

REV. PAVOL DANCÁK

University of Prešov in Prešov, Slovakia

<https://orcid.org/0000-0002-8067-5651>

MOLECULAR EDITING AND CHRISTIAN BIOETHICS¹

The CRISPR/CAS9 molecular editing tool is a phenomenal biomolecular discovery of the 21st century and is revolutionizing fields such as molecular biology, medicine and gene therapy. It is a very simple, effective and affordable molecular tool derived from the bacterial immune system that has been designed to target the editing of genetic information at a precise location in the DNA sequence. Although the tool works very efficiently, there is a risk of inadvertent interference outside the desired target sequence. A number of factors influence the effectiveness of the method, such as cell type, cell cycle phase, cell culture conditions, editing strategy and choice of subsequent gene repair. A key requirement for the success of the method is an appropriately chosen combination of all these and other factors to avoid unwanted interference of the editing tool outside the target sequence (possible risk of triggering oncogenes).²

The method for molecular editing immediately aroused great interest in the world. It began to be applied in plant and animal production. Already in 2000, the Report of the American Association for the Advancement of Science took a position on non-heritable modifications on the human genome.³ It gained particular attention in China, where the first treatment trials were launched, first in mice⁴ and later in

¹ The study was developed as an output of the KEGA project 030PU-4/2022 entitled *Design of Teaching Materials for University Study of Relevant Moral Values with a Focus on Allround and Sustainable Development of Society*.

² J.A. Doudna, E. Charpentier, *Genome Editing. The New Frontier of Genome Engineering with CRISPR-Cas9*, "Science" 346 (2014), Issue 6213. K. Servick, *Gene Therapy Clinical Trial Halted as Cancer Risk Surfaces*, "Science" August 11, 2021, <https://www.science.org/content/article/gene-therapy-clinical-trial-halted-cancer-risk-surfaces> [access: 20 II 2023].

³ M.S. Frankel, A.R. Chapman, *Human Inheritable Genetic Modifications: Assessing Scientific, Ethical, Religious and Policy Issues*, Washington, DC: American Association for the Advancement of Science 2000, p. 19.

⁴ Y. Wu et al., *Correction of Genetic Disease in Mouse via Use of CRISPR/Cas9*, "Cell Stem" 13 (2013) pp. 659–662.

embryos in monkeys.⁵ The UK was the first country in the world to approve the clinical use of CRISPR in humans on somatic cells in 2016.⁶ Especially monogenic diseases (sickle cell anemia, thalassemia, cystic fibrosis, etc.) have become rewarding targets for CRISPR treatment. In the field of sports, considerations of increased sports performance, increased muscle mass of athletes, better oxygen supply as well as considerations of life extension immediately emerged. Eventually, the topic of CRISPR/CAS9 also reached the general public, who reacted rather embarrassed.⁷ However, the first objections to the introduction of the method into life appeared.⁸

In 2018, another breakthrough occurred, despite scientists warning against using the method on a germline genetic line. Chinese scientist He Jiankui used the CRISPR/CAS9 method to purposefully alter the human genome. He created a zygote as part of assisted reproduction, and at this stage of development, he “excised” a piece of DNA that coded for the production of a protein responsible for attaching the HIV virus to the cell surface. Twins were born, girls, one of whom cannot get AIDS. In other words, He Jiankui has created a kind of “genetic vaccine.” The main circumstance that caused a wave of dissent in the world was that these changes would be inherited in future generations.⁹ The whole case stirred up attention in the world and led to heated debates not only among doctors, but especially among theologians and lawyers. It was not just a medical issue, but primarily an ethical and legal issue that could lead to far-reaching negative consequences, especially if the method was misused.

In 2021, an unreviewed study was published online on BioRxiv, which reported on the results of research in the laboratory of the Francis Crick Institute in England.¹⁰ The authors removed genes on embryos using the CRISPR/CAS9 molecular method. They used 25 human embryos, 18 of which were edited for the *pou5f1* gene. The rest of the embryos served as negative controls. Ten embryos looked normal after the intervention, but in eight they observed unwanted interventions along the entire chromosome carrying the gene, and in four of them they observed unwanted deletions and DNA gains near the gene. The study authors stress that

⁵ Y. Niu et al., *Generation of Gene-Modified Cynomolgus Monkey via Cas9/RNA-Mediated Gene Targeting in One-Cell Embryos*, “Cell” 156 (2014), no. 4, p. 845.

⁶ A. Joseph, *UK Government Agency Approves Editing Genes in Human Embryos*, “Stat” 1 II 2016, <https://www.statnews.com/2016/02/01/uk-gene-editing-embryos/> [access: 20 II 2023].

⁷ A. Regolado, *Atale of Do-it-yourself Gene Therapy*, “MIT Technology Review” 14 X 2015, <https://www.technologyreview.com/2015/10/14/165802/a-tale-of-do-it-yourself-gene-therapy/> [access: 24 III 2022].

⁸ P. Knoepfler, *First Anti-CRISPR Political Campaign is Born in Europe*, “The Niche” June 2, 2016, <https://ipsell.com/2016/06/first-anti-crispr-political-campaign-is-born-in-europe> [access: 20 II 2023].

⁹ D. Cyranoski, *The CRISPR-baby Scandal: What Next for Human Gene-editing?*, “Nature” February 26, 2019, <https://www.nature.com/articles/d41586-019-00673-1> [access: 20 II 2023].

¹⁰ G. Alanis-Lobato et al., *Frequent Loss of Heterozygosity in CRISPR-Cas9-edited Early Human Embryos*, “Proceedings of the National Academy of Sciences” 118 (2021), no. 22, p. e2004832117.

their work highlights the importance of further basic research to assess the safety of genome editing techniques in human embryos, which will lead to discussions on the potential clinical use of this technology. The study has earned condemnation from the wider scientific community because it is ethically unacceptable to experiment on a child in the laboratory.

It follows that not everything that modern genetic research provides is good and beneficial. This situation calls for an ethical reflection which, in line with the latest scientific discoveries, examines the issue of human dignity and the fundamental human right to life as the highest possible good, from its beginning to natural death.¹¹ The aim of the paper will be to present Christian principles in the context of the possibilities offered by molecular editing using CRISPR/CAS9. Christian bioethical principles will be defined first, followed by a bioethical consideration of gene therapy.

1. THE CATHOLIC CHURCH'S ATTITUDE TOWARDS MOLECULAR EDITING

The attitude of the Catholic Church towards current developments in the field of biomedicine, even at a time of significant biomedical discoveries, is based on a holistic view of human life, its value and its mission. Scientific progress is only real and beneficial to humanity when it protects and respects human dignity of every human person. The teaching office of the Church promotes this development for the common good of human life and seeks to preserve the dignity and integrity of every human being.¹² In 2008, the Congregation for the Doctrine of the Faith issued a bioethical instruction, *Dignitas Personae (on Certain Bioethical Questions)*,¹³ which will serve to assess the moral quality of the use of CRISPR/CAS9 for the editing of both somatic and germ cells in clinical practice from the perspective of the Catholic Church. The instruction *Dignitas Personae* is based on the 1987 instruction *Donum Vitae*¹⁴ and is enriched with the current bioethical stance in the context of the rapid development of research in biomedicine and molecular biology.

¹¹ M. Machinek, *Etyczne implikacje Projektu Poznania Ludzkiego Genomu*, "Przegląd Powszechny" 10 (2000), pp. 9–26.

¹² J. Mariański, *Nowe problemy bioetyczne w narracji społecznej*, "Chowanna" 1(58) (2022), pp. 1–41.

¹³ Congregation for the Doctrine of the Faith, Instruction *Dignitas Personae* on Certain Bioethical Questions (September 8, 2008), https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html#_ftnref27 [access: 20 II 2023].

¹⁴ Congregation for the Doctrine of the Faith, Instruction *Donum Vitae* on Respect for Human Life in its Origin and on the Dignity of Procreation Replies to Certain Questions of the Day (February

One of the basic bioethical principles of Christian ethics concerning the protection of human life and its dignity is that the embryo, from the moment of its creation, i.e. the fusion of the sperm and the egg to form the diploid zygote, is to be regarded as a human being who has the status of a person. From the moment the diploid zygote is formed the person is entitled to unconditional respect in his or her physical and spiritual integrity (DP 4, 5). In opposition to this ontological personalism stands empirical functionalism, in which a distinction is made between the human being and the human person. A human being becomes a person in the course of his or her development, but can also cease to be a person in the course of his or her life.¹⁵ In Christian ethics, the universally valid ethical principles of dignity, autonomy, integrity, and vulnerability are complemented by the bioethical principles of beneficence, non-maleficence, and justice.¹⁶

The confrontation between the value of human dignity and new scientific discoveries reveals many borderline situations¹⁷ resulting from a misunderstanding of the complex view on the person, which is based on either natural or social reductionism.

Natural reductionism is based on the assumption that human life is only one of many elements of a natural evolution towards a new species with special and more perfect characteristics. Human physicality is not different in nature from animal physicality, and therefore it is possible for it to be regulated by genetic and biological interventions in the individual. The dimension of man as a person is not taken into account; the value of the body is reduced to the material aspect only. In the hedonistic conception it is considered as an object of pleasure, enjoyment and utility, and in the utilitarian conception the human body is reduced to an object of utility. As a consequence of natural reductionism, man is regarded as matter, which is the object of modern scientific discoveries and their applications. Social reductionism holds that the value of human life and human dignity is determined by society according to the degree to which human life is useful to that society. As

22, 1987), https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html [access: 20 II 2023].

¹⁵ M.O. Vácha, R. Königová, M. Mauer, *Základy moderní lékařské etiky*, Praha: Portál 2012, pp. 55–59.

¹⁶ The ethical principles of dignity, autonomy, integrity and vulnerability are the reference criteria for assessing various ethical issues concerning human beings. In the European setting, these principles were defined on the basis of research by the European Commission entitled ‘Basic Ethical Principles in European Bioethics’ in 1995–1998 and the result is known as the Barcelona Declaration of 1998. In it, authors Peter Kemp and Jacob Dahl Rendtorff provide a philosophical synthesis of four basic ethical principles: dignity, autonomy, integrity and vulnerability. P. Kemp, J.D. Rendtorff, *The Barcelona Declaration*, “Synthesis Philosophica” 23 (2008), no. 2, pp. 239–251.

¹⁷ M. Rembierz, *Etyka wobec postmodernistycznej nocy aksjologicznej*, in: E. Okońska, K. Stachiewicz (eds.), *Co się dzieje z wartościami? Próby diagnozy* (Colloquia Disputationes, t. 12), Poznań: Uniwersytet im. Adama Mickiewicza Wydział Teologiczny 2009, pp. 91–102.

a result of this approach, the understanding of human dignity is distorted and the utilitarian conception of human existence is deepened.¹⁸

According to the Catholic Church, the human being must not be reduced to a mere living organism subjected to physical laws. Man cannot merely be an object of experimentation to serve the good of all, but is himself the highest good and deserves the highest possible degree of respect, dignity and protection.¹⁹ Scientific knowledge, biomedical applications and interventions must therefore become part of a much broader anthropological reflection which considers the human person as a whole, and not just in terms of piecemeal approaches, when morally evaluating biomedical interventions.²⁰ From the point of view of Christian anthropology, man as a human person has the highest possible degree of dignity because he was created in the image and likeness of God. Here is the source and origin of human identity and dignity.²¹ Man, by his existence, participates in God's life, draws from it and tends towards it. According to the constitution *Gaudium et Spes*, man is in his deepest essence a unity of body and soul; he is endowed with an intellect by which he participates in the light of God's mind; he has a consciousness by which he listens to his God; he has freedom as the supreme existential principle of man created in the image of God (GS 12–17).

According to the instruction *Dignitas Personae*, it is clearly established that the dignity of a person must be accorded to every human being from conception to natural death. In the age of modern biological discovery, this fundamental Christian anthropological principle must be in the center of ethical considerations in bioethical research (DP 1). The cells of the first stages of embryonic development must not be reduced to a mere clump of cells. The key ethical argument in favour of the dignity of the human being at these stages is the continuity of the development of the individual, i.e. that without the earlier simpler stages of embryonic development, the more complex and complicated ones would not have arisen. The instruction *Donum Vitae* further develops these principles: "Thus the fruit of human generation, from the first moment of its existence, that is to say from the moment the zygote has formed, demands the unconditional respect that is morally due to the human being in his bodily and spiritual totality. The human being is to be respected and treated as a person from the moment of conception; and therefore from that same moment his rights as a person must be recognized, among which in the first place is the inviolable right of every innocent human being to life" (DV 1).

¹⁸ A. Sarmiento, *Genetica ed eugenetica alla luce della Teologia morale*, in: J. Laffitte, I. Carasco de Paula, Pontificia Accademia per la Vita (eds.), *Le nuove frontiere della genetica e il rischio dell'eugenetica*, Città del Vaticano: Libreria Editrice Vaticana 2010, pp. 164–165.

¹⁹ M. Petro, *Génové technológie: kritické zhodnotenie súčasných argumentov z teologickej perspektívy*, "Theologos" 22 (2020), no. 2, pp. 148–159.

²⁰ A. Sarmiento, *Genetica ed eugenetica*, p. 166.

²¹ M. Machinek, *Spór o status ludzkiego embrionu*, Olsztyn: Wydawnictwo Uniwersytetu Warmińsko-Mazurskiego 2007, pp. 229–230.

The human embryo therefore has the right to the dignity that belongs to a person. This dignity belongs to every human being, because every human being has his or her own dignity and worth indelibly engraved in his or her interior (DP 6). The value of human dignity is further complemented by the ontological principle, which derives from the intrinsic connection between the ontological dimension and the particular value of each human life. On this basis, the bioethical principle of the inviolability of human life, from its beginning to its natural end, should become the basis of all legislation (DP 5). Pope Benedict XVI drew attention to this in his address to the United Nations General Assembly. The right of every human being to life has its basis in the natural law, which is inscribed on human hearts and present in different cultures and civilizations. Removing human rights from this context would mean restricting their range and yielding to a relativistic conception, according to which the meaning and interpretation of rights could vary and their universality would be denied in the name of different cultural, political, social and even religious outlooks. This great variety of viewpoints must not be allowed to obscure the fact that not only rights are universal, but so is the human person, the subject of those rights.²²

The dignity of every human being contains within itself the secret of masculine and feminine originality. By mutual self-giving, respect and fidelity, by sexual intercourse reserved for them alone, spouses strive to create a communion of persons in which they perfect one another and cooperate with God in the creation and education of new living beings (HV 8). God, who is love and life, has placed in man and woman the vocation to participate in a special way in his mystery of communion of persons and in his work as Creator and Father (DV 3). Therefore, each human being is valued for his or her existence, which is a gift from God.

The conclusion of the instruction *Dignitas Personae* emphasizes the moral teaching of the Church, which is based on the recognition and promotion of all the gifts that God the Creator has bestowed on man. These gifts are life, knowledge, freedom, charity, intellectual activity and practical ability. Through all of these, man is called to serve God, to share in God's creative power. By this conscious human activity in unity with God's purpose, man participates in the protection and development of human dignity, as well as in the good of all human beings and the human person in his wholeness. The history of humanity shows that true progress lies in the understanding and recognition of the worth and dignity of every human being. This is the basis of law and the consequence of the validity of the ethical principles on which human society is organized. The document stresses that any form of behavior that tramples on and violates human dignity is forbidden. The Catholic Church does not oppose scientific progress, but warns that it must not

²² Benedikt XVI, *Address of his Holiness Benedict XVI, 18 IV 2008*, https://www.vatican.va/content/benedict-xvi/en/speeches/2008/april/documents/hf_ben-xvi_spe_20080418_un-visit.html [access: 20 II 2023].

become a means of obvious and unacceptable abuse for purposes that violate human dignity. The legitimacy of any prohibition is based on the need to protect the real moral good of the individual and of society as a whole (DP 36–37). When the Church comments on ethical aspects related to scientific progress, she does so not to interfere in the field of medical science, but rather to call all people to ethical and social responsibility for their actions (DP 10).

2. SOMATIC GENE THERAPY

Gene therapy can be applied to somatic cells or to germ and embryonic stem cells. “*Somatic cell gene therapy* seeks to eliminate or reduce genetic defects on the level of somatic cells, that is, cells other than the reproductive cells, but which make up the tissue and organs of the body. It involves procedures aimed at certain individual cells with effects that are limited to a single person. *Germ line cell therapy* aims instead at correcting genetic defects present in germ line cells with the purpose of transmitting the therapeutic effects to the offspring of the individual. Such methods of gene therapy, whether somatic or germ line cell therapy, can be undertaken on a fetus *before his or her birth* as gene therapy in the uterus or *after birth* on a child or adult” (DP 25).

Because the editing tool CRISPR/CAS9 is one of the most effective gene therapy tools in current biomedicine and clinical gene therapy, we subordinate its clinical use on the basis of Christian-anthropological reflection to the fundamental moral and bioethical criteria set forth in Article 26 of the instruction *Dignitas Personae*, which states verbatim: molecular “For a moral evaluation the following distinctions need to be kept in mind. *Procedures used on somatic cells for strictly therapeutic purposes are in principle morally licit*. Such actions seek to restore the normal genetic configuration of the patient or to counter damage caused by genetic anomalies or those related to other pathologies. Given that gene therapy can involve significant risks for the patient, the ethical principle must be observed according to which, in order to proceed to a therapeutic intervention, it is necessary to establish beforehand that the person being treated will not be exposed to risks to his health or physical integrity which are excessive or disproportionate to the gravity of the pathology for which a cure is sought. The informed consent of the patient or his legitimate representative is also required.”

It is thus clear that the CRISPR/CAS9 editing tool can be used as a clinical therapeutic method in the case of somatic gene therapy, under strict conditions and adherence to the ethical principles that such applications require in practice. The investigation and evaluation of somatic gene therapy on the basis of bioethical principles corresponds directly to the bioethical principles of beneficence, justice,

autonomy and informed consent. Somatic gene therapy must not pose a threat to the person concerned. The risks arising from the clinical application of somatic gene therapy must be limited as far as possible. In the case of the CRISPR/CAS9 method, these will of course be applications that are approved and strictly controlled by the relevant health regulatory authorities. Sufficient clinical study will be ensured and, of course, the device will be calibrated to a highly effective and safe regimen without the risk of adverse interference or other side effects that would worsen the course of the disease. It is thus clear that the appropriate use of somatic gene therapy is directly related to the conviction of perfect knowledge of the method and the efficacy of its use. On the other hand, if clinical experience shows that the application of gene therapy does not have the desired effect, the need to protect the individual concerned from possible danger outweighs the need to alleviate his suffering and there is a moral obligation to suspend the application of gene therapy and to find another way of treating the affected patient.²³

As regards the question of the permissible risks associated with somatic gene therapy, in this respect it is absolutely essential to see the application of gene therapy in the full range of consequences that it can bring. It is therefore necessary to ask what are the benefits and what are the risks for the individual concerned when applying a particular gene therapy in the case of a particular disease, the current state of development and the severity of the disease.²⁴ If we have a set of patients who are suffering from advanced cancer, the equation naturally leans towards the side of trying everything that might reverse this condition. Here we are talking about compassionate use or last hope use, where patients are willing to take a much greater risk of a new, not fully explored gene therapy application.²⁵

Experimental treatment in phase I and II clinical trials would be appropriate for a group of patients with advanced cancer undergoing palliative treatment, as there is no other unproven effective treatment. These patients have nothing to lose, but nothing to gain either. If these patients give informed consent, knowing that the benefit/risk ratio is zero in their case, they can, from a kind of altruistic position, help the good, i.e. those who will become ill in the future.²⁶

Another aspect of the ethical perspective on somatic gene therapy is the slippery slope principle. As somatic gene therapy becomes part of clinical practice, as current developments indicate, it is very important to realize that this is also an area of abuse of a proven method in non-therapeutic clinical practice, such as

²³ J. Suaudeau, *Attuali possibilità di intervento genetico*, in: J. Laffitte, I. Carrasco de Paula, Pontificia Accademia per la Vita (eds.), *Le nuove frontiere della genetica e il rischio dell'eugenetica*, Città del Vaticano: Libreria Editrice Vaticana 2010, pp. 79–81.

²⁴ J.C. Fletcher, *Ethical Issues in and Beyond Prospective Clinical Trials of Human Gene Therapy*, "The Journal of Medicine and Philosophy" 10 (1985), no. 3, p. 295.

²⁵ J. Suaudeau, *Attuali possibilità di intervento genetico*, p. 84.

²⁶ S. Nicholson et al., *Ethical and Regulatory Issues in Gene Therapy*, "British Journal of Urology" 76 (1995), no. 2, pp. 71–74.

human germline gene therapy, enhancement of the individual or enhancement of the human species. This means that somatic gene therapy would become the basis for controversial non-therapeutic genetic approaches.²⁷

The risk of eugenic selection and other eugenic tendencies, which are also inherent in the clinical application of the CRISPR/CAS9 method, are clearly evident here. The clinical application of this method, with knowledge of the function of a given gene, can very precisely alter not only the defective genes, but also influence the action of others in favour of the wishes of the applicants. Changes in intelligence, musculature, hair color, skin color, sex, these are the clear applications of positive eugenics. It should be pointed out that the distinction between what is considered medical therapy and what is considered enhancement is not entirely clear. Both concepts share the common goal of providing enhancement, although enhancement is commonly understood as 'a change that alters what is normal,' whether for humanity as a whole or in the case of a particular individual. However, what is considered normal is ambiguous and changes over time. The question remains whether deviation from normality constitutes 'disease.' For example, in the Deaf community, many people reject the notion that deafness is something that needs to be treated. As a result, there is a need to clearly identify which diseases are severe enough to require modification, taking into account different views and existing alternative treatments.²⁸ The ambiguous vocabulary of normal/abnormal, defective/indefective, perfect/imperfect is very worrying and evokes the return of eugenic tendencies under the guise of molecular clinical medicine and modern gene therapy.²⁹

It is highly unlikely that somatic gene therapy will be available to all people regardless of culture, affiliation, race, social status and economic background. This violates the ethical principle of fairness. The consequence will be even greater social division, disunity, inequality and, in a sense, stigmatization of those who have not undergone any genetically controlled modification.³⁰ It is therefore necessary to constantly reassess the concept of somatic gene therapy, both in the light of established and generally valid bioethical principles and in the light of technologically mastered and thoroughly tested clinical applications.

²⁷ M. Machinek, *Spór o status ludzkiego embrionu*, pp. 148–151.

²⁸ T. Brigden, A. Hall, *Somatic Genome Editing: Ethics and Regulation*, <https://www.phgfoundation.org/briefing/somatic-genome-editing-ethics-regulation> [access: 21 II 2023].

²⁹ J. Suaudeau, *Attuali possibilità di intervento genetico*, pp. 88–89.

³⁰ The dystopian society according to A. Huxley's *Brave New World* is often referred to in connection with interventions in the genome, e.g. J. Isensee, *Der grundrechtliche Status des Embryos*, in: O. Höffe et al., *Gentechnik und Menschenwürde. An den Grenzen von Ethik und Recht*, Köln: DuMont 2002, pp. 37–77.

3. ETHICAL UNACCEPTABILITY OF GENE THERAPY AND NON-THERAPEUTIC APPLICATIONS

The reasoning principles set out in the *Dignitas Personae* instruction imply that germline gene therapy based on genome editing using CRISPR/CAS9 is one of the experimental approaches that are considered ethically unacceptable. “The moral evaluation of *germ line cell therapy* is different. Whatever genetic modifications are effected on the germ cells of a person will be transmitted to any potential offspring. Because the risks connected to any genetic manipulation are considerable and as yet not fully controllable, in the present state of research, it is not morally permissible to act in a way that may cause possible harm to the resulting progeny. In the hypothesis of gene therapy on the embryo, it needs to be added that this only takes place in the context of *in vitro* fertilization and thus runs up against all the ethical objections to such procedures. For these reasons, therefore, it must be stated that, in its current state, germ line cell therapy in all its forms is morally illicit” (DP 26).

In Article 27 of the instruction *Dignitas Personae* we find a very important position of the Congregation for the Doctrine of the Faith in the case of the use of gene therapy for non-therapeutic purposes. Specifically, it deals with interventions that should lead to the improvement and refinement of the human gene pool. In this section, the Congregation clearly emphasizes that such tendencies are declared unacceptable and outlines the basic ethical issues that arise from such applications.

“Apart from technical difficulties and the real and potential risks involved, such manipulation would promote a eugenic mentality and would lead to indirect social stigma with regard to people who lack certain qualities, while privileging qualities that happen to be appreciated by a certain culture or society; such qualities do not constitute what is specifically human. This would be in contrast with the fundamental truth of the equality of all human beings which is expressed in the principle of justice, the violation of which, in the long run, would harm peaceful coexistence among individuals. Furthermore, one wonders who would be able to establish which modifications were to be held as positive and which not, or what limits should be placed on individual requests for improvement since it would be materially impossible to fulfil the wishes of every single person. Any conceivable response to these questions would, however, derive from arbitrary and questionable criteria. All of this leads to the conclusion that the prospect of such an intervention would end sooner or later by harming the common good, by favouring the will of some over the freedom of others. Finally it must also be noted that in the attempt to create *a new type of human being* one can recognize *an ideological element* in which man tries to take the place of his Creator” (DP 27).

The above findings clarify that although the CRISPR/CAS9 molecular editing tool is a breakthrough tool in biomedicine and molecular biology due to its

efficiency, simplicity, low cost and accuracy, it cannot be used arbitrarily in clinical practice. From an ethical and Christian point of view, germline genome editing and derived uses of CRISPR/CAS9, such as non-therapeutic applications, enhancement of the individual and improvement of the human gene pool, are considered unacceptable.

The ethical impermissibility of these procedures is also justified by caution and prudence in view of the potential technical problems involved in calibrating the method to individual clinical use cases, the risk of non-specific genomic interference and the risk of mosaicism. Concerns about the possible legalization of germline editing procedures are also raised in the guidance. The risk is the social and cultural division of society, the categorization of society into modified and unmodified, which would seriously upset the sociological equilibrium based on the principle of fairness. There could also be a danger of changing attitudes in society when intervening in the germ line. These would then jeopardise not only the protection of human dignity, but also solidarity with one another. This would be the case if, at some point, pressure was put on parents to carry out the desired interventions on their own children in order to ensure their future competitiveness.³¹ The question is who would be the arbiter, who would decide which modification would be carried out and which would not. Moreover, how would the principle of fairness be preserved so that all people would have the opportunity to undergo the modification of their liking when only for some would the application be available? This would lead to a very serious widening of the gap between rich and poor and to the stigmatization of society. This approach clearly declares eugenic behaviour that suppresses human dignity.

There is a consensus in the scientific community that, given the current state of knowledge of the CRISPR/CAS9 method, it is morally and ethically unacceptable to legalize germline gene therapy; the principles of human dignity, integrity, utility, justice and harmlessness are emphasized. Germline gene therapy is considered morally unacceptable from the point of view of the magisterium. These procedures include all available biomedical generative applications, such as in vitro fertilization, pre-implantation diagnostics to eliminate genetically damaged or unhealthy embryos, and the selection of the most viable and properly modified embryos. The dignity of the embryo and the dignity of human life are not respected during the entire process of genetic manipulation. These processes are eugenic.³²

³¹ *Eingriffe in die menschliche Keimbahn. Stellungnahme*, Berlin: Deutscher Ethikrat 2019, p. 42.

³² J. Suaudeau, *Attuali possibilità di intervento genetico*, pp. 95–96.

4. CONCLUSION

From the discovery of CRISPR/CAS9 to the present day, scientific opinion on germline editing has changed from an absolute prohibition to a reserved openness to the therapeutic use of germline editing under very strict scientific and legal criteria, which will be controlled by the relevant scientific and ethical institutions and committees. We refer to the introduction of human germline editing into clinical practice as the translational pathway. This sets out strict criteria for the therapeutic use of human germline editing in germ cells or embryonic cells, followed by implantation of the edited embryo in the womb and the birth of a genetically modified individual.

The use of the CRISPR/CAS9 editing tool in somatic gene therapy procedures is considered morally permissible from the point of view of Christian ethics, while preserving the fundamental ethical principles of the human individual concerned, as well as the bioethical principles of beneficence, non-maleficence, autonomy and justice. The final say in the proposed treatment procedure is, of course, with the patient, who freely decides, on the basis of informed consent, whether or not to undergo somatic gene therapy. Informed consent is a practical consequence of the validity of the principle of human dignity and integrity in medical practice. Conversely, genetic manipulation of germ and embryonic cells is forbidden in Church documents for ethical reasons.

Germline gene therapy and the applications of human enhancement derived from it, the creation of children on demand, blind experiments on living beings, etc., harbour a dangerous selective eugenic mentality that threatens human dignity at its deepest core, and thus endangers the general ethical principles of human integrity, autonomy and vulnerability that belong to every human being.

The translational route for selected genetic diseases would thus appear to become a legal and professional strategy to eliminate the growing risk of misuse of the CRISPR/CAS9 method by uncontrolled and non-therapeutic procedures that are banned by the scientific community. The translational route raises a large number of bioethical, methodological, social, legal and cultural issues that must become the subject of public scientific debate.

In the deepest sense of the word, gene therapy should be a therapy for a specific disease of a given organism, respecting the integral good of the person with its physical, emotional, intellectual and spiritual dimensions, while respecting all applicable bioethical parameters and principles. Clinical interventions aimed at improving the genome of the individual, and therefore of society, are unacceptable. Human life must not become the object of a positivist-materialist mentality with a eugenic basis. It is of great value because it is life. This conviction is written into the essence of human existence. The inviolability and inviolability of human life applies to every human being. At the beginning of every human existence is God, the giver of life. To Him alone belongs the place of the Creator, while man only shares in God's creative power. From this truth of Revelation flows the key

moral-theological orientation of ontological personalism as the fundamental principle of the dignity of every human being from conception to natural death. This clearly lays the foundation for the uniqueness of the person and personal identity.

ABBREVIATIONS

- DV – Congregation for the Doctrine of the Faith, Instruction *Donum Vitae* on Respect for Human Life in its Origin and on the Dignity of Procreation Replies to Certain Questions of the Day
- DP – Congregation for the Doctrine of the Faith, Instruction *Dignitas Personae* on Certain Bioethical Questions
- GS – Second Vatican Council, Pastoral Constitution on the Church in the Modern World *Gaudium et Spes*
- HV – Paul VI, Encyclical Letter *Humanae Vitae*

EDYCJA MOLEKULARNA A BIOETYKA CHRZEŚCJAŃSKA

Abstrakt

W badaniach w dziedzinie genetyki molekularnej poczyniono w ostatnich latach ogromne postępy, które mają szerokie zastosowanie praktyczne. Jednocześnie potwierdzono, że nie wszystko, czego dostarczają współczesne badania genetyczne, jest dobre i korzystne dla ludzi. W szczególności odkrycie metody CRISPR/CAS9 umożliwiło bardzo skuteczną ingerencję w cechy dziedziczne jednostki, co zmusiło lekarzy, prawników, etyków, socjologów, teologów i przedstawicieli Kościołów do zajęcia jasnego stanowiska w tej kwestii. Potrzeba dalszego rozwoju naukowego wymaga określenia granic badań w celu uniknięcia nieodwracalnych szkód w puli genowej ludzkości. Celem niniejszego artykułu jest analiza dokumentów Magisterium Kościoła katolickiego w zakresie bieżących kwestii bioetycznych wynikających z nowych odkryć naukowych oraz przedstawienie zasad chrześcijańskich w kontekście możliwości oferowanych przez edycję molekularną z wykorzystaniem CRISPR/CAS9. Stanowisko Kościoła katolickiego wobec aktualnych osiągnięć w dziedzinie biomedycyny, nawet w czasach znaczących odkryć biomedycznych, opiera się na holistycznym spojrzeniu na ludzkie życie, jego wartość i misję. W najgłębszym znaczeniu tego słowa terapia genowa powinna być terapią konkretnej choroby danego organizmu, która szanuje integralne dobro osoby ludzkiej. Interwencje kliniczne mające na celu poprawę genomu jednostki, a tym samym społeczeństwa, są niedopuszczalne. Życie ludzkie nie może stać się przedmiotem eugenicznej mentalności pozytywistyczno-materialistycznej. Urząd Nauczycielski Kościoła promuje rozwój naukowy dla wspólnego dobra ludzkości, a jednocześnie dąży do zachowania godności i integralności każdej istoty ludzkiej.

Słowa kluczowe: CRISPR/CAS9, terapia genowa, terapia linii zarodkowej, prawa człowieka, etyka chrześcijańska.

MOLECULAR EDITING AND CHRISTIAN BIOETHICS

Abstract

Research in molecular genetics has made great advances in recent years that have wide practical applications. At the same time, it has been confirmed that not everything provided by modern genetic research is good and beneficial for humans. In particular, the discovery of the CRISPR/CAS9 method has made it possible to interfere very effectively with an individual's hereditary characteristics, which has forced doctors, lawyers, ethicists, sociologists, theologians and representatives of churches to take a clear stance on the issue. The need for further scientific development requires the limits of research to be defined in order to avoid irreparable damage to the gene pool of humanity. The aim of this article is to examine the Magisterium of the Catholic Church in dealing with current bioethical issues arising from new scientific discoveries and to present Christian principles in the context of the possibilities offered by molecular editing using CRISPR/CAS9. The position of the Catholic Church on current developments in the field of biomedicine, even at a time of significant biomedical discoveries, is based on a holistic view on human life, its value and mission. In the deepest sense of the word, gene therapy should be a therapy for a specific disease of a given organism that respects the integral good of the human person. Clinical interventions aimed at improving the genome of an individual, and therefore of society, are unacceptable. Human life must not become the object of a eugenic positivist-materialist mentality. The teaching office of the Church promotes scientific development for the common good of humanity and, at the same time, strives to preserve the dignity and integrity of every human being.

Key words: CRISPR/CAS9, gene therapy, germline gene therapy, human rights, Christian ethics.

MOLEKULARE EDITION UND CHRISTLICHE BIOETHIK

Abstrakt

Die Forschung auf dem Gebiet der Molekulargenetik hat in den letzten Jahren enorme Fortschritte gemacht, die eine breite praktische Anwendung finden. Gleichzeitig hat sich bestätigt, dass nicht alles, was die moderne Genforschung zu bieten hat, gut oder nützlich für den Menschen ist. Insbesondere die Entdeckung der CRISPR/CAS9-Methode hat es ermöglicht, in die Erbanlagen eines Menschen sehr effektiv einzugreifen, was Mediziner, Juristen, Ethiker, Soziologen, Theologen und Kirchenvertreter zu einer klaren Stellungnahme zu diesem Thema gezwungen hat. Die Notwendigkeit der weiteren wissenschaftlichen Entwicklung macht es erforderlich, die Grenzen der Forschung zu definieren, um irreversible Schäden am Genpool der Menschheit zu vermeiden. Ziel dieses Artikels ist es, die Dokumente des Lehramtes der katholischen Kirche zu aktuellen bioethischen Fragen, die sich aus neuen wissenschaftlichen Entdeckungen ergeben, zu analysieren und die christlichen Grundsätze im Zusammenhang mit den Möglichkeiten der molekularen Edition mittels CRISPR/CAS9 darzustellen. Die Position der katholischen Kirche zu aktuellen Entwicklungen in der Biomedizin, auch in Zeiten bedeutender biomedizinischer Entdeckungen,

basiert auf einer ganzheitlichen Sicht des menschlichen Lebens, seines Wertes und seiner Aufgabe. Im tiefsten Sinne sollte die Gentherapie eine Behandlung für eine spezifische Krankheit eines bestimmten Organismus sein, die das ganzheitliche Wohl der menschlichen Person respektiert. Klinische Eingriffe mit dem Ziel, das Genom des Einzelnen und damit der Gesellschaft zu verbessern, sind inakzeptabel. Das menschliche Leben darf nicht zum Gegenstand einer eugenischen, positivistisch-materialistischen Mentalität werden. Das Lehramt der Kirche fördert die wissenschaftliche Entwicklung zum Wohle der Menschheit und ist dabei bestrebt, die Würde und Integrität eines jeden Menschen zu bewahren.

Schlüsselwörter: CRISPR/CAS9, Gentherapie, Keimbahntherapie, Menschenrechte, christliche Ethik.

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Pavol Dancák – priest of the Greek Catholic Church (Prešov Archdiocese, Slovakia), Professor of History of Philosophy, Head of the Department of Philosophy and Religious Studies at the Greek Catholic Faculty of Theology of the University of Prešov, expert of the Holy See Agency for Quality Assessment and Promotion of Universities and Faculties of the Church. In 2001, at the Faculty of Philosophy of the Pontifical Academy of Theology in Krakow, under the supervision of Professor Karol Tarnowski, he defended his doctoral thesis *The Issue of Upbringing in the Work of John Paul II*. In his scientific and research activities, he focuses primarily on the history of human philosophy, education and ethics, with a particular emphasis on personalism and phenomenology. He is a member of several scientific and editorial boards and since 1997 has organised the annual scientific colloquium “Disputationes quodlibetales”. Correspondence address: pavol.dancak@unipo.sk.

