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Civil liability for damages related to germline and embryo editing against the legal admissibility of gene editing

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ABSTRACT The creators of CRISPR-Cas9 method have turned to the world community, including lawyers, to undertake a public discussion on the implications that it can create. One of the most important problems to be resolved in the future, will be the issue of establishing very clear legal principles of compensatory liability for damages resulting from the editing of genes in human embryos and reproductive cells. It is necessary to show possible legal problems that may arise and—what is more—the fact that they will certainly appear in future legislative work in the world. Questions must be asked to which world legal experts will seek answers. And this is the goal of this paper was set—showing possible legal problems and asking questions related to liability for damages resulting from the editing of genes in human embryos and reproductive cells that will be answered in the future. The most important research questions are therefore: what is the genetic nature of the genes edition—is it a treatment whose aim is to treat infertility of parents or the future child? How to determine the scope of responsibility in the situation when it comes to the "cure" of one mutation, but there is a tendency to develop a disease in the future? What then is the scope of the doctor's duty to inform? How to qualify the editing of a gene that is not intended to cure the existing disease, but to obtain a certain specific immunity? What legal obligations will weigh on parents who decide to edit the genes of the embryo or in the preconception phase? Finally, the question arises about the time limits of this gene-editing responsibility. If we make genetic modification of hereditary nature, then will the children or grandchildren subjected to gene editing be able to make claims? In this paper, the provisions of international European law, common law and continental law on the example of Polish law have been analysed. The key findings of this paper are to show that legal problems in gene editing are not limited to answering the question whether it should be admissible or not. For this reason, the role of legal discourse, and in particular of private law, should focus on the reinterpretation of traditional compensation structures, so that they also protect the rights of people whose genome has been modified.

The newest developments in genome editing will demand that we think again about how to balance hope and fear (Caroll and Charo, 2015).

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Introduction

The development of gene therapy, in particular gene editing using the CRISPR-Cas9 method, has prompted a lively discussion around the world about how deeply you can interfere with the human genome. The creators of this method have turned to the world community, including lawyers, to undertake a public discussion of the implications that it can create (The National Academies of Sciences Engineering Medicine, 2015). The most important problem to be resolved in the future, in my opinion, will be the issue of establishing very clear legal principles of liability for damages resulting from the editing of genes in human embryos and reproductive cells. However, before this happens, it is necessary to show the possible legal problems that may arise and that will certainly appear in future legislative work in the world. Questions must be asked to which world legal experts will need to seek answers. The goal of this paper is to show the possible legal problems and ask questions related to the liability for damages resulting from the editing of genes in human embryos and reproductive cells that will be answered in the future.

Private law considerations will be based on Polish law, although it should be pointed out that the conclusions derived from them appear to be of universal nature for different legal systems. Despite the fact that legal considerations will refer to the regulation of Polish law, the subject of the analysis will also be the differences in the legal qualification of reproductive cells and embryos in other European legislations. It seems that nowhere in the world are there special regulations regarding the liability for damage related to the genetic editing of reproductive cells or embryos. Therefore, there is a need to present new challenges for classic private law institutions, such as legal abilities, torts, or liability for damages. Due to the lack of uniform European regulations and different conflicts of rights the subject of analysis will not be wrongful life and wrongful birth actions, but only claims of prenatal damage to a child.

The first major legal problem facing the international community is, of course, the question of the legal acceptability of the editing of genes of human reproductive cells and embryos (van Dijke et al., 2018). In this regard, it should be pointed out that despite the initial demand to ban such editing, over time, increasingly more scientists have pointed to the fact that it is not possible to maintain such a moratorium (Doudna and Sternberg, 2017). Jiankui's presentation at the Second International Summit on Human Genome Editing on November 27, 2018, showed that the introduction of a moratorium on genetic modifications of embryos in Europe, the condemnation of such research by a group of 120 of the greatest geneticists, even the Chinese regulations (Zhang and Lie, 2018) will not limit its conduct (Cyranoski and Ledford, 2018). Globalization of the medical market means that if any procedures are allowed on other continents, they will also become available to Europeans (Lunshof, 2016). It should be noted that even without proper legal approval some scientists in various countries intend to genetically modify embryos (Cohen, 2019).

This issue is even more important because for years, we have been observing the expansion of protection of human health in earlier stages of development both in Poland and other European countries. (Kmieciak, 2015). Across Europe, we are struggling with falling birth rates and a significant number of miscarriages caused by various foetal abnormalities, including genetic mutations (Araki and Ishii, 2014). It should therefore be assumed that as soon as geneticists and biotechnologists allow the elimination of these mutations, giving parents the chance to give birth to healthy children, lawmakers will also be forced to start working on the legalization of such therapy (Simonstein, 2017).

The controversial CRISPR-Cas9 method and new conflicts of law between protected rights

The possibilities offered by gene editing are undoubtedly very promising for the future. Gene editing can involve modifying somatic or reproductive cells. In the first case, the modification is not hereditary. The second type of modification affects not only the performance of a particular unit but also the possible transmission of this modification to subsequent generations (Sykora, 2018).

Visions regarding genetic modifications and gene therapies have been the subject of deliberations and medical activities for several years, but the discovery of the CRIPSP-Cas9 method has given rise to the greatest controversy (De Miguel Beriaina and Marcos del Cano, 2018). Undoubtedly, this is because this method allows the precise removal of a damaged gene and its replacement with the correct one. This method is much cheaper, easier, safer and faster than the ones used before. The method may be used to genetically modify plants, animals and humans. For the first time, therefore, we have a method by which we can control the randomness of the evolutionary processes in all of nature (Ishii, 2017).

The first publication about using gene editing on a person infected with HIV appeared in 2014 (Tebas et al., 2014). Then the next use of gene editing took place in the UK in 2015, where this treatment was given to a one-year old girl with leukaemia (Reardon, 2015). The treatment was carried out using immune cells derived from a donor. The application of this method to living people (on somatic cells) does not raise major controversies and is considered acceptable in the world of experimental medical treatments (van Dijke et al., 2018). However, there are more doubts about the use of this method on human reproductive cells and embryos due to the possible inheritability of the modifications made. These fears are related not so much to the possibility of a future child's health being threatened as to the transmission of such changes to the next generations and—connected to this—taking of control over the evolution of humanity, the possibility of deepening social differences, etc. (Doudna and Sternberg, 2017). However, there are opposite views indicating the moral obligation to continue research on gene editing (Savulescu et al., 2015; De Miguel et al., 2018).

The discussion on methods of genetic editing of embryos and germ cells shows the competition between two legally protected rights: the right to undertake therapy, i.e., enabling the birth of a healthy child, and the right to protect the biodiversity of future generations. This is a conflict between relatively new values and is significantly different from the "traditional" considerations regarding the prenatal stage. Until now, there was only a possibility of conflict in internal relations, i.e., between parents and a child, and not in external relations, i.e., between the child's right to health and life and the rights of future generations, as has been indicated. Traditionally, therefore, there have been indications of possible conflicts between women's rights and children's rights (this conflict has been mainly analysed in relation to the termination of pregnancy and medically assisted procreation procedures) (Davey, 1989) and the rights of a man (father) and the rights of a child/woman regarding the right not to consent to the implanting of the embryo (Cohen, 2010).

In the field of gene editing of embryos and the human germline, this conflict directly translates into the classic division between the good of humanity and the good of the individual (Agar, 2019).

International legal regulations and international community's opinions on gene therapy in embryos and reproductive cells

It is widely recognized that both the majority of the European legislation and acts of international law prohibit genetic

modification of human embryos (Ishii, 2017; Charo, 2016). Further analysis will show that this prohibition is not absolute. The only definitive ban can be based on art. 90 al. 2 of the new Regulation no. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC that was not yet transposed to the member states of the European Union (Howard et al., 2018). However, this article does not seem to ban all types of gene editing but only those that alter "the subject's germ line genetic identity". This prohibition is also present in the art 9 of Directive 2001/20/EC of The European Parliament and of The Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

The first act of international law in this area is the Universal Declaration on the Human Genome and Human Rights of United Nations Educational, Scientific and Cultural Organization (UNESCO). The declaration has no subjective limitations and due to its nature, it refers not only to the protection of living human beings but also to the protection of humanity as such, including future generations.

The declaration permits modifications of the human genome, specifying in art. 12 that everyone should have access to achievements in the field of genetics and medicine related to the human genome. The content of the declaration shows that modifications of the human genome can be carried out for health and scientific purposes. It seems that in both cases, according to art. 12 b, we should aim to relieve suffering and improve the health of individuals and humanity as such.

In addition, it should be pointed out that the UNESCO declaration does not prohibit genetic modification of human embryos but restricts the possibility of such modifications in reproductive cells. According to article 24, interventions regarding the germ cell line may (but not need) be considered as practices that "could be contrary to human dignity". It should be emphasized that the regulation of article 24 therefore differs from Article 11 of the declaration, which explicitly prohibits the use of reproductive cloning as a practice contrary to human dignity. Therefore, it cannot be categorically indicated that according to the declaration, any form of genetic interference in reproductive cells is unacceptable; on the contrary, it must be recognized that such interference is possible and does not have to be a threat to human dignity (humanity). In addition, it should be noted that pursuant to article 24 of the declaration, the UNESCO International Bioethics Committee should present recommendations and guidelines on the application of the declaration, presumably also with regard to genetic interference in the germline.

The lack of a complete ban on gene editing makes it possible to recognize the right of a person, as expressed in article 8 of the declaration, to be compensated for losses caused by direct and decisive interference in his or her genome.

Another legal act relating to the recognition of the genome as a common good is the Bioethical Convention (The 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 No. 164, so-called Oviedo Convention). According to its article 13, an intervention aimed at making changes in the human genome can only be carried out for prophylactic, therapeutic or diagnostic purposes when its aim is not to cause hereditary genetic changes in the offspring. As pointed out by Sykora and Caplan (2017), one can argue that the ban on germline gene therapy in article 13 is in contradiction with one of the motivations of the Oviedo Convention: that progress in biomedicine would be used solely for the benefit of future generations". Nevertheless in 2015, the International Bioethics Committee called on the member states to adopt a joint temporary moratorium on germline editing. According to point 46 of the report "Updating its Reflection on the Human Genome and Human Rights", the reasons for a ban on gene editing are the "uncertainties on the effect of germline modification on the future generations".

With this formulation of the Oviedo Convention, it seems necessary to interpret the very concept of purpose; if the purpose of the intervention is to "repair" the genome of the embryo or reproductive cells, causing the possible transmission of these modifications to subsequent generations, can it be concluded that the inheritance of these changes is the goal of the intervention or only a side effect that we know of? This is important in the context of article 1 of the convention, which shows that the main purpose of the convention is the protection of individual rights. I do not find any justification for the view presented in the literature that this prohibition also applies to the "modification of the genome of spermatozoids and oocytes intended for fertilization". In my opinion, it is impossible to explicitly exclude such an interpretation of article 13 of the convention, according to which interventions aimed at a significant therapeutic or prophylactic goal for the individual should be treated differently from those whose main purpose is to cause changes in the offspring. In the first case, it should be pointed out that because the primary purpose is to protect the health and life of the future child embryo, such interventions cannot be considered contrary to the convention (Sykora Peter and Caplan Arthur, 2017). According to de Miguel Beriain et al. (2019) article 13 of Oviedo Convection prohibits only clinical applications of germline gene editing. They forecast that there will be new redaction of Article 13 that allows clinical use of germline gene editing.

There is also no general prohibition on gene editing in the Charter of Fundamental Rights of the European Union. There is no doubt that the charter indicates a total ban on all eugenic practices, but in a situation in which gene editing is to be used for therapeutic purposes, it is difficult to clearly interpret such a prohibition.

According to point 40 of the preamble of the directive on the legal protection of biotechnological interventions of the European Parliament and the Council of the European Union, there are prohibitions on the patentability of processes modifying the germline genetic identity of human beings, and germline gene editing is treated as an offence against public order and morality.

According to the recommendations of the German Ethics Council from the 9th of May 2019, a temporary ban on gene editing of the human germline is also needed. The temporality of this prohibition is justified, among others, by the fact that genome editing is a very young field of research and that only two cases are known in which intervention in the germline to prevent polygenic and multifactorial disease would have any chance of success. According to point 99 of the executive summary of the recommendations, it will be possible to use germline gene editing only if the technology is sufficiently safe, effective and tolerable. In the executive summary of the recommendations, it is pointed out that "Germline interventions will presumably change the network of relationships between the members of a society". However, the "ethical concepts of the protection of life, of freedom and of beneficence suggest some a duty to permit such interventions". Based on point 4 of recommendations, the moratorium should undergo a regular transparent review. International groups of ethicists and researchers also call for a global but not permanent moratorium, including some of those who originally developed CRISPR-Cas9 as a gene-editing tool (Lander et al., 2019).

The Nuffield Council on Bioethics recommends that heritable genome editing interventions should only be permitted provided that arrangements are in place to monitor the effects on those

whose interests can be collaterally affected and on society more generally and provided that effective mechanisms are in place to redress any such effects (The Nuffield Council on Bioethics, 2018).

The report of an international committee convened by the U.S. National Academy of Sciences (NAS) and the National Academy of Medicine in Washington, DC, concludes that human embryo editing "might be permitted, but only following much more research" on risks and benefits and "only for compelling reasons and under strict oversight". The U.S. government prohibits the use of federal funding for research involving human embryos. However, gene editing of human embryos can be performed using private funding. The Food and Drug Administration is barred from considering any studies that would involve using genetically modified human embryos to create a pregnancy. However, laws that govern the creation of genetically modified babies vary widely internationally.

The analysis clearly shows that there are still no definitive prohibitions on gene editing of embryos or the germline. Existing prohibitions have a temporary character that protects the permissiveness of such operations before they are better known and safe (Nordberg et al., 2019). S. Holm indicates that the concept "only when it is safe" can be deceptive and hides "the full implications of the arguments made about ethics of gene editing and their underlying philosophical justifications" (Holm, 2018). Transferring these doubts to private law, one should ask questions about the legal nature of such treatment.

The legal nature of germline and embryo gene editing

Legal regulations regarding gene editing of embryos and reproductive cells can be found in legal acts regarding clinical trials, biomedical research (EU Regulation), medically assisted procreation procedures or codes of medical ethics. The first method of regulation has already been discussed above, and it refers to the public law regulation answering the question of whether such a procedure should be prohibited. The second and third refer to the personal rights of the patient and thus to private law.

Such legal solutions will be discussed on the basis of Polish law. However, it should be noted that in this respect Polish law is modelled on the Oviedo Convention (Haberko, 2016) and is therefore not significantly different from the regulations adopted by other European countries.

In Polish law, two acts can be pointed out that directly refer to genetic modifications. The first is the act on the treatment of infertility, and the second is the code of medical ethics.

According to article 25 para. 2 of the act on the treatment of infertility (Ustawa o leczeniu niepłodności Ustawa z dnia 26 czerwca 2015 r. o leczeniu niepłodności), "(n) creation with the use of techniques for the medically assisted procreation of chimeras and hybrids and intervention aimed at making inheritable changes in the human genome that can be passed on to next generations is not allowed". A fundamental question arises here about the interpretation of this norm and its *ratio legis* that guides the legislator. Assuming the rationality of this legislator, it should be recognized that the lawmaker did not forbid the editing of genes with the preceding technique for assisted procreation but only forbids the type of intervention which can be passed on to future generations.

Analysing in depth the content of article 25 para. 2, it should be pointed out that two models of interpretation are possible. The first would lead to the conclusion that the act on the treatment of infertility is more restrictive than the Bioethical Convention and that it prohibits any genetic modification that may (or not, as the convention indicates "are intended") change the offspring. An open question arises in this respect: what does the term "may" mean? Is it possible, according to current knowledge, that modifications will appear in the offspring or that on the contrary, modifications are forbidden because theoretically we cannot exclude their hereditary nature, although we lack evidence for their heredity?

The second model of linguistic interpretation would hold that because gene editing is not a technique of assisted procreation, the prohibition does not apply to it. Such an interpretation would be consistent with article 4 of the act, assuming that "infertility treatment is carried out (…) with particular emphasis on the legal protection of life, health, good and the rights of the child". Therefore, it is difficult to argue that a situation where genetic modification would allow the birth of a healthy child could be covered by the prohibition in article 25.

Again, an open question arises—in a situation where the main purpose of the modification is to remove from a particular embryo a particular mutation and the secondary goal is to transfer the modified gene to the next generations, is prohibiting such practices justified?

Referring to the Code of Medical Ethics (Kodeks Etyki Lekarskiej), it should be pointed out that pursuant to article 51 par. 4, "(l) the doctor may not participate in activities aimed at inducing hereditary genetic changes in a human being". Assuming that in most cases genetic modification will be done by a geneticist, not a doctor, the regulation of the code will not apply to the medical practitioner. In such cases, gene editing will be qualified as a medical experiment and will require, among others, the opinion of the bioethics commission.

Summarizing this part of the considerations, it should be emphasized that it is extremely difficult to unequivocally indicate that Polish law prohibits gene editing of embryos and germline cells. In Poland, no such modifications have been carried out. There is no doubt, however, that in the coming years, we will also face the dilemma as to whether to destroy embryos that due to their genetic mutations cannot be implanted in a woman's body or whether to treat them with the help of gene editing. The question then arises as to whether a child or his or her parents will have claims to compensation and if so to whom, if gene therapy causes harm to the child or if it is not performed despite its availability.

Legal classification of genetic modifications of human embryos and reproductive cells

At the beginning of the second part of the study, the following questions should be asked: who would be the patient in a situation where genetic modifications were made to reproductive cells and would such modifications be considered a medical procedure?

To answer these questions, the legal status of human germ cells and embryos should be determined. In many European legislations the term embryo is defined by law of medically assisted procreation. However, *nasciturus* is the term of traditional civil law based on Roman's origin law. In some countries there is a debate as to whether it is possible to extend the concept of *nasciturus* to the embryo (Cacace, 2013). In Polish law, the term embryo has been defined as a group of cells formed as a result of the extracorporeal connection of the female and male reproductive cells, from the end of the process of fusion of the germ cells (karyogamy) to implantation in the endometrium witch is a stage without legal personality. After the implementation in the endometrium the embryo is considered to be a *nasciturus* and a potential human who has conditional legal capacity. The doctrine indicates that despite the lack of explicit statutory regulation in the field of compensation for damages, the embryo should be considered a *nasciturus*. In reference to cells of human origin, in

the absence of explicit statutory regulation, it is postulated to consider them as the subject of law (*res* with a very limited turnover).

Similarly, it should be pointed out that the issue of the status of human body parts in various European countries raises a lot of controversy. In Italian law, it can be indicated that the recognition of whether a given element can be protected by legal claims or by the protection of personal rights depends on the nature of the body parts and the purpose for which they were disconnected from the human body. As De Cupis (1985) points out, parts detached from the human body, the disconnection of which is not associated with irreversible damage to the body, become movable goods that can be disposed of with certain restrictions arising from article 5 of *codice civile* (Civil Code Regio Decreto 16 marzo 1942, n. 262 (G. U. n. 79 del 4-4-1942)). It should be noted that things (*beni*) within the meaning of article 810 c.c. are things that can be subject to rights. According to this theory, parts of the human body become things when they become detached from the body.

As in Polish law, the Italian Civil Code uses the concept of *nasciturus*, guaranteeing, for example, rights related to inheritance, and the concept of embryo was specified in the Act on Medically Assisted Procreation Legge 19 febbraio 2004, n 40, Norme in materia di procreazione medicalmente assistita (l.40/2004).

The German jurist Wolf (Simić, 2018) stated: "Research into the civil law confirmed that *nasciturus* does have legal personality", concluding that *nasciturus*, as a legal subject can suffer harm to his/her health. According to the German Civil Code, in order to provide future right to support, it is possible to obtain a temporary order in favour of *nasciturus* and in the order to preserve his/her future rights, it is possible to appoint his/her a guardian".

Initially, in Great Britain there was no doubt that the human body or even a human being could be the object of property, the best proof of which was slavery and feudal relations. This view was maintained until the beginning of the 19th century, i.e. until the abolition of slavery, although in jurisprudence it had aroused much controversy (Nwabueze, 2007). It should be noted that English positive law does not de facto determine the legal status of the human body, leaving the regulation to case-law. The general principle arising from common law is therefore the recognition that it has no property on the human body, but the development of medical science and commercialization of scientific research results have led the jurisprudence to create many exceptions to this principle. Referring to the subject of reproductive cells, the courts often referred to exceptions to the rule of no property on human body. The admissibility of qualifying male semen as an object of property rights was indicated (R v. Welsh (1974) RTR478).

Under Polish law, all relations between the patient and healthcare service providers are regulated by civil law obligations (Borysiak, 2019).

There is no doubt that as long as the cells are in the human body, they share its legal status (Krekora-Zając The legal … 2015a, 2015b). This means, therefore, that in a situation where reproductive cells are genetically modified, the patient is the person from whom they originate. Regarding this treatment, it should be pointed out that the therapeutic goal is reproductive cell therapy aimed at the treatment of infertility. Despite its title, the act does not apply to every infertility treatment. Gene modifications of reproductive cells would only be acceptable if the mutations held by these cells could not lead to the conception and birth of a child before the modification was applied. I am referring to the most serious diseases that cause infertility or a high risk of foetal death (or spontaneous abortion). There is no doubt, that the concept of serious illnesses has not been defined, and as Kleiderman et al. (2019) show it can be interpreted differently and based on objective criteria (morbidity) or flexible and evolving elements (disability as impacted by social arrangements or treatability as impacted by effectiveness and cost of the treatment).

The situation would look differently if the occurrence of a genetic disease did not cause a foetus to die (or its non-existence) or cause the birth of a sick child. It is difficult to stipulate that such a treatment that affects the genotype is therapeutic for the patient who is a cell donor. Is it possible to indicate that in this regard the doctor performs a medical treatment for a future legal person, that is, the person who the child will become? The answer to this question is not easy, although some proponents of the doctrine indicate that legal subjectivity is not a feature that determines the status of a patient. Traditionally, however, the subject of consideration was the legal nature of *nasciturus*, the embryo, and not the reproductive cells from which it would arise. Karkowska (2010) explicitly indicates that an unborn child has the right to the protection of his or her life and health, although due to the lack of legal capacity, he or she is not subject to all patients' rights. In turn, according to Kmiciak (2018), "(n) I doubt that a child conceived de facto is automatically put in the "position" of the patient." In the opinion of Gałązka (2018), the very fact of conception with the help of medically assisted procreation is a sui generis medical procedure whereby one of the patients is a future child.

Since most of the doctrine's proponents detach the state of being a patient from being a legal entity, pointing to the separateness of the rights of the future child in relation to the mother, it must be assumed that in the field of genetic modification of human cells and embryos, we can also determine such rights of the future child (Karkowska, 2010; Kmiecika, 2018, Gałązka, 2018). At the same time, it should be emphasized that such a view seems more justified/unmistakable in the cases discussed here than in the case of "traditional" procedures on the *nasciturus* because treatments on the embryo and reproductive cells are performed on a separate being without interfering with a woman's body. Of course the procedure precedes the collection of cells from the body but genetic modification is performed on a cell taken from the woman's body.

Prenatal damage and preconception injures

Prenatal damage was directly defined in article 446^1 of the Polish civil code (c.c.). Similar regulations exist in many European countries (Simić, 2018). This regulation has made it possible for a child to claim damages for the damage that he or she has suffered before birth. Using the language interpretation, it should be noted that art. 446^1 c.c. does not indicate the child's right to claim for damages caused only during pregnancy. In my opinion, there are no grounds for limiting the scope of article 446^1 c.c. to only the damage that has occurred since the conception of the child. Moreover, it should be pointed out that in situations where the legislator wants to link permission with the "status" of the *nasciturus*, this directly defines the status in the regulation. For example, it can be pointed out that such a referral can be found in article 927 § 2 c.c. (a child already conceived). I therefore accept that article 446^1 c.c. is the basis for a child's claims related to events that arose during foetal life as well as during preconception.

In her article, Wojtaszek (1990) aptly pointed out that legal subjectivity matters only when the claim is made and that compensation for preconception damage is subject to damage consisting in a health disorder. The author, referring to the views of Rezler, indicates that unlawfulness is a feature of a cause and may be a future violation of the legally protected interests of an entity that is to be created in the future.

Preconception damages have traditionally been combined with damages that are de facto suffered by the mother of the child and that are only secondary in terms of the child, in contrast to prenatal damage, in regard to which Kaliński (2018) aptly points out that "an act directed against the mother is also an act directly aimed at the child".

The procedures of assisted procreation and genetic modification of human reproductive cells have shown, however, that it is possible to cause damage that will only become apparent after the birth of the child and that will not be damage done to the mother. This issue is not only related to genetic modification but also occurs in relation to mistakes in the in vitro procedure, e.g., in situations where the implantation of a non-maternal embryo is done (Krekora-Zając W świetle… 2015a, 2015b).

Another problem that can arise with regard to legal subjectivity is the argument of identity (Soniewicka, 2018). It is difficult to indicate the possibility of pursuing claims showing the guilt of the doctor (Article 415 of the Polish Civil Code). It will also be difficult to indicate the causal relationship between the damage and the event.

An example of such a situation may be the correction of both mutated copies of the gene encoding beta-globin in people with sickle cell of anaemia, which will relieve them of the disease but deprive them of the mutation's protection against malaria. When such a child develops malaria, it will be difficult to prove that the immediate cause was the modification, not the mosquito infection. Such a relationship can be demonstrated in two cases: first, in a situation where the child has a high probability of contact with malaria, e.g., living in an area where this disease occurs, and second, in a situation where the doctor/legal guardian did not fulfil the information obligation towards the parents/child.

Even greater doubts may arise when the gene is not edited to cure the existing disease but to obtain a certain specific immunity. Therefore, this case is about making a modification that has no therapeutic purpose and that is preventive. It is well known that a modification in the CCR5 gene (a similar modification has just been carried out by He Jiankui) causes resistance to HIV but increases the probability of becoming sick (susceptibility to a virus) with the West Nile fever. Undoubtedly, for the legality of such a medical experiment, a comparison of benefits and risks will be required. However, the question remains open whether a child who is ill with West Nile fever will have a claim against the entity that made these modifications. As in the previous case, will we be able to indicate an adequate causal relationship between the event and the damage?

Another problem is identifying the entity responsible for the damage. Fundamental in this respect is the problem of the responsibility of the parents who would agree to such a modification. It seems unresolved whether pursuant to article 441 c.c. they will become entities jointly and severally liable and whether in general they are entitled to give such consent. These issues are directly related to the rights and obligations of future parents towards future children and the legal status of the human embryo and reproductive cells. There is no doubt that it can be problematic to justify blaming the parents (the classic association of guilt in supervision). According to R. Scott (2000) there are very restrictive limitations to a duty of care toward an unborn child. First, it is doubtful whether there would be a legal basis for the consent of future parents. Indeed, it cannot be said that by agreeing the parents would be making decisions that fall under parental authority, which would arise only if the child was born. Therefore, it would be possible to consider their responsibility only when the parental authority was also extended to the prenatal period. Second, according to the current legal doctrine, there are no cases in which consent to a child's legal medical procedure could be the basis of parents' responsibility.

Another important threat associated with gene editing is the right to privacy and autonomy. Many scientists indicate that children who were conceived from genetically modified cells or from embryos subjected to gene editing should be monitored for a long time (Ishii and de Miguel Berian, 2019).

Finally, a question arises about the time limits on this responsibility. According to art. 442^1 c.c. the limitation of claims by a minor for remedying a person's injury cannot end before the expiration of 2 years from the date when he or she reaches the age of majority. If we make a genetic modification of a hereditary nature, will the children or grandchildren of the subject whose genome had been subjected to gene editing be able to make claims? It seems that responsibility will always be limited by the *sine qua non* premise and an adequate causal relationship. At the current level of knowledge, we can indicate that the genome of each new generation will result not only from a single modification but also from subsequent modifications associated with environmental and associated changes that will naturally arise as a result of conception. However, it cannot be ruled out that in the future, as genetics develop, this reasoning should be rejected.

Conclusions

The belief that legal regulation will prohibit the editing of human genes seems illusory. As pointed out by Łętowska (2018), the faith that the law will secure all possibilities is an illusion. It can help a little, but it will not change the world. For this reason, the legal discourse, and in particular private law, should be focused on the reinterpretation of traditional compensation structures so that they can also protect the rights of people whose genome has been modified. Today, it is too early to formulate such solutions. It seems that the aim of the discussion, including the legal one, should be to indicate problems in the area of liability for damages, which is relevant not only for us as lawyers but also for us as people (Savulescu et al., 2015). This discussion should take place even if today we believe that the clinical use of gene editing is premature and irresponsible (Team of experts from the Polish Episcopate for bioethical matters 2016) and we have a lot of doubts related to using gene editing to human enhancement (Soniewicka and Lewandowski, 2019).

The ability to edit genes creates some new legal problems but also forces legal reconsiderations of previously existing issues, ultimately unresolved by law and lawyers, such as the legal status of the embryo and sex cells and the rights and duties of future parents, especially in the period before conception (Sykora, 2018).

As I pointed out in the "Introduction", this paper did not aim to solve these problems—which is a long-term process—but aimed only to show the problems to start the discussion.

Data availability

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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References

Agar N (2019) Why we should defend gene editing as eugenics. Camb Q Healthc Ethics 28:9–19. https://www.cambridge.org/core/journals/cambridge-quarterly-of-healthcare-ethics/article/why-we-should-defend-gene-editing-as-eugenics/00B15AEB625379F8543C43E286160B87

Araki M, Ishii T (2014) International regulatory landscape and integration of corrective genome editing into in vitro fertilization. Reprod Biol Endocrinol 12:108. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4251934

Borysiak W (2019) Freedom of contract in the medical legal relationship. Stud Prawa Prywatnego 52:71–82. https://czasopisma.beck.pl/studia-prawa-prywatnego/artykul/freedom-of-contract-in-the-medical-legal-relationship/

Cacace S (2013) Identità e Statuto Dell'embrione Umano: Soggetto di Diritto/Oggetto Di Tutela? Riv Ital Med Leg (e del Diritto in campo sanitario) 4:1736–1751.

https://www.iusexplorer.it/Rivista/Rivista_Italiana_di_Medicina_Legale/Identità_e_statuto_dell'embrione_u?IdDatabanks=144&IdDocMaster=4087732
Caroll D, Charo RA (2015) The societal opportunities and challenges of genome editing. Genome Biol 16:242
Charo RA (2016) The legal and regulatory context for human gene editing. Issues Sci Technol 32. https://issues.org/the-legal-and-regulatory-context-for-human-gene-editing/. Accessed 22 July 2019
Charter of Fundamental Rights of the European Union (OJ C 364/1). https://www.europarl.europa.eu/charter/pdf/text_en.pdf
Codice Civile Regio Decreto 16 marzo 1942, n. 262 (G. U. n. 79 del 4-4-1942). https://www.gazzettaufficiale.it/anteprima/codici/codiceCivile
Cohen G (2010) The right not to be a genetic parent? South Calif Law Rev 81:1115–1196. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1116269
Cohen J (2019) Russian geneticist answers challenges to his plan to make gene-edited babies. Science (advance online publication 12 June). https://doi.org/10.1126/science.aay3879
The 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 No. 164). https://rm.coe.int/16808ff399
De Cupis A (1985) I diritti della personalità. In: Cicu A, Messineo F (ed) Trattato di diritto civile e comerciale. Milano, p. 159
Cyranoski D, Ledford H (2018) Genome-edited baby claim provokes international outcry. *Nature* (advance online publication November). https://doi.org/10.1038/d41586-018-07545-0
Davey DA (1989) The right to be born. Med Law 7(5):475–482
De Miguel Beriain I, Marcos del Cano AM (2018) Gene editing in human embryos. A comment on the Ethical Issues Involved. In: Soniewicka M (ed) The ethics of reproductive, philosophy and medicine, vol. 128. Springer, Cham, pp. 173–187
Van Dijke I, Bosch L, Bredenoord AL, Cornel M, Repping S, Hendriks S (2018) The ethics of clinical applications of germline genome modification: a systematic review of reasons. Hum Reprod 9(33):1777–1796. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6454467/
Directive 2001/20/EC of The European Parliament and of The Council of 4 April 2001on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34). https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf
Doudna JA, Sternberg SH (2017) A crack in creation: gene editing and the unthinkable power to control evolution. Houghton Mifflin Harcourt, Houghton
Gałązka M (2018) Świadczenia zdrowotne wspomagające prokreację. In: Bosek L, Wnukiewicz-Kozłowska A (ed) System Prawa Medycznego. Szczególne świadczenia zdrowotne, vol. 2. C.H. Beck, Warsaw, p. 138
German Civil Code BGB 2002 (FLG I p. 738). https://www.gesetze-im-internet.de/englisch_bgb/englisch_bgb.pdf
German Ethics Council (2019) Intervening in the human germline opinion Executive summary & recommendations. https://www.ethikrat.org/en/press-releases/2019/ethics-council-germline-interventions-currently-too-risky-but-not-ethically-out-of-the-question/. Accessed 22nd July 2019
Haberko J (2016) Ustawa o leczeniu niepłodności. Komentarz. Wolters Kluwer Polska, Warsaw
Holm S (2018) Let us assume that gene editing is safe-the role of safety arguments in the gene editing debate. Camb Q Healthc Eth 28:110–111. https://www.cambridge.org/core/journals/cambridge-quarterly-of-healthcare-ethics/article/let-us-assume-that-gene-editing-is-safethe-role-of-safety-arguments-in-the-gene-editing-debate/E760EB3B2463C32DF5F08DEE2F39AF0E
Howard HC, van El CG, Forzano F, Radojkovic D, Rial-Sebbag E, de wert G, Borry P, Cornel MC (2018) One small edit for humans, one giant edit for humankind? Points and questions to consider for a responsible way forward for gene editing humans. Eur J Hum Genet 26:1–11. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5839051/
International Bioethics Committee UNESCO (2015) Report of the IBC on updating its reflection on the Human Genome and Human Rights. https://unesdoc.unesco.org/ark:/48223/pf0000233258. Accessed 22 Jul 2019
Ishii T (2017) Germ line genome editing in clinics: the approaches, objective and global society. Brief Funct Genomics 16(1):46–56. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5291189/
Ishii T, de Miguel Beriain I (2019) Safety of germline genome editing for genetically related "future" children as perceived by parents. CRISPR J (published online 19 Nov 2019). https://doi.org/10.1089/crispr.2019.0010
Kaliński M (2018) Odpowiedzialność odszkodowawcza. In: Olejniczak A (ed.) System Prawa Prywatnego. Prawo zobowiązań-część ogólna. C. H. Beck, Warsaw, pp. 48–49
Karkowska D (2010) Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Komentarz, Wolters Kluwer Polska, Warsaw
Kmieciak B (2015) W stronę chirurgii zarodka. Socjoprawne aspekty innowacyjnych technik wspomaganego rozrodu. Ethics Prog 6(1):141–153
Kmiciak B (2018) Pacjent i jego status prawny. In: Kubiak R, Kubicki L (eds) System Prawa Medycznego. Pojęcie, źródła i zakres prawa medycznego. Tom I. Wolters Kluwer Polska, Warsaw, p. 156
Kleiderman E, Ravitsky V, Knoppers BM (2019) The 'serious' factor in germline modification J Med Eth 45:508–513. https://jme.bmj.com/content/45/8/508
Kodeks Etyki Lekarskiej. https://www.nil.org.pl/__data/assets/pdf_file/0003/4764/Kodeks-Etyki-Lekarskiej.pdf
Krekora-Zając (2015a) The legal status of human biological samples used in research purposes. Stud Prawnicze 203:89–134. http://cejsh.icm.edu.pl/cejsh/element/bwmeta1.element.desklight-04af6bb2-cfd7-489d-8607-e81cd9dcd31f
Krekora-Zając (2015b) W świetle prawa matka jest pewna, ale …, *Gazeta Prawna* 27.02.2015. https://prawo.gazetaprawna.pl/artykuly/855751,w-swietle-prawa-matka-jest-pewna-ale-sa-pewne-wyjatki.html
Lander E, Baylis F, Zhang F, Charpentier E, Berg P, Baurgain C, Friedrich B, Joung JK Li. J, Liu D, Naldino L, Nie J-B, Qui R, Schoene-seifer B, Shao F, Terry S, Wei W, Wunnacker E-L (2019) Adopt a moratorium on heritable genome editing. *Nature* (advance online publication 13 March). https://doi.org/10.1038/d41586-019-00726-5
Legge 19 febbraio 2004, n 40, Norme in materia di procreazione medicalmente assistita (G. U. n 45 del 24-2.2004). http://www.parlamento.it/parlam/leggi/04040l.htm
Lunshof JE (2016) Human germ line editing-roles and responsibilities. Protein Cell 7(1):7–10. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4707153/
Łętowska E, Woś R (2018) Kiedy prawo ma wąsy. Tygodnik Powszechny 49. https://www.tygodnikpowszechny.pl/kiedy-prawo-ma-wasy-156563
de Miguel Beriain I, Armaza Armaza E, Sánchez AD (2019) Human germline editing is not prohibited by the Oviedo Convention: an argument. Med Law Int (first published July). https://doi.org/10.1177/0968533219862590
National Academies of Sciences Engineering Medicine, Baltimore D, Baylis F, Berg P, Daley GQ,Doudna JA, Lander ES, Lovell-Badge R, Ossorio P, Pei D, Thrasher A, Winnacker E-L, Zhou Q (2015) On Human Gene Editing: International Summit Statement. http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12032015a. Accessed 22 Jul 2019
Nordberg A, Minssen T, Feeney O, de Miguel Beriain I, Galvagni L, Wartiovaara K (2019) Regulating germline editing in assisted reproductive technology: an EU cross-disciplinary perspective. Bioethics (special issue: Human germline editing) 12:16–32. https://doi.org/10.1111/bioe.12705
Nuffield Council on Bioethics (2018) Genome editing and human reproduction: social and ethical issues. http://nuffieldbioethics.org/project/genome-editing-human-reproduction. Accessed 22 Jul 2019
Nwabueze RN (2007) Biotechnology and the challenge of property. Property rights in dead body, body parts, and genetic information. Routledge, Hampshire, p. 44
Reardon S (2015) Leukaemia success herald wave of gene-editing therapies. Nature 527:146–147. https://www.nature.com/news/leukaemia-success-heralds-wave-of-gene-editing-therapies-1.18737
Regulation no. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, pp. 1–76). https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf
Savulescu J, Pungh J, Doiglas T, Gyngell Ch (2015) The moral imperative to continue gene editing research on human embryos. Protein Cell 6 (7):476–479. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4491050/
Scott R (2000) Maternal duties toward the Unborn? Sounding from the Law of Tort Med Law Rev 8(1):1–68. https://academic.oup.com/medlaw/article-abstract/8/1/1/938923?redirectedFrom=fulltext
Simić J (2018) The Protection of Nasciturus within the civil law. Pravno Zapisi God. IX. http://pravnifakultet.rs/wp-content/uploads/2018/12/Pravni-zapisi-2018-02-03-Simic.pdf
Simonstein F (2017) Gene editing, enhancing and women's role. Sci Eng Eth (advance online publication 2 February). https://doi.org/10.1007/s11948-017-9875-5
Soniewicka M (2018) Selekcja Genetyczna w Prokreacji Medycznie Wspomaganej. Wolters Kluwer, Warsaw
Soniewicka M, Lewandowski W (2019) Human genetic selection and enhancement. Parental perspectives and law. Peter Lang GmbH.
Sykora P, Caplan A (2017) Germline gene therapy in compatible with human dignity. EMBO Rep. 18(12):2086. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5709747/
Syrkora P (2018) Germline gene therapy in the era of precise genome editing: how far should we go? In: Soniewicka M (ed.) The ethics of reproductive, philosophy and medicine, vol. 128. Springer, Cham, pp. 157–171
Tebas P, Stein D, Tang WW, Frank I, Wang SQ, Lee G, Spratt SK, Surosky RT, Giedlin MA, Nichol G, Holmes MC, Gregory PD, Ando DG, Kalos M, Collman RG,

Binder-Scholl G, Plesa G, Hwang W-T, Levine BL, June CH (2014) Gene editing of CCR% in autologous CD4T cells of persons infected with HIV. N Engl J Med 370:901–910. https://www.nejm.org/doi/10.1056/NEJMoa1300662

Universal Declaration on the Human Genome and Human Rights of United Nations Educational, Scientific and Cultural Organisation (UNESCO) adopted on 11 November 1997. http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights/

Ustawa z dnia 26 czerwca 2015 r. o leczeniu niepłodności (Dz.U. 2015, poz. 1087). http://prawo.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001087

Wojtaszek E (1990) Odpowiedzialność cywilna z tytułu szkody wyrządzonej dziecku przed jego poczęciem. Nowe Prawo 10–12:96

Zhang D, Lie RK (2018) Ethical issues in human germline gene editing; a perspective from China. Monash Bioeth Rev 36:23–35. https://link.springer.com/article/10.1007/s40592-018-0091-0

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Competing interests

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