the process.[54] Once the result is reinterpreted, the ordering physician should update the health records and communicate the results to the patient together with an explanation of the consequences, otherwise there would be a risk of the patient not understanding what the

[50] *Ibid.*, p. 635.
[51] *Ibid.*, p. 636.
[52] *Ibid.*
[53] *Ibid.*
[54] Aronson, S. J., Clark, E. H., Varugheese, M., Baxter, S., Babb, L. J., & Rehm, H. L. (2012). Communicating New Knowledge on Previously Reported Genetic Variants. *Genetics in Medicine*, *14*(8), 713–719, pp. 716-717.

findings mean. This duty can be seen as a continuation of an initial obligation to interpret the results, which was previously not possible due to the lack of information.

Thus, we propose to distinguish two types of actions for disclosing new information from the health records. The first is the communication of information from family health records, which, we agreed, should be expected from primary care physicians – either GPs and pediatricians with whom a patient is registered or the last one he/she visited, or family doctors. Communication of familial information would require actions from both the patient and the physician. Those patients who opt to skip the primary care level should understand that they might be deprived from some benefits of having extensive family records. Potentially, this can also motivate people to visit PCPs from time to time even when they feel healthy, as sharing genetic information and keeping unified records for each patient can make the process less time-consuming by eliminating repetitive testing and unnecessary procedures. The second is the duty to recontact resulting from the updates to personal health records. This duty is to be shouldered by the physician who ordered the test in the first place, usually a geneticist or a secondary care physician, such as oncologists and cardiologists. When a patient expresses his/her preference to not be informed, the responsible healthcare professional should still update the patient's health record. This will also guarantee that the family records contain correct information. Test results that the patient does not wish to see, as well other undesired information can be stored in the section hidden from the patient. The limits to the right not to know that we proposed in previous chapters can apply to any situation of healthcare data circulation.

Comparing the duty to warn proposed by the conventional system to these two modes of communication of health-related information, it is noticeable that under our model, the duty to warn transforms to the duty to recontact, or duty to reinterpret. It represents a natural extension of duty of care, where it is more about extension in time, or simply prolongation, than extension in scope. It would be appropriate to expect the physician who was not able to provide full or correct medical care to the patient by interpreting the genetic test results and diagnosing the patient based on the result to accomplish it when the correct results become available. Whilst currently the courts mandate physicians to warn family members of a patient about the risks they learn of during patient's treatment, we propose this obligation to be split between the PCP and the patient. For this reason, PCPs are obliged to inform the patient about familial information but are not required to

chase after the patient. It is important that each individual takes some responsibility for his/her own health and consult the PCP or any other healthcare professional from time to time. As the patient is presumed to be familiar with both levels of his/her health record, personal and familial, starting from a very early age – first through parents or legal representatives, then independently by himself/herself, there should be no urgent situations deserving immediate attention wherein the PCPs are expected to actively reach out to the patient.

7.1.4. Need for a unified system

As mentioned previously, a prerequisite to effective sharing of genetic information and its use in medical care is the creation of a unified information system in the healthcare sector. Such a system should include, besides PHR-like personal and family medical records, electronic registry, registers of healthcare professionals and institutions, as well as relevant documentation, medical appointments, statistical and financial reporting. There is a need for a common informational space for public and private healthcare providers, pharmacies, physicians, and their patients, as well as for institutions of medical and social expertise. While this kind of system can make medical processes smoother for both the physician and the patient, the government can control the activity of healthcare institutions. In the private sector, such a system is important for private healthcare providers to comply with laws and regulations. In the public sector, the system can help monitor the spending of public funds. For this reason, unlike existing PHR systems, the unified informational model should be run by the government. This kind of system is also an important step towards eHealth, a relatively recent concept in health care, which is supported by electronic processes and communication.

In Italy, for example, the development of the lifelong PHR system was initiated about 10 years ago in Lombardy, and now represents a successful scenario in serving around 10 million people living in the region.[55] This system, being capable of combining with other booking or informational systems, integrates all the documentation from all regional healthcare providers, which is directly updated without patient's mediation, and provides all residents of the region with

[55] Barbarito, F., Pinciroli, F., Barone, A., Pizzo, F., Ranza, R., Mason, J., Mazzola, L., Bonacina, S., & Marceglia, S. (2015). *Op. cit.*, p. 165.

their health-related documents.[56] Each PHR contains a patient's demographic information, administrative information, e-prescriptions, clinical documents and the patient summary, informed consent section, and uncertified data that belongs to and is managed by the patient.[57] The first two types of information are synchronized with the Ministry of Finance.[58] The clinical documentation of the lifelong PHR of Lombardy represents a compilation of links to all clinical documents from different medical institutions of the region, which are stored locally in those institutions that issued them.[59] The section of uncertified data contains documents that patients perceive are relevant to their health and well-being.[60]

The first country in the world that launched an electronic records system nationwide was Estonia. Since 2008, a fully unified electronic record system has been covering every individual's medical history from birth to death.[61] One year later, Estonia implemented an exchange mechanism for uploading all medical records into the system.[62] Public and private healthcare providers must upload patient data from their own systems to the national one, which also contains digital medical images, allowing to improve the efficiency of diagnosis and to avoid duplication of clinical analysis.[63] In order to upload information to this national system, there is no need to obtain a separate consent from a patient, however, there is an option for the patient to partially or completely restrict access to his/her EHR.[64] All Estonian residents, including foreign residents, can login to their health records, as well as to check who accessed it and when it was accessed, and when in doubt, they can ask the purpose for which the access was made.[65] This is possible because all the information is stored securely using the blockchain technology that records each access to the medical records. In 2019, Estonia and Finland, the latter being another leader in the implementation of medical information technologies, initiated the exchange of electronic

[56] *Ibid.*
[57] *Ibid.*, p. 167.
[58] *Ibid.*, p. 168.
[59] *Ibid.*
[60] *Ibid.*, p. 171.
[61] World Health Organization, regional office for Europe. (2016). *From innovation to implementation – eHealth in the WHO European Region*, p. 22. Retrieved June 6, 2021, from https://www.euro.who.int/__data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf/
[62] *Ibid.*
[63] *Ibid.*
[64] *Ibid.*
[65] *Ibid.*

documentation for prescriptions, making it possible to use the prescriptions electronically issued by Finnish healthcare providers in Estonian pharmacies to retrieve the medications.[66] Notably, in Nordic countries, the registers of population are mandatory and contain medical information about the residents, sometimes about the entire population over long period of time.[67] The use of personal identifiers facilitate cross-search and linkage between the registers.[68]

Under the ESPON 2020 Cooperation Program, other countries in Europe are also on the way to fully digitalizing their healthcare systems and gradually joining the practice of cross-border exchange of medical information. The cross-border sharing of medical information is associated with a number of problems, especially in relation to standardization and interoperability of electronic records,[69] together with privacy regulations. Given the impact of the digital technologies on health care, the EU members need to improve the ability to exchange documentation without any additional effort and to perform new actions with the shared documentation. Even though the European Commission (EC) advised the member states to achieve interoperability on the EHR on technical, semantic, organizational, and legal levels, majority of them still do not have legal framework relating to these levels.[70] All the efforts to overcome the interoperability problems are reflected in the Recommendation 2019/243, issued by the EC in 2019, which represents a big step in unifying the EHR system.[71] Although further studies might be needed to analyze technical and legal standards and their application to ensure flawless exchange of medical information between countries, existing informational systems, fully or partially unified, show that they can serve as prototypes for our two-tier model.

[66] European Commission. (2019, January 21). *First EU citizens using ePrescriptions in other EU country* [Press release]. Retrieved June 6, 2021, from https://ec.europa.eu/commission/presscorner/detail/en/IP_18_6808/
[67] Bakken, I. J., Ariansen, A. M. S., Knudsen, G. P., Johansen, K. I., & Vollset, S. E. (2020). The Norwegian Patient Registry and the Norwegian Registry for Primary Health Care: Research potential of Two Nationwide Health-Care Registries. *Scandinavian Journal of Public Health*, *48*(1), 49–55, p. 49.
[68] *Ibid.*
[69] European Commission. (2018). Communication from the commission to the European parliament, the council, the European economic and social committee and the committee of the regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (COM/2018/233 final), p. 4.
[70] Bincoletto, G. (2020). Data Protection Issues in Cross-border Interoperability of Electronic Health Record Systems Within the European Union. *Data & Policy*, *2*, E3, p. e3-3.
[71] *Ibid.*

7.1.5. Possible objections to the model

Our proposal may face several challenges. We are going to envisage these objections and provide counterarguments. First of these objections is that some, especially healthcare professionals, might view this approach as overburdening their workflow and impeding their main obligation – to provide adequate medical care to patients. This criticism is based on reluctance to accept the development of science and the necessity of its incorporation into practice. On the one hand, the standard of care, as we mentioned earlier, is heavily influenced by rapid development in genetics. Let us refer once again to the history of medicine and remind that Ancient Romans already paid special attention to the link between development of science and medical practice. The standard of care, traditionally defined as a degree of prudence and caution required from an individual under specific circumstances, depends directly on the current state of medical science. In Switzerland, for example, the rules of the medical art are of high importance, even though its relevance to the judgment is decided by discretion of the judge. The breach of these rules represents a strong presumption of the failure to meet the standard of care.[72] The evaluation is based on an objective criterion of how another physician would act in the same situation according to objective level of medical science.[73] However, it does not imply that it is a comparison to an acme of perfection, but rather a competent member of a professional society.

In contrast, the standard of care in the U.S. was generally established based on customs of the medical profession. If a particular custom exists in medical practice, physicians who conform to this custom do not commit medical malpractice, even though their colleagues might use other subjectively more reasonable methods in their practice. Historically, the standard of care was measured differently across the country from one state to another. This custom-based approach used to provide a legal shield to physicians, especially in jurisdictions applying local standards of care.[74] However, more states are moving towards a more objective national standard of care, depriving local physicians of this "liability life jacket".[75] Thus, whereas the standard of care might vary between different countries as it depends on different factors, especially economic and social

[72] TF 4P.271/2002 du 27 mars 2003, c. 3.
[73] *Ibid.*; ATF 130 I 337 du 19 octobre 2004.
[74] Marchant, G., Barnes, M., Evans, J. P., LeRoy, B., & Wolf, S. M. (2020). From Genetics to Genomics: Facing the Liability Implications in Clinical Care. *The Journal of Law, Medicine & Ethics*, *48*(1), 11–43, p. 17.
[75] *Ibid.*

development of a society, new discoveries in genetics and constantly reducing cost of genetic testing make it reasonable to expect that genetic technologies become a part of standard of care at least in the analyzed countries.

On the other hand, our approach to genetic information and genetic privacy resembles the concept of family medical history, widely used in medicine for thousands of years. The healthcare professionals were always advised to obtain any information about familial health from the patients. The difference is that genetic information, in the sense provided by current regulations, and family medical history do not usually coincide. While physicians are required to examine the family medical history of their patients, they do not normally have access to the information obtained from genetic testing. Our approach makes it easier for physicians to access family medical history, which should make their work in diagnosing and treating more comfortable. As for updating personal and health records, our model would not prove much different from the conventional practice wherein the physicians are required to keep patients' medical records up to date. The communication between healthcare professionals and patients, including informing and notifying of new data in the record, is supposed to be automated without creating any obligations outside of the duty of care and the standard of care.

The second objection can relate to the difficulty to organize our system into two semi-separate tiers – personal and familial. To distinguish personal information from familial information, it is possible to use our definition of genetic information and current guidelines on collecting family medical history. We believe that the family record should contain all genetic information in the sense we propose, except individual genetic information. That is, any information that might concern family members of the index patient. If a piece of information cannot be classified in terms of its significance to biological relatives of the patient, then the personal privacy rules should prevail, and this kind of information should be kept in personal records until it is confirmed to be of importance to the rest of the family. It is true that the line between personal and familial information is unclear. However, the idea that there is a distinction between individual and familial genetic information finds support even in current regulations.[76]

[76] Lucassen, A., & Gilbar, R. (2018). *Op. cit.*, p. 3.

The third criticism concerns the security of such a system and, indirectly, diminishing trust in healthcare professionals and elevated risk of discrimination. We decided to link the issues with trust and discrimination to the security as undermined confidence and reasons for discrimination are the repercussions of insufficient protection. If a patient's personal information is out of reach of any third party other than the treating healthcare personnel, and familial information is available only to genetic group members and their physicians, there should be no fear of breached confidentiality and subsequent discrimination. The abovementioned example of the Estonian system illustrated the level of security guaranteed by the blockchain technology. The possibility of the patient to monitor the history of access to his/her records can assure that the patient privacy is protected. Moreover, it should be possible to monitor the access of third parties to the family records. Here, it is very important to show only the access of individuals who are not biological relatives to protect individual privacy of family members. For instance, the program may provide clearance when a reference key that links the records is used. In such situations, only the relative to whom the key belongs would be able to see who accessed the record with this key. In all other cases, when a reference was not provided, the access details should be visible to all family members. If any of them thinks that the person who accessed the family record breached their group privacy, he/she can represent the group and defend the right. This scheme can protect family records from being requested by employers, insurance companies, including government services, etc. The point of these health records is to provide better care to the public and to protect the information that currently can be left unprotected. Possibly, it can be used for research purposes if anonymized, which we will discuss later, for recruiting patients into clinical trials, but not for imposing treatments, vaccinations, and other manipulations against consent.

Finally, the fourth issue is funding. To design and to implement such a system, as well as to store and manage all the data for all individuals and their ancestors, will definitely require a large budget. However, work on creating a unified electronic health records system, which may become the most important tool for sharing genetic information among relatives, has already started. Regardless of the cost, the implementation of a unified system together with two-tier health records will eventually pay off by reducing spending on repetitive tests, unnecessary testing that can be substituted by family medical history, additional medical procedures due to incomplete records, etc. Evidence suggests that a strategy using highly accurate and comprehensive family history,

which is strongly concordant with the presence of clinically actionable genetic variants, to select individuals for genome sequencing "appears to be financially prudent, particularly in a resource constrained environment", despite the reduction in sequencing costs.[77] Health care costs are increasing without dramatic improvement in quality. For this reason, digital technologies are seen as a solution for this problem, which, by collecting and analyzing information, can make it possible to predict the health status of an entire population and to optimize costs.

7.2. Impact on development of science and technologies

7.2.1. Big deal for Big Pharma

Health information, including genetic data, is critical not only in the context of patient-physician relationship and organization of health care, but for operating clinical trials as well. Provided that genetic groups have rights with regard to genetic information, it can affect the organization of clinical trials. Clinicals trials are scientific studies involving human subjects conducted to assess the efficacy and safety of a new medication or medical devices, expanded use of existing medication or medical devices, or a new method of treatment or diagnostics. Clinical trials represent an important step in the drug development process which provides a lot of valuable data on how a potential drug works in the study participants. This data helps the regulatory authorities decide on approval or refusal of the registration of a drug for wide use.

Cumulatively, the number of registered clinical trials has increased from 2,000 trials registered by 2000 to 366,000 trials registered by 2021, with as much as 3,000 trials having been registered within the first month of 2021.[78] Clinical trials can be sponsored by various organizations, such as governments, medical and research institutions, pharmaceutical companies, and require considerable funds to implement. Despite the obvious link between clinical trials and health care, they have very different goals – while the former aims to gather and produce useful knowledge to

[77] Bylstra, Y., Lim, W. K., Kam, S., Tham, K. W., Wu, R. R., Teo, J. X., Davila, S., Kuan, J. L., Chan, S. H., Bertin, N., Yang, C. X., Rozen, S., Teh, B. T., Yeo, K. K., Cook, S. A., Jamuar, S. S., Ginsburg, G. S., Orlando, L. A., & Tan, P. (2021). Family History Assessment Significantly Enhances Delivery of Precision Medicine in the Genomics Era. *Genome medicine*, *13*(1), 3, p. 9.

[78] Mikulic, M. (2021). Total number of registered clinical studies worldwide since 2000 (as of February 2021). *Statista.* Retrieved June 8, 2021, from https://www.statista.com/statistics/732997/number-of-registered-clinical-studies-worldwide/

improve medical care for future patients, the latter focuses on promoting well-being of individual patients.[79]

Nowadays, clinical trials are very stringently regulated, even though this was not always the case. As mentioned in earlier chapters, the decisive factor that radically changed the nature of clinical trials on human subjects was World War II, when the development of science, in this case medical science, was closely connected with militaristic interests. Back then, the desire to maximize the benefits for a larger number of people did not require consent from participants to be involved in research studies as subjects, and clearly ignored the welfare of the latter. The rights of study participants were not protected until the second half of XX Century, when most of them did not even know that they were participating in a trial. Traditional example from the post-war era is the Tuskegee syphilis study, wherein 399 sick men were observed without any or effective treatment for years, even after the discovery of the high efficacy of penicillin in treating syphilis. The study had been going on for 40 years in the U.S., from 1932 to 1972, and was stopped due to a media leak and after many of the participants had already died from the disease or complications.

The rule of voluntary participation in clinical trials was first anchored in the Nuremberg Code in 1947, then in the World Medical Association Declaration of Helsinki in 1964, adoption of which was spurred by historically clear abuse of study participants. Other important tools for protecting the rights of clinical trial participants are the Oviedo Convention, the Universal Declaration on Bioethics and Human Rights, International ethical guidelines for health-related research involving humans 2016, etc. Currently, the obligation to ensure that the rights of participants in clinical studies are respected lies with ethics committees. Moreover, the study protocol, which must be followed by all parties implementing a clinical trial, should be approved by appropriate authorities, including institutional review boards and regulatory authorities, such as the United States FDA and the European Medicines Agency (EMA).

Before taking part in a clinical study, potential participants should sign an inform consent form. Much like when receiving normal medical care, the study subject must receive complete information about a study prior to any involvement in it. However, due to the study-related

[79] Litton, P., & Miller, F. G. (2005). A Normative Justification for Distinguishing the Ethics of Clinical Research from the Ethics of Medical Care. *The Journal of Law, Medicine & Ethics*, *33*(3), 566–574, p. 566.

elevated health risks that participants expose themselves to in the name of science, the requirements for the consent process are much stricter then in routine medical care. A standard informed consent form (ICF) is a long document written in plain understandable language, the contents of which is thoroughly regulated by laws and guidelines.[80] A typical ICF provides a detailed description of the study, its objectives and goals, explanation of every single study procedure, possible risks and benefits associated with the study, known side effects, contact information, as well as the information pertaining to compensation and insurance. A participant should also be informed about alternatives to the study treatment that are available, his/her rights and obligations, including privacy and confidentiality rules.

Overall, clinical trials become more and more complex, and employ more compound and sensitive data. Participants receive a subject identification number which is used to encode their health information, thereby guaranteeing confidentiality. The participant's health documentation includes family anamnesis, test results, study-related observations, patient diary entries, etc. Sometimes, a participant can be asked to allow the study personnel to contact his/her regular treating physician for more information. Legal documents on clinical trials call on taking every precaution to protect the study participants' privacy and the confidentiality of their personal information.[81] However, protecting privacy and confidentiality in research might face some difficulties.

For instance, since clinical trials can involve patients from different medical institutions in different countries, the information can be transferred outside of the jurisdiction of patient's place of residence to countries with weaker level of privacy protection. Another example is unlimited possibility to use data which was obtained beforehand. For research integrity, the participants can withdraw their consent and prohibit the use of their data only prospectively, which means that all previously analyzed information and results will remain a part of study documentation. Moreover, the principle of transparent reporting in clinical trials can sometimes be at odds with privacy principles. Transparency means that clinical trial details are recorded in a publicly accessible registry, and is important for the purpose of the trial, as well as for protecting the rights of

[80] *E.g.*, 45 CFR § 46.116 (2018); 21 CFR § 50.25 (2012); Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance).
[81] World Medical Association. (2001). World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects, Art. 24.

participants. Until recently, only the results of clinical trials were openly accessible, while the rest of data remained confidential.[82] The U.S. and European political initiatives and new clinical trial legislation, namely the EU Regulation No. 536/2014 and the EMA Policy 0070, made changes to the usual order by considerably increasing public access to the clinical trial data, including participant-level information.[83] The latter potentially creates privacy concerns and requires effective anonymization.

The variability in drug response shown by patients is attributed to non-genetic factors, such as metabolism, and genetic factors.[84] In clinical studies, participants are often proposed to take part in a pharmacogenetics or pharmacogenomics (PGx) study by providing additional biological samples for analysis. As was outlined earlier, the goal of pharmacogenomics studies is to understand the role of gene mutations in response to drug therapies in people, namely genetic variants affecting drug metabolism, efficacy, and toxicity. While pharmacogenetics emerged with studies of single genes, pharmacogenomics is a broader term that encompasses all genes in genome affecting the drug response.[85] For the purpose of this discussion there is no need to distinguish these terms, so they will be used interchangeably. The knowledge obtained in PGx is becoming increasingly important and clinically relevant, as genetic factors are responsible for up to 95% in the variations in response to treatment.[86] In order to identify whether a patient is responsive or not to an investigational treatment, suffers or not from side effects, requires dosage adjustment, PGx testing is widely used in clinical research. In some cases, participation in PGx study is optional, and does not determine participation in the main study. In other cases, patients do not have much choice, as participation in the main study depends on participation in the PGx study. The patient's biological samples collected for the PGx study can be kept for a very long time after the completion of the study. Generally, neither participants nor their family members receive the results of PGx tests.

[82] Minssen, T., Rajam, N., & Bogers, M. (2020). Clinical Trial Data Transparency and GDPR Compliance: Implications for Data Sharing and Open Innovation. *Science and Public Policy*, *47*(5), 616-626, p. 616.
[83] *Ibid.*
[84] Chang, M. T., McCarthy, J. J., & Shin, J. (2015). Clinical Application of Pharmacogenetics: Focusing on Practical Issues. *Pharmacogenomics*, *16*(15), 1733–1741, p. 1733.
[85] Kalow, W. (2006). Pharmacogenetics and Pharmacogenomics: Origin, Status and the Hope for Personalized Medicine. *The Pharmacogenomics Journal*, *6*(3), 162–165, p. 162.
[86] Belle, D. J., & Singh, H. (2008). Genetic Factors in Drug Metabolism. *American family physician*, *77*(11), 1553–1560, p. 1553.

Family anamnesis is of particular interest for PGx studies. For example, family medication history that contains information about inefficacy and adverse reactions across biological relatives throughout generations can be an impetus for PGx testing to optimize pharmacotherapy.[87] The link between inherited factors and serious adverse drug reactions, that can result, among other things, in death, life-threatening conditions, hospitalization, persistent incapacity to conduct normal life, has been documented in literature.[88] Nowadays, family anamnesis available to the study team and the sponsor is considerably more limited than what they would have once we begin to treat genetic information differently. The information which is accessible to the sponsor is regarded as a part of the participant's record in the study dossier. Each participant individually agrees that the family history can be used by study doctors, study personnel, sponsor, and other third-parties involved in the clinical study. If a two-tier health records system is created and familial information is accumulated in a separate file available for individual patients and their treating physicians, family records will contain a lot more information which will be of greater value to research.

Initially, the use of EHR as the primary data source was intended for observational studies, embedded in pragmatic or post-marketing registry-based randomized trials or comparative efficacy studies.[89] In the absence of a unified records network, anonymized medical information can be routinely collected from local EHR systems by regional or national registers for public health purposes and statistics, without the need to obtain consent from data subjects.[90] Additionally, it has been noted that increased application of the EHR in clinical research can provide great

[87] Smith, T. R., Kearney, E., Hulick, P. J., & Kisor, D. F. (2016). History Repeats Itself: The Family Medication History and Pharmacogenomics. *Pharmacogenomics*, *17*(7), 669–678, p. 669.

[88] *E.g.*, Wilke, R. A., Lin, D. W., Roden, D. M., Watkins, P. B., Flockhart, D., Zineh, I., Giacomini, K. M., & Krauss, R. M. (2007). Identifying Genetic Risk Factors for Serious Adverse Drug Reactions: Current Progress and Challenges. *Nature reviews. Drug discovery*, *6*(11), 904–916; Evans, W. E., & Johnson, J. A. (2001). Pharmacogenomics: The Inherited Basis for Interindividual Differences in Drug Response. *Annual review of genomics and human genetics*, *2*, 9–39.

[89] Cowie, M. R., Blomster, J. I., Curtis, L. H., Duclaux, S., Ford, I., Fritz, F., Goldman, S., Janmohamed, S., Kreuzer, J., Leenay, M., Michel, A., Ong, S., Pell, J. P., Southworth, M. R., Stough, W. G., Thoenes, M., Zannad, F., & Zalewski, A. (2017). Electronic Health Records to Facilitate Clinical Research. *Clinical research in cardiology: official journal of the German Cardiac Society*, *106*(1), 1–9, p. 1.

[90] Coorevits, P., Sundgren, M., Klein, G. O., Bahr, A., Claerhout, B., Daniel, C., Dugas, M., Dupont, D., Schmidt, A., Singleton, P., De Moor, G., & Kalra, D. (2013). Electronic Health Records: New Opportunities for Clinical Research. *Journal of internal medicine*, *274*(6), 547–560, p. 552.

opportunities for the field, by allowing to assess the feasibility of a study, facilitating patient recruitment, and optimizing data collection on baseline and follow-up periods.[91]

To improve trial design and to reduce drug development costs, the Electronic Health Records for Clinical Research (EHR4CR) project was launched in Europe in 2011. The main outcome of this project is the commercial platform InSite, later acquired by the TriNetX company,[92] that enabled scientists to search for suitable candidates for trials from millions of EHRs in Europe. The EHR4CR architecture and reference implementation rely on pseudonymization services ensuring that re-identification requests are authorized, allowing the re-identification only through a healthcare professional who has a patient-physician relationship with a potential participant.[93] Thus, unlike the case of statistical research, patient information available for the pharmaceutical industry by means of this platform is far from being effectively anonymized.

Whilst the reuse of key-coded EHR information without explicit consent remains debatable,[94] re-identification and reuse of personal information in trials require patient approval. Thus, as randomized clinical trials of investigational drugs and devices are often conducted in healthcare facilities like hospitals that concurrently provide medical care to potential participants, the EHR data are used for their source documentation in trials. Having received a participant's informed consent, the investigator can retrieve necessary data from the participant's health record and register it in the study. This manner of reusing information is limited only to clinical trial purposes. The question is whether such data that belongs to the genetic family can be used without additional consent in clinical trials to which only one of the group members is taking part.

The importance of family participation in the informed consent process for clinical trials, especially in PGx, has been pointed out previously. Usually, the ICF encourages the study subject to discuss the study and their participation in it with family members too. However, such information is advisory in nature and, at best, affects only close relatives of the study participant.

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[91] Cowie, M. R. et al. (2017). *Op. cit.*, p. 1.
[92] TriNetX. (2019, April 2). *TriNetX, InSite Unite to Establish World's Largest Clinical Research Network* [Press release]. Retrieved June 9, 2021, from https://trinetx.com/insite/
[93] The European Federation of Pharmaceutical Industries and Association. (2016). *IMI1 Final Project Report Public Summary: Electronic Health Record systems for Clinical Research (EHR4CR).* Retrieved June 9, 2021, from https://www.imi.europa.eu/sites/default/files/uploads/documents/projects/EHR4CR_summary_final_report.pdf/
[94] Coorevits, P. et al. (2013). *Op. cit.*, p. 552.

The fact that the clinical trials involve specialized physicians, rather than PCPs who have a lot closer relationship with patients, makes it more difficult for investigators conducting the informed consent process to contact a participant's family members. Furthermore, all the previously listed obstacles to communication with family are relevant when discussing research participation.

Apart from using and generating information that is meaningful to family, PGx studies diverge from the established approach to ethics of medical research by also raising concerns about informational harm, rather than physical.[95] In our opinion, one family member's consent is not enough to provide the investigator, study team and the sponsor access to genetic information contained in familial medical files. Considering that the purpose of any clinical study goes beyond medical needs of an individual, even though participants may benefit from being enrolled in a study, the use of group information would require some kind of authorization from the group. There are, at least, two possibilities to guarantee the execution of the right to genetic privacy by the family.

The first option is to actively ask for permission for their information to be used in the clinical trial. Once a patient has joined a study, a letter with a summary of the study and question whether they are willing to provide their familial information to accompany a family member's participation in the study can be sent through the unified health record system to all living members of the genetic group. The communication should be realized in that way that the identity of each member, including the one who is going to take part in the study, is kept in confidence. The summary should contain the title and the number of the study to enable each biological relative to learn more by searching the study in registers, such as the EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/) and ClinicalTrials.gov (https://clinicaltrials.gov/). A collective agreement may be deemed to have been reached in case of simple majority and should be provided the same way the letter is sent, namely without breaching privacy of individual members of the group. This collective or group consent would be an example of a case when the right to genetic privacy is exercised jointly.

[95] Boddington P. (2010). Relative Responsibilities: Is There an Obligation to Discuss Genomics Research Participation with Family Members? *Public health genomics*, *13*(7-8), 504–513, p. 505.

The second possibility is to obtain a general informed consent from each relative, the same as it would be for preferences about the right not to know, recontacting, etc. For example, a special section of personal health record can contain questions about a member's position towards the use of familial information in research. Based on the responses provided, the status of availability for each family member can be automatically determined and appear as available or unavailable to the investigator. Perhaps, this model would be easier to implement than the previous one, but the control over information is more limited. This resembles the "broad consent" model which has been used in many biobanks projects to justify uncertain and diverse range of outcomes when people essentially delegate their decisions about future research with their samples.[96] This broader concept of consent still can be regarded as informed, and, therefore autonomous for the same reasons as the decision to not know certain information about oneself that we have qualified as an informed decision. For this reason, for PGx drug trials, this model of consent from the part of the family might be acceptable.

While the two models mentioned above attempt to address the problem of use of previously extracted familial information contained in medical records, the position on the information that is to be recorded after the PGx study is less clear. This issue concerns not only PGx studies conducted along with a parent randomized study, but other types of genomics studies as well as, such as direct-to-participant (DTP) genomic studies that recruit participants via Internet. The latter in particular has proven to be a very effective way of enrolling individuals with rare diseases.[97] Unlike routine medical care, especially family medicine, clinical research usually lacks direct interaction between practitioners and family members. Hereupon, it seems that there is no ground to treat third-party relatives as study participants by obtaining their consent for the index patient participation. The decision to join a clinical study is regarded as an autonomous act of an individual who is going to take active part in the study. For this reason, some scholars argue that it would be

[96] Sheehan, M. (2011). Can Broad Consent Be Informed Consent? *Public Health Ethics*, *4*(3), 226–235, pp. 226-227.
[97] Rothstein, M. A., Zawati, M. H., Beskow, L. M., Brelsford, K. M., Brothers, K. B., Hammack-Aviran, C. M., Hazel, J. W., Joly, Y., Lang, M., Patrinos, D., Saltzman, A., & Knoppers, B. M. (2019). Legal and Ethical Challenges of International Direct-to-Participant Genomic Research: Conclusions and Recommendations. *The Journal of law, medicine & ethics: a journal of the American Society of Law, Medicine & Ethics*, *47*(4), 705–731, p. 705.

wrong to assume that biological relatives can veto the index patient's participation in a PGx study only out of the interests for their own autonomy.[98]

On the one hand, this is true. Even though the primary goal of clinical research is not to improve the state of health of participants and is rather to develop or improve treatments for the future, each study participant is motivated to enroll in a study because of the possible personal medical benefits or desire to help other people who suffer from the same condition by contributing to development of treatments. Monetary interests should be excluded as study participants, aside from healthy volunteers, do not receive any payment for the participation. Thus, from the point of view of the study subject, familial health information is used in the same way as in routine health care – either to improve health, or for public interests. Therefore, if biological relatives, as a group, can easily prevent a member of their genetic group from making decisions that affect his/her own life, it risks leading to the radical shift towards the recognition of the supremacy of group rights over individual, endangering the latter. On the other hand, information collected for research purposes is exempt from personal privacy regulation and can be used for other purposes.[99] Thus, publications based on study results, especially in case of whole genome sequencing, can identify if not specific individuals, the groups to which they belong. In population-based or family-based genomic research, the community or family consultations and consent are acquired in addition to individual consent.[100]

The involvement of biological relatives and their information security needs a lot of rework. In many ways, research is very different from routine medical care, which explains the gap between the status of a patient and a study subject. This difference leaves its mark on the situation of genetic family as well. The position of a study subject is more vulnerable and disproportionate than a patient in routine medical care because pharmaceutical companies have commercial interests when using the data obtained from the study. Currently, majority of biological relatives are left in complete ignorance of how and where information concerning them is used. We have outlined the

[98] McGuire, A. L., Caulfield, T., & Cho, M. K. (2008). Research Ethics and the Challenge of Whole-Genome Sequencin. *Nature Reviews Genetics*, *9*(2), 152–156, p. 154.
[99] *E.g.*, Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), Art. 89.
[100] Boddington P. (2010). *Op. cit.*, pp. 505-506.

issues of the family members' privacy, which need to be reconsidered in future along with the privacy of study participants. While there may be no need to involve all biological relatives of a potential study participant in the informed consent process, which is also impossible to organize, it is plausible that they are able to give a broader form of consent and to be informed about the further use of data at least to the same extent that the study participants are. We believe that redesigning the healthcare information infrastructure may help in future to safeguard informational rights of biological relatives as well. It is important to find a balance between research and health care, especially because PGx studies are an important step towards precision medicine.

7.2.2. Precision medicine

Precision medicine, sometimes called personalized medicine or personalized care, is an emerging tool in medicine that harnesses the individualistic differences in the genetic information of people to tailor-make treatment regimens for various genetic populations of patients affected with a particular disease, so that treatments are most efficacious and safest for each population of patients. The process of designing treatment plans for patients require detailed knowledge about the genetic information of patients, and physicians address specific problems seen in the genetic information of patients by prescribing specific drugs or treatments that can circumvent the issue.

The seed of precision medicine may have been planted as far back as in 1902 by Archibald E. Garrod, where he describes the duty of a healthcare practitioner as helping a patient while doing him/her the least damage by respecting the individual chemical differences.[101] The "chemical individuality" which Garrod speaks of,[102] albeit not understood into detail in his time, is our individual genetic peculiarity that we speak of today. Patient genetic information provide practitioners with understanding of this 'chemical individuality', which are today referred to as biomarkers – a measurable indicator (a gene, a protein, or another chemical) showing whether someone is sick, and by how much – and thousands of studies are conducted every year to examine the association between biomarkers and diseases. Once a connection between a biomarker and a

[101] Garrod, A. E. (1931). *The Inborn Factors in Disease: An Essay*. Oxford: Oxford University Press, p. 24, as cited in Perlman, R. L., & Govindaraju, D. R. (2016). Archibald E. Garrod: The Father of Precision Medicine. *Genetics in Medicine*, *18*(11), 1088–1089, p. 1089.

[102] Garrod A. E. (1996). The incidence of alkaptonuria: a study in chemical individuality ["The Incidence of Alkaptonuria: A Study of Chemical Individuality" by A. E. Garrod was reproduced with permission from *The Lancet*, 1902, ii:1616-1620.]. *Molecular medicine (Cambridge, Mass.)*, *2*(3), 274–282.

disease is verified by basic research, in the clinical setting, physicians can approach treatment of patients and patient populations exhibiting a particular biomarker in a specific manner, much like understanding which key to use to open a door when you know what the keyhole is shaped like.

Cancer is perhaps the most commonly scrutinized disease when we speak of precision medicine. It is notorious for being a disease that is difficult to treat and cure, because no two cancers are the same. Unlike some other diseases which may be caused by one faulty gene, cells in malignant tumors may have many faulty genes, and what is faulty may differ between two patients having the same cancer and even between two tumors in a single patient.[103] This would mean that a given treatment can have contrasting outcome in two different patients, and even in two tumors. The only way that medicine could hope to defeat cancer is by understanding the cancer and its tumors at the genetic level (i.e., its biomarkers) to see what is providing them the advantage to survive in the patient's body. As discussed in previous sections, genetic information, or biomarkers, serve for more purposes than treatment decisions. As shown by BRCA1 and BRCA2 mutations being a risk factor for breast cancer development, certain information may contribute to preventive precision medicine.

On the other hand, knowledge of biomarker profile for a certain cancer may help improve the efficacy of certain treatments. One example is the research and development of antibody-drug conjugates.[104] Examining the genetic and biomarker profile of cancer found in a patient can reveal proteins that are specific to the cancer or found in significantly greater abundance than in healthy tissue. If a drug can be modified to hit specific characteristics like these, it is more likely to be effective against cancer cells while leaving healthy cells alone – thus reducing side effects. Antibodies are proteins that bind to another specific protein. Antibody-drug conjugates join antibodies with toxic chemotherapy agents and help reduce the side effects of the native drug. This means that genetic and biomarker profiling has potential for repurposing failed treatments and produce more benefit from them. With biomarkers being such a vital part of cancer medical care,

[103] Huang, L., Jiang, X. L., Liang, H. B., Li, J. C., Chin, L. H., Wei, J. P., Wang, R. R., Cai, J., Xiong, Q., Wang, L. T., Cram, D. S., & Liu, A. W. (2020). Genetic Profiling of Primary and Secondary Tumors from Patients with Lung Adenocarcinoma and Bone Metastases Reveals Targeted Therapy Options. *Molecular medicine (Cambridge, Mass.)*, *26*(1), 88.

[104] *E.g.*, Nejadmoghaddam, M. R., Minai-Tehrani, A., Ghahremanzadeh, R., Mahmoudi, M., Dinarvand, R., & Zarnani, A. H. (2019). Antibody-Drug Conjugates: Possibilities and Challenges. *Avicenna journal of medical biotechnology*, *11*(1), 3–23.

it is no surprise that the market for cancer biomarkers research is projected to expand to a whopping USD 48.20 Billion by 2026, from the USD 18.94 Billion market share in 2018.[105] Precision medicine is about going after the root of the disease by looking at the body's blueprint, and both in the clinic and laboratory, genetic information of patients and family members fuel the search for better treatments. Needless to say, precision medicine is the future of healthcare.

Genetic information is bringing about a paradigm shift in clinical psychiatry too. While the most prominent examples of precision medicine still concern somatic diseases (diseases of the body), advancing knowledge about our brain and improvement in neurogenetic testing has paved the way for such data to be applied to personalized treatment of psychiatric patients, in what is colloquially referred to as "precision psychiatry".[106] In theory, precision psychiatry may benefit psychiatrists and patients alike by predicting who may develop schizophrenia, or identifying who would benefit from being prescribed antidepressants.[107] With mental health being an increasingly prevalent issue around the world, the benefits of precision medicine for somatic diseases are likely to be seen in mental illnesses too.

However, we must face the stark reality that the general public, and therefore the beneficiary of precision psychiatry, may not be prepared to regard mental health at the same level of importance as physical health. While great strides are being made in Western countries to raise awareness about mental health and encouraging the public to receive proper care, in some of the other parts of the world, mental health struggles are considered deeply personal and a stigma that is difficult to discuss openly or seek help for.[108] In a situation where an individual that should receive care is not actively seeking the attention of a psychiatrist, it is difficult to imagine the benefits of precision psychiatry, which would involve examination of genetic information and thus family information, permeating through. Without proper regard for mental health, patients may always be conflicted

[105] Fortune Business Insights (2021, April 1). *Cancer Biomarkers Market Size 2021 | To Exhibit 12.4% CAGR and Hit USD 48.20 Billion by 2026* [Press release]. Retrieved June 11, 2021, from https://www.globenewswire.com/news-release/2021/04/01/2203414/0/en/Cancer-Biomarkers-Market-Size-2021-To-Exhibit-12-4-CAGR-and-Hit-USD-48-20-Billion-by-2026.html/

[106] Fernandes, B. S., Williams, L. M., Steiner, J., Leboyer, M., Carvalho, A. F., & Berk, M. (2017). The New Field of 'Precision Psychiatry'. *BMC medicine*, *15*(1), 80.

[107] Rahm, C., & Sörman, K. (2019, February 23). *Karolinska Institutet, Introduction to Neuroscientific Psychiatry Course* [Video]. YouTube. Retrieved June 11, 2021, from https://www.youtube.com/watch?v=KbHORDvZ0No/

[108] Krendl, A., & Pescosolido, B. (2020). Countries and Cultural Differences in the Stigma of Mental Illness: The East–West Divide. *Journal of Cross-Cultural Psychology*, *51*(2), 149–167, p. 163.

between exposing genetic and family profile and receiving care which they are not sure they truly need.

In contrast to this, there may also be a situation where treatment may not necessarily be ready to respond to the information obtained by genetic testing. That is, while we are now equipped with tools to test and analyze genes and find a host of valuable information, the number of actionable findings from these analyses is limited.[109] This means that while information about mutations may be useful to understand what is wrong, there may not necessarily be an approved treatment that overcomes the problem. Patients in clinical trials are often informed that they may not necessarily gain direct benefits (therapeutic or otherwise) from participating in the trial, but their contribution would certainly help improve treatments for the future. Perhaps the process of undergoing genetic testing, providing genetic information, and receiving genetic counseling only to learn of a variant of unknown significance or presence of a pathogenic but non-actionable genetic problem may be comparable to this situation in clinical trials. Ideally, every genetic finding related to a disease would have a response in the form of an approved treatment ready. With drugs and treatments taking a matter of decades to arrive to the market, the reality is that some patients may only enjoy the benefits of knowing truly what is wrong with them. It is noteworthy, however, that this does not take away from the value of genetic technology and its regulation as tools in precision medicine. Co-ownership of genetic information as a family could mean that a non-actionable finding in one patient may one day become a useful and actionable finding for a relative, offspring or later descendants.

Having looked at some examples of how precision medicine can come into play in routine healthcare, we have come to understand that it is not without its own shortcomings. Social obstacles to acceptance of mental health issues not only highlighted the limitations to precision psychiatry as a subcategory of precision medicine, but also suggested that a thorough intercultural examination may be needed to assess the success of implementing our system in various different places around the world, as cultural views on having family and genetic information managed centrally may vary. Remembering that the primary motive for an individual or a group to contribute

[109] Simmons, H. (2019, February 27). Is Personalized Medicine the Future of Healthcare? *News Medical Life Sciences*. Retrieved June 11, 2021, from https://www.news-medical.net/health/Is-Personalized-Medicine-the-Future-of-Healthcare.aspx/

their genetic information to clinical records or research is to resolve or prevent their own health issues, the possibility of non-actionable findings and lack of a fitting treatment to address the issues identified by genetic testing is a tough pill to swallow. However, it is also reality that genetic information provides us infinitely greater volume of information about our bodies and ailments than any other tool available, and it will undoubtedly be the most vital factor, even in precision medicine. As such, we believe that our two-tier system of genetic bookkeeping will play a pivotal role in streamlining precision medicine and improving treatment efficacy and patient safety.

7.2.3. Whole genome sequencing and the family

Precision medicine is also associated with whole genome sequencing (WGS) testing that gives a possibility for physicians to examine the complete genetic code of a patient. WGS is a laboratory procedure to determine nearly all nucleotides of an individual's DNA sequence, which also includes non-coding sequences.[110] Thus, it represents an image of an individual and contains a lot more than health-related (individual) genetic information. Unlike targeted genome sequencing and genetic testing for a particular mutation, WGS does not focus on biomarkers known to be associated with pathogenesis of disease or clinical relevance. WGS itself does not answer any particular questions other than to provide a read-out of an individual's DNA.

Currently, while still not common in routine medical practice, WGS is performed in a research context or by request from individual consumers. In order to learn anything from WGS in research, genomes of healthy or sick people need to be compared. From a medical perspective, there should be a clear understanding of what is being looked for in an individual's genome. This means that while the value of WGS is emerging in science, it does not have much practical use for most patients in routine medical care. For the above reasons, it is unnecessary to share the WGS itself of a member of genetic group with the rest of the group, unless some specific knowledge obtained in research, or some conclusions are drawn during medical treatment. Moreover, it is impractical

[110] National Cancer Institute. (n.d.). *NCI Dictionary of Genetic Terms:* whole genome sequencing. Retrieved on June 13, 2021, from https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/whole-genome-sequencing/

to include WGS into the EHR system as a single read-out requires about 150 gigabytes of storage, but rather to store them in a separate repository linked to the record.[111]

A genome sequence needs to be protected because, regardless of whether it has practical use or not for the index patient's biological family, it still contains information about the latter. For this reason, family members have a right to be involved somehow. In this context, the correlation between personal autonomy and group privacy takes on a different character. An example is when undergoing a normal genetic test has a direct practical meaning for the tested individual and, hence, practical meaning for the rest of the family. Therefore, the results have any sense only for the genetic group, exactly like family anamnesis. In randomized clinical trials, including PGx, the results have impact on the participants, their family, people with the same disease and pharmaceutical companies. In WGS studies the results may be significant, aside from the participants and their families, not only to other individuals with the same conditions, like in case of rare diseases, but literally to all people. Therefore, the question of whether an individual can or cannot undergo WGS, changes to whether he/she must or not, due to a potential duty to all mankind with whom we share 99.9% of the same genetic information.

In the context of WGS, relational autonomy which was previously discussed in the context of family medicine, is conceptualized in a social sense, rather than in a familial sense like before. Social level of relational autonomy also presumes that a person engages in a process that requires others to use their experience and skills to interpret that individual's genetic code.[112] To make it happen, it is important to listen to the public opinion and involve as many people as possible in the discussion and decision-making related to the genome. For instance, the 100,000 Genome Project, a UK Government project to sequence the whole genome from NHS patients carried out from 2013 to 2018, had a Participant Panel inviting participants to the governance process over their data interpretation.[113] In addition to this, a secure system to protect the sequences is needed to support public trust, by minimizing the number of copies of a whole genome sequence, limiting

[111] Kolbasuk McGee, M. (2013, May 30). Personalized Medicine: Privacy Issues. Dixie Baker Sorts Through Critical Challenges. *HealthcareInfoSecurity.* Retrieved June 13, 2021, from https://www.healthcareinfosecurity.com/interviews/personalized-medicine-privacy-issues-i-1941/
[112] Horton, R., & Lucassen, A. (2019). Consent and Autonomy in the Genomics Era. *Current Genetic Medicine Reports*, *7*(2), 85–91, pp. 89-90.
[113] *Ibid.*, p. 87.

direct access when partial access is sufficient, limiting the access to viewing instead of downloading, and encrypting the data.[114]

7.2.4. Once again, what about direct-to-consumer genetic tests?

Besides the threat to group privacy posed by clinical research when using family history or genetic testing, it is important to reconsider the direct-to-consumer genetic tests in light of our account of genetic information. As it was illustrated in the previous chapters, the use of DTC-GT has numerous ethical, social, and legal repercussions, including confidentiality and privacy issues. Since DTC-GT companies do not properly protect privacy of their clients, there is no point in discussing how to legally protect the privacy of a client's biological relatives. Unless DTC-GTs are banned, it is unlikely that the biological family, especially distant ones, will be involved in the decision-making process on DTC tests. Since these companies are privately owned and are not linked with the healthcare system, it seems impossible for the rest of the family to control whether any genetic test results related to them are contained in the company's database. Not even banning would be a solution, as these are available to order via the Internet from another country, which goes beyond the legal restrictions.[115] For this reason, without dwelling into the issues of regulating DTC tests, in this chapter we will discuss how DTC tests affect the sharing of genetic information in medical care and what can be changed to improve the outcomes.

When available, anyone can buy a kit and send a sample to one of the companies that provide this kind of services without considering its impact on family members. Leveraging the last advantages in next-generation sequencing, the DTC-GT companies provide, aside from genealogy or pedigree services, medical reports that draw conclusions about hereditary health status of the consumer.[116] The first category of genetic services is beyond the scope of genetic privacy concerns, since they result in extracting non-health-related information, of course provided the biological samples are

[114] Kolbasuk McGee, M. (2013, May 30). *Op. cit.*
[115] Howard, H. C., & Borry, P. (2012). To Ban or Not to Ban? Clinical Geneticists' Views on the Regulation of Direct-To-Consumer Genetic Testing. *EMBO reports*, *13*(9), 791–794, p. 794.
[116] Hendricks-Sturrup, R. M., & Lu, C. Y. (2019). Direct-to-Consumer Genetic Testing Data Privacy: Key Concerns and Recommendations Based on Consumer Perspectives. *Journal of personalized medicine*, *9*(2), 25, pp. 1-2.

destroyed and not re-tested, and thereby they are not covered by our definition of genetic information. The second category, on the contrary, is of particular interest.

Arguing on consumer perception of genetic privacy, Rachele M. Hendricks-Sturrup and Christine Y. Lu bring up an example of a warning to the customers of Ancestry – one of the biggest DTC-GT companies, written by consumer protection attorney and former New Jersey deputy and Department of Justice Attorney General Joel Winston in 2017.[117] Apparently, the company owned the consumers' DNA perpetually in royalty-free manner and worldwide.[118] Moreover, in Ancestry's Terms and Conditions it was specified that the information can be used by the company against the consumers or their genetic relatives and that the consumers waive their legal rights by accepting the terms of use.[119] Aside from using very complicated language and illegible font for such clauses, such companies normally do not include specific information about any third parties to whom they could grant access to consumers' genetic data.[120]

We have established that, according to the right to genetic privacy, all members of a genetic group owe each other moral obligation to protect familial privacy, which is grounded in their participation in producing a group good. For this reason, each member of a genetic group owes an obligation to the rest of the group to fully comprehend the terms based on which the DTC-GT is going to be performed and do not resort to services they have serious concerns about. The abovementioned issues of the service agreements used by DTC-GT companies question whether the consumers fully understand the terms they sign under.[121] The evidence suggests that key consumer concerns are centered on "governmental oversight and regulation of DTC-GT company activities, third-party access to DTC-GT information, consumer motivations to participate in the sharing or exchange of genetic information, and consumer expectations of privacy after publicly sharing personal genetic health information".[122] There are some examples of eroding public trust

[117] *Ibid.*
[118] Winston, J. (2017, May 17). Ancestry.com takes DNA ownership rights from customers and their relatives – A word to the wise: Read the complete terms of service. *ThinkProgress*. Retrieved June 12, 2021, from https://thinkprogress.org/ancestry-com-takes-dna-ownership-rights-from-customers-and-their-relatives-dbafeed02b9e/
[119] *Ibid.*
[120] *E.g.*, Laestadius, L. I., Rich, J. R., & Auer, P. L. (2017). *Op. cit.*; Phillips, A. M. (2017). Reading the Fine Print When Buying Your Genetic Self Online: Direct-To-Consumer Genetic Testing Terms and Conditions. *New Genetics and Society*, *36*(3), 273–295.
[121] Hendricks-Sturrup, R. M., & Lu, C. Y. (2019). *Op. cit.*, p. 2.
[122] *Ibid.*

when sharing data that can identify individuals who initially gave the biological samples and their family members, such as the agreement announced in 2018 between 23andMe and GlaxoSmithKline to share data of more than 5 million 23andMe consumers for translating genetic and phenotypic data into targeted pharmaceutical treatments.[123]

As we earlier noted, undergoing a DTC-GT is a manifestation of individual autonomy and self-determination. In a situation where there is potential and questionable future use of familial information, mutual obligations of the genetic group members would imply abstaining from the services. This creates a conflict between individual right and group right. The right to genetic privacy was not intended to threaten individual rights of the members of the group which they have regarding genetic information. We established that there is no need for additional approval from the rest of the group to use information for medical reasons for themselves or for future generations, while it should not be allowed to sell it or employ for any other exclusively personal reasons due to the participatory nature of health-related genetic information. Even though DTC-GT companies provide medical reports on a consumer's health status, there are a lot of uncertainties about the validity of these reports due to their inaccuracy and the need for them to be interpreted by geneticists or specialized companies. This means that a DCT-GT itself does not serve as a valid medical interest to allow a single member of a genetic group to use familial information, especially in the absence of adequate regulations. However, this is very difficult to enforce.

While it is unclear whether and how biological relatives can influence the access of other biological relatives to DTC-GT and the decision about sharing the data, let us see whether and how they should be informed about such results. The DTC-GT results contain raw genetic data which is neither accurate nor applicable for medical use. For this reason, DTC-GT consumers usually consult geneticists or third-party interpretation (TPI) companies to get their results interpreted.[124] While geneticists can provide competent analysis provided that the raw data is valid, the TPI

[123] GlaxoSmithKline. (2018, July 25). *GSK and 23andMe sign agreement to leverage genetic insights for the development of novel medicines* [Press release]. Retrieved June 12, 2021, from https://www.gsk.com/en-gb/media/press-releases/gsk-and-23andme-sign-agreement-to-leverage-genetic-insights-for-the-development-of-novel-medicines/#

[124] Badalato, L., Kalokairinou, L., & Borry, P. (2017). Third Party Interpretation of Raw Genetic Data: An Ethical Exploration. *European journal of human genetics: EJHG*, *25*(11), 1189–1194, p. 1189.

websites operate on publicly available databases regardless their incorrect classifications, which results in misinterpretation.[125] For this reason, there is no advantage for biological relatives to have this TPI reports included in familial records. Some scholars are persuaded that "medical providers should order confirmatory genetic testing from an experienced clinical diagnostic laboratory to guide patients' medical care".[126] The results of confirmatory tests should be added to the family records. The DTC-GT results interpreted by geneticists may be allocated in a special section of the records. However, some studies reveal that increasing use of DTC-GT is directly proportional to the number of referrals, which adds burden onto the healthcare system.[127] As many consumers are not sure what to do with the DTC-GT results and the PCPs are not trained to help in such situations, the latter write referrals to clinical genetic services who, due to limited funding support, have long lists of patients who are proven to truly need genetic testing for diagnostic purposes.[128]

Thus, we can observe that it is more feasible to guarantee that the genetic group has access to the DTC-GT results after they are properly interpreted, but they are not involved in the control over the use of their data by the DTC-GT companies and possible third parties. Yet, the aspect of controlling is essential to the right to genetic privacy, while the access to the results is not that important because of the high probability of data inaccuracy. On the one hand, when developing strategies for regulating the DTC industry, the continuous growth of which has been predicted, it is important to keep in mind the point of view of consumers' families as well. On the other hand, we believe that there is possibility that with complete family anamnesis and a more approachable medical system available, the hype for these tests will subside.

7.2.5. Required revision of laws and regulations

To meet these new challenges to use genetic diagnostics, the law must evolve. The patient-physician relationship is regulated by legal norms of different branches of the law. The acceptance

[125] *Ibid.*, p. 1190.
[126] Tandy-Connor, S., Guiltinan, J., Krempely, K., LaDuca, H., Reineke, P., Gutierrez, S., Gray, P., & Tippin Davis, B. (2018). False-Positive Results Released by Direct-To-Consumer Genetic Tests Highlight the Importance of Clinical Confirmation Testing for Appropriate Patient Care. *Genetics in medicine: official journal of the American College of Medical Genetics*, *20*(12), 1515–1521, p. 1516.
[127] Millward, M., Tiller, J., Bogwitz, M., Kincaid, H., Taylor, S., Trainer, A. H., & Lacaze, P. (2020). Impact of Direct-To-Consumer Genetic Testing on Australian Clinical Genetics Services. *European journal of medical genetics*, *63*(9), 103968, p. 1.
[128] *Ibid.*

of the genetic privacy concept will eventually lead to some changes in various laws and guidelines. However, there is no need for a lot of new legal norms. What is more important is that the practice of courts and the law itself are more flexible and ready to adapt to new values, without falling behind science and creating legal uncertainty. Once new problems are identified and understood, patients, physicians, government and all third parties who are concerned must take steps in order to improve healthcare relationships. Admittedly, the adaptation of legislations and implementation of our alternative open-access-family-history model would take time and resources. However, it is not necessary to change all relevant legal documents to start putting it into practice and allowing more and more people to benefit from it. For this reason, without aiming to provide specific correction to each article or section of laws or normative acts, we are going to outline the main lines of development to consider.

No matter how much work needs to be done to fully implement our approach, it can be used, to some extent, in practice right away. This is possible because the concept of genetic privacy is ultimately based on the fundamental principle of human dignity. As we have previously established, privacy, regardless of what is considered private, is a necessary condition for a life with dignity. Even though the concept of dignity is very vague, and its essence can vary in different societies, it is important to keep in mind that it has not only an individual component, but also a public one. For this reason, life with dignity should be also regarded through the prism of society, which does not mean in contrast to it.

The part of society which is the closest to a particular individual is one's friends, family, and colleagues, etc. All these examples of the closest circles represent a sort of a group. These groups may be organized based on different criteria and have different purposes. Nevertheless, all these groups contribute to the individual's self-perception, or identity. To recognize the identity of an individual is a step forward in respecting his/her dignity. For this reason, in order to provide life in the closest part of society, namely in a group, it is important to provide a certain level of privacy, which is not equivalent to a simple sum of individual privacies. This demonstrates that our approach is based on the same concepts and principles as the system of human rights, and as a general rule, should not contradict current regulations.

On the one hand, privacy laws seem to follow this idea by taking into account a social nature of an individual and guaranteeing, for example, family privacy or confidentiality of correspondence, where family obviously means more than a single person and correspondence is carried out with someone else. The notion of private life includes not only an intimate sphere but also personal interactions with the outside world. On the other hand, an individual cannot control and protect privacy of a whole group, nor protect it against or on behalf of another participant. This happens because the right to family privacy is regarded as individual privacy rights of all family members, rather than a right that belongs to a family. Therefore, it seems that in the context of legal protection, the law isolates individuals from the society, or from a group, by rejecting that their interaction can go beyond the limits of an individual's private life, but still be relevant for requiring protection. In the context of informational privacy, this discrepancy needs to be adjusted. To divide the right to privacy into three levels reflecting three levels of the sphere of personal activity – intimate, secret, and private, would be impractical due to its nominal separation. To divide into two levels, depending on the nature of relationship, such as individual and group, would be feasible. In this case, perhaps the idea of genetic privacy can be applicable to informational privacy within other groups as well.

Yet, proceeding with the rights in medical care, it is important to define what is protected genetic information. We have proposed a definition that can be used to update medical confidentiality regulations. The same definition can be added to all privacy laws, especially the GDPR and national privacy legislation. Absence of a clear definition and understanding of the object of regulation is the root of most problems. Currently, there is no consensus on the definition of genetic information between analyzed countries. It is noteworthy that our definition is applicable only for the purposes of protection of privacy and confidentiality and should not be used for other purposes.

The particularity of genetic information and its familial nature affects the physicians' duties as well. On the one hand, our approach resolves the conflict of duties the healthcare professionals have – a duty of confidentiality and a duty to warn. On the other hand, genetic technology, as any new treatment or diagnostic procedure, influences the standard of care, which is followed by new legal expectations and obligations. The examples of new situations where physicians may be held liable involve, among others, a duty to recognize the patient's inherited genetic predisposition for a disease based on family history, obligation to identify a drug-gene interaction, extended

obligation to inform the patient and communicate new information, as well a duty to recontact. These cases certainly affect the existing approach to informed consent and lead to a revision of the informed consent process in order to ensure more active engagement of patients and their family members in the decision-making process.

In addition to all of the above, the implementation of our proposal calls for the revision of the research regulations, especially in relation to the autonomy and privacy of study subjects as well as the involvement of their families. There should be some consensus on DTC-GT companies as well, as for now the gap in their regulation represent one of the biggest threats to genetic privacy. After all, changes may reverberate on a number of special laws and regulations. For instance, a wasteful number of legal documents at the national and international level were used in this research. Comparison of the framework of patient rights, physician's liability, and privacy rules in these nations allowed us to see that there are a lot of common aspects in their regulation, which means that the responses of these legal systems to implementation of genetic technology will not differ greatly, and the experience can be mutually beneficial. We need effective tools to bring together science, healthcare, and people, especially in the interests of the latter.

7.3. Interim conclusion

The alternative approach involves creating a unified two-tier electronic health record system, called open-access-family-history model. Designed to resolve the main conflict of interest between the patient, the family, and the physician, which appeared in era of genetics, this system can be built based on ongoing projects of personal lifelong health records. Classification of information between the two tiers of records aims to provide access and control over the data to the genetic group, while improving the quality of medical services. Aside from this, unification of medical system in general, and medical documentation in particular, has positives effects on interactions between all parties. Lifelong records, which would contain personal and familial health-related information, are intended to provide a complete summary of an individual's medical anamnesis. While family history has been treated as an important tool for diagnosis and treatment for thousands of years, there is still no working system to facilitate the collection of family anamnesis. The value of family anamnesis in modern medicine is nearly lost because the information that

patients collect by themselves is limited and contains mistakes and discrepancies. In some cases, healthcare professionals might be biased towards using such data in diagnosis and treatment.

In fact, genetic information and family anamnesis are the two sides of the same coin. Genetic information, aside from individual genetic information, reveals medically relevant particularities of a family, as does the family anamnesis. Once it was established that genetic information goes far beyond the results of genetic testing and in a lot of cases even makes these tests redundant, it became clear that (individual) genetic information is (personal and) family anamnesis. The open-access-family history models does not distinguish genetic information and family history. Any information about an individual's health status, such as allergies, adverse drug reactions, or chronic diseases, can be detected both by undergoing genetic testing and observing the patterns in biological relatives' health. Once the same items are prevented from being classified under different tags, a great number of repetitive laboratory tests and medical procedures can be avoided to optimize the diagnostics and the costs of maintaining the healthcare system. In the long run, this proposal can help economize the budget by saving the healthcare system from redundant spending. Health is one of the most important values together with life, yet the healthcare system is usually underfunded, overloaded and can easily collapse under unforeseen circumstances, as exemplified by the novel coronavirus pandemic between 2019 and 2021. There are other possible objections to the system, which can be overcome. After all, analysis has shown that, at least in the chosen jurisdictions, long-term benefits from redesigning the medical system outweigh the costs.

The model can be implemented gradually. Ideally, it needs to work on a national scale. At the same time, it is possible to start from regions and to combine them as the work progresses. What is most important is to elaborate the same for all participating regions, be it within one country or within one geopolitical region. This requires joint efforts from all parties – the state, the medical personnel, and the patients. The latter in particular should be motivated to collaborate and to take an active role in developing the healthcare system.

Switching to family-based or group-based initiatives in medical care will definitely affect other areas as well. The closest to the healthcare industry is research. Even though research and routine medical care have different goals and priorities, the status of a patient and of a study participant is somewhat similar. Research involving genetic and genomic testing, like genetic diagnostics in

health care, has consequences for others beyond the person who is being tested. However, while in healthcare patients and their families receive direct health-related benefits from sharing their information with other relatives, their physicians, etc., in research even the study participant might not receive a direct benefit from participation, while the information collected for the study is used for the purpose of research anyway. Often, the study participant cannot control their own data, not to mention that of their biological relatives. For this reason, it is important to link family-based and group-based approach to medical care with research as well.

Implementation of this alternative approach to health care cannot be achieved without regulatory work. Healthcare relationships fall under the scope of various branches of law. Therefore, some legal norms will need to be adjusted to reflect and to facilitate the practice. The improvements are more technical in nature, rather than fundamental, as the concept of genetic privacy, in its essence, is based on fundamental legal principles.

CONCLUSIONS

The main hypothesis presented in this work was that genetic privacy extends beyond the scope of individual rights, and rather affects a wider range of individuals, that is, all biological relatives from a given genetic family. We have demonstrated in this research that, under current circumstances, individuals are not guaranteed the right to access the whole information about their own health. The reason for this limitation is that a considerable portion of medical data is not covered by this right as it is considered private information of others and stays confidential. This approach to privacy regulation resulted in a serious limitation of individual autonomy. On the contrary, conceptualizing genetic privacy on a group level allows not only to resolve, but also to avoid the conflict between the interests of a patient and his/her family members.

1. The analysis of the history of patient's rights, especially how the idea of privacy developed in health care, has revealed that during the last decades the law and the needs of individuals involved in medical care went in separate directions. Even though, physicians and, later, courts, have already been protecting patient privacy for centuries, only relatively recently has the patient become completely "detached" from the family. History has testified to a logical shift from a physician's professional commitment to maintain confidentiality of patient's information to a patient's right backed by a correlative duty of a physician. Hippocratic view of confidentiality, that served for a very long time, was based on the physician's judgment which could also result in exception, when the physician decided that for the patient's interest it was better to discuss the illness with the family instead of the patient.

2. Modern patient-physician relationship almost does not permit for such a therapeutic privilege and presumes the same level of privacy for all patients. Aside from all advantages, this individualistic model of medical confidentiality excluded direct participation of relatives in patient-physician relationship, which seems to be somewhat counterproductive considering the importance of heredity in medical anamnesis.

3. The necessity of changes in the prevailing approach to privacy regulation was endorsed by a comparative analysis of modern legislation in Spain, Switzerland, the United Kingdom, and the United States. The study of legal documents specific to genetics reaffirmed the discrepancy

between the law and science. While there are numerous laws regulating the circulation of genetic information, there is no consensus on what genetic information is. The analyzed legal systems provide similar rights to patients within their jurisdiction, including the right to privacy. Nevertheless, the absence of a definition of the object of this right raised concerns about the practicality of privacy laws.

4. Having compared the definitions of genetic information provided at the international and national levels, we have identified the issues to be addressed and taking them into account, proposed a comprehensive definition of genetic information to be used for data protection purposes. This definition reflected the idea of familial nature of genetic information, at the same time rejecting its special status. We have demonstrated that genetic information is not different from medical information in general. It represents a block of medical information that has been called "family anamnesis" for thousands of years. Thus, implementation of genetic technologies into health care explained and proved the assumptions of the physicians throughout the history of medicine about the importance of this tool for diagnostics and treatment. However, this breakthrough was not reflected fully by privacy laws, as they still treat all health-related information without considering the interests of the index patient's family.

5. Instead of opposing genetic information to other medical information, it is more practical to distinguish genetic information and individual genetic information. Perhaps, it will take more time for medical research to shed a light on where exactly to draw the line. Nevertheless, scientists are finding patterns of heritability for an increasing number of diseases. This means that the volume of information that should be available to the whole family is far greater than what is available now. This kind of information is an indispensable tool in the context of medical decision-making process of every member of a genetic family. The concept of autonomy in health care has been interweaving with the concept of privacy throughout the history of patient rights. In fact, privacy in health care, not only informational but also bodily, spring from the principle of autonomy in the sense that a physician cannot examine a patient unless there is an informed consent provided by the latter and cannot disclose information unless the patient allows the disclosure. However, under these circumstances, it is nearly impossible to make a truly autonomous decision while having access only to fragments of relevant data.

6. Having compared laws and regulations of selected countries, we identified that the lawmakers have chosen to follow the path towards restriction of privacy. This tendency has been traced in modern society for a while. In all countries analyzed, the access of the patient's relatives to genetic information is considered an exception to the patient's right to privacy. On the one hand, it may seem that privacy is protected strongly unless there are prevailing interests, usually matter of life and death, of the patient's relatives. On the other hand, adding another exception to the right may not necessarily guarantee the best protection.

7. Using the analogy of regulating privacy when applying new technologies outside of health care, such as Internet and surveillance, we viewed the current approach to privacy in health care to be another step towards the end of privacy. By treating genetic information as being personal to the patient and denying the patient's family the access does not provide better protection, but rather, makes each party more vulnerable. As genetic information can reveal facts about more than one individual, it is very imprudent to presume individual authority of disposal of such information. Disclosure of genetic information is fraught with adverse consequences such as discrimination. Under the current approach to privacy regulation, the fate of the health of the whole family may rest in the hands of the index patient.

8. This situation proved that in reality, the conflict between patient privacy and patient's relatives' autonomy is merely the tip of the iceberg. Individuals are not only deprived of their right to know their health-related information, but they are also unable to protect this information if it was derived from someone else in the family. In this case, neither the patient, nor his/her family are sufficiently protected through the system of individual rights. The scale of blind spot not protected by individual privacy forces us to enrich our approach to privacy.

9. To adapt the regulations to the current needs of the society, especially in health care, we defined the content of the right to genetic privacy. Bearing in mind all skepticism regarding the concept of collective or group rights, we, however, argued that this approach is capable of providing the balance needed to regulate privacy. Having analyzed the object of genetic privacy – genetic information – from the point of view of classifications of goods, we demonstrated that majority of medical information share similarities with non-individual goods. Based on this finding, we conceptualized the right to genetic privacy at the group level, implying a genetic group, or genetic

family, to be a right holder. Genetic privacy concerns the sharing of familial health-related information that takes place within a defined circle of relatives. Instead of opposing this "group" right to genetic privacy to individual rights of blood relatives, we proposed that this right serves as an extra level of protection of individual rights.

10. The content of the right to genetic privacy proved that it cannot be viewed as an "over-right", or more important than the rights of individual members of a genetic family. This right of a genetic group can be justified so that individuals are sure that their individual privacy is not called into question. As it reflects exclusively the relationship within the group regarding their common medical information, there is no possibility of the individual privacy of each member being jeopardized for the sake of the group. This concept should not be suitable for use by an individual to achieve his/her own interests at the expense of the rest of the group.

11. In this context, we have studied the professional liability of medical professionals, as well as the mutual obligations of relatives, and have proposed its limits. The analysis of case law showed that healthcare professionals, especially in the U.S., have been facing considerable difficulties in balancing their obligation of confidentiality and duty to warn. We found the examples of expanding duty of care towards an unlimited number of family members to be onerous and impeding the main obligation of healthcare professionals – to provide the best possible medical care. At the same time, we found that there is no sufficient ground to burden biological relatives with such a counter-obligation. For this reason, we recommend abandoning the scenarios proposed by current regulations while accepting the extension of professional duty only within family-centered care, if it is available.

12. These theoretical suggestions can be applied in practice through the open-access-family-history model and the two-tier electronic health record system that we have designed. Given that there are examples of unified health record systems, we conclude that the proposed model would be logistically feasible to implement such a system. There are working mechanisms to guarantee the transfer and security of stored information. Despite certain challenges, our approach represents a scheme capable of increasing cooperation and allow individuals to engage in the decision-making processes about their own health, without reducing physicians' involvement. The model aims to provide patients and their family members with more control over their information while making

it accessible to healthcare professionals at the same time in order to improve the quality of care they can provide.

13. Aside from balancing the interest of patients and their families and sparing physicians from ethical conflict, this model meets the needs of technological progress. After all, the goal of medicine is to strengthen and maintain health, prolong life, and prevent and treat diseases based on scientific knowledge and practice. Careful organization of family anamnesis will eventually contribute to the development of medical care. Furthermore, it can be used to bring medical research closer to health care. A special advantage of this model is that it can serve as a prototype to reconsider privacy beyond health care as well, taking into consideration the versatility of private life of individuals.

At this point, we suggest that the open-access-family-history model would be able to resolve the existing legal, ethical, and practical problems associated with the status of genetic information. This model can be regarded as a solution to guarantee privacy and autonomy of individuals in modern health care. The two-tier record system allows to ensure the circulation of health-related information in such a way that the protection of individual privacy of the family members is reinforced by protection of genetic privacy of the family without limiting their autonomy.

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