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# EPIDEMICS, GENOME EDITING AND HUMAN RIGHTS

*Two planets meet in centre of the universe and one of them is asking: „You look so unwell? What's the matter?" The second one is responding: „Don't ask at all. I got homo sapiens…"*

## Summary

The article deals with the contemporary legal and ethical challenges, caused by coronavirus COVID-19. It analyses the reason why the western world was so much surprized by that pandemics. The text mentions the succeses of western medicine in the battle against epidemics in the 20th century and sees it as one of the reason for underestimating the public health issues in 21st century. The article also emphasizes on other contemporary threat, the antimicrobiotic resistance and the need for new legal answers to pandemics. It deals with problem of human genome editing as the central topic by creating of hereditary immunity against new viral threats. The text also mentions the risks of such new treatment and the impact on human dignity that is understood as leading value in the contemporary legal regulation on biotechnology.

**Keywords:** *epidemics – public health–genome editing – human dignity – legal regulation–legal certainty*

## Europe surprized by pandemics?

The anecdote may be funny, but human beings are definitelly not the oldest species on the Earth and may be considered only as a temporary phenomenon in the history of nature. The legal documents however assign the value to human beings and moral anthropocentrism is a key ethical theory [1]. Humans however come into contact with various forms of life in their activity and the living nature meets them in different forms and different ways. The nature manifests itself in giving them a glimpse of the beauty, but also exposing them to dangers. It amazes with its grandeur, but also with its usefulness. Various plant or animal life forms, whether at a lower or higher stage of development, are extremely valuable to humankind, especially to the human body. Many philosophers assign moral value to all the life [2]. On the other hand, some forms of life, such as dangerous viruses or bacteria threaten human beings and therefore it is necessary to fight them.

Diseases, epidemics and pandemics can really be ranked among the most common dramatic dangers in the history of mankind. Those phenomena many times influenced the development of human race, and led to greatest changes in political and social relations in the human history. The famous example of a pandemic in the history of the "black death" in Europe of 14th century, which caused the death of about a third of the population of the continent. It has also led to a fundamental changes in social and economic relations in the areas it has affected [3]. Since the" Black Death", the epidemic appeared to a greater extent every 20-25 years, but the European Society did not know the answer to it: nor medicines neighter papal compendiums helped [4]. An example of a more successful measures against the epidemic could be considered the quarantine in Marseille and southern France in 1720s. The measures like creation of a large Lazaret should be regarded as succesful. The state authorities in due time also created supply centers for food imports, thus preventing deaths due to hunger, which occurred massively during previous pandemics [5].

[1] Körtner, U. H. J. *Ethische Fragen der Biotechnologie.* In: KOPETZKI, Ch., MEYER, H.(Hrsg.) *Biotechnologie und Recht*. Wien: MANZ, 2002, 1-14, p. 3

[2] Jacobi, Th. *Predigt über das Vermächtnis von Albert Schweitzer (1875-1965) „Ehrfurcht vor dem Leben"* . Pozri: http://www.degpa.be/wp-content/uploads/Reformationspredigt-VII.pdf [2021-06-06]

[3] Bergdolt, K.: *Černá smrt v Evropě.* Praha: Vyšehrad, 2002, p. 159

[4] Ibid., p. 162

[5] Naphy, W. – Spicer, A. *Der schwarze Tod. Die Pest in Europa.* Essen: Magnus, 2006, p. 139-140.

Epidemics and pandemics however vere no extemptions in the world of the 20th century, although they usually occured outside Europe or North America. Despite measures against pandemics were not commonplace in Europe, but the pandemics continued in most of the world. From 20th century, however, the real threat was the threat of viruses, especially influenza viruses. The most famous case occured during so-called Spanish Flu of 1918-20 with tens of millions of deads. However, other pandemics are also well known: Asian flu (1957-58), Hong Kong flu (1968-70), etc. In the 21st the pandemics were also very present: it should be mentioned at least bird flu (since 2004) or swine flu (2009-10), despite they were not such deadly by number of victims. Very dangerous, however, were other viral diseases like SARS (2002-03), Ebola (2014-16, 2018), etc [6].

Despite all the pandemics in the world, many unprecedented successes in sphere of public health have been achieved. It led to the situation that large epidemics and pandemics were almost completely eradicated in Europe and North America. This idea of winning medicine was associated with the discovery of new drugs, especially antibiotics [7]. Public health and health education have also played a key role. The second fundamental reason for that succes was the huge increase in vaccines and vaccination as such. The idea of winning medicine that is present in the Western world until now has its limits. The contemporary West forgott to understand the reasons why such complex welfare state with strong public health system was created in the 20th century [8]. In many countries there a simple idea of health as a private good prevailed and since 1980s the discussion on limitation of public institutions was omnipresent. The thesis that the state is a bad owner [9] has become also a political dogma and one of reasons why the public health care system got under pressure. From today's point of view, it is really surprising how much self-confidence the neoliberal reformers of the health system have had. Many

[6] World Health Organisation: *Past pandemics*. See: https://www.euro.who.int/en/health-topics/communicable-diseases/influenza/pandemic-influenza/past-pandemics [2021-06-06]
[7] González – Crussi, F.: *Medicína. Stručné dejiny*. Bratislava: Slovart, 2008, p. 151-152
[8] Boston School Of Public Health: *20th Century Public Health Achievements*. See: https://sphweb.bumc.bu.edu/otlt/MPH-Modules/PH/PublicHealthHistory/publichealthhistory9.html [2021-06-06]
[9] Pažitný, P. – Zajac, R. *Stratégia reformy zdravotníctva – reálnej reformy pre občana*. Bratislava: M.E.S.A. 10, 2001, p. 10

of them, without any modesty, weren't able to imagine that there would be something like COVID-19 pandemics, so they did not count on the public health institutions too much.

There is however no reason for blind trust to the idea of epidemics as an issue of the past. The threats are real and not limited to viuses. Noo doubt, that main contemporary problems are caused by viruses, especially COVID-19, but there is another vivid contemporary threat in growing antimicrobiotic resistance against antibiotica. In 2019 the European Antimicrobial Resistance Surveillance Network (EARS-Net) named key issues in the occurrence of antimicrobial resistance (AMR) across the EU/EEA, depending on the bacterial species, antimicrobial group and geographical region [10]. According to EARS-Net, more than a third of the K. pneumoniae isolates were resistant to at least one antimicrobial group under surveillance, and combined resistance to several antimicrobial groups was frequent. In general, lower percentages of resistance were reported by countries in the north of Europe and higher percentages by countries in the south and east of Europe [11]. That is also very dangerous development, as the deficits of public health systems in Southern and Eastern Europe are much more alarming.

World Health Organisation (WHO) also sounds alarm on drug-resistant bacteria. The Organization has warned none of the antibiotics currently being developed against antimicrobial resistance are enough to tackle drug-resistant bacteria that are expected to kill millions by 2050. In one of its reports [12], WHO said that none of the 43 drugs in the pipeline addressed the 13 most dangerous superbugs it had identified. Antimicrobial resistance (AMR) has been described by experts as a silent pandemic. Research suggests the spread of bugs that tolerate drugs kills about 700,000 people a year, a figure that could rise to 10 millions by 2050 [13] — the same number of lives claimed by cancer

[10] The most commonly reported bacterial species was E. coli (44.2%), followed by S. aureus (20.6%), K. pneumoniae (11.3%), E. faecalis (6.8%), P. aeruginosa (5.6%), S. pneumoniae (5.3%), E. faecium (4.5%) and Acinetobacter species (1.7%).

[11] European Center For Disease Prevention And Control. *Surveillance of antimicrobial resistance in Europe 2018*. See: https://www.ecdc.europa.eu/en/publications-data/surveillance-antimicrobial-resistance-europe-2018 [2021-06-06]

[12] World Health Organisation. *2020 antibacterial agents in clinical and preclinical development: an overview and analysis*. See: https://www.who.int/publications/i/item/9789240021303 [2021-06-06]

[13] Ibid.

each year. While observers and industry members had expressed hope the current pandemic could alert the world to the perils of under-investment in new drug research, progress should be limited by one crucial problem: AMR drugs should be used as sparingly as possible. The impact of AMR is most evident in poorer nations and among the elderly and young children. There are reflections, that we might be soon headed towards a post-antibiotic era [14].

## Genome editing as answer to viral pandemics?

As the future seems to be endangered by new viral and microbiotic threats, and all the remedies have their limits, we should consider new ways of medicine, even those that look like a fundamental breakthrough in the field of evolution. At the beginning of 21st century, there were turning events in genetics in the development of new, especially using of CRISP / Cas9 method [15]. It is a genetic tool that has evolved in some bacteria such as defense against viruses. It is also molecular tool used in laboratories that is relatively precise in billions of base pairs of human DNA and can be directed to one particular base and somehow change it. This process means that the one particular place in the genome through the said DNA method the scientists break, edit or delete a gene, and the cell is then able to link the DNA strand. Technically, the method is relatively simple and inexpensive and used for various genetic techniques.

The method became publicly known when twins were born in 2018 in China, after a scientist purposefully and meaningfully changed their human genome. The Chinese scientist He used precisely the CRISP / Cas9 method and, formed a zygote and at this stage of development he "cut out" that part of the DNA that encoded the formation of the protein responsible for the attachment [16]. That event in China 2018 led to heated debates only among

[14] Kåhström, Ch T.: *Entering a post-antibiotic era?* In: Nature reviews micrbiology. 11, 146 (2013)
[15] Pak, E. *Crispr: a game changing genetic engineering technique*. In: Sciene in the news. Blog. Harvard University, 31th July 2014. See: https://sitn.hms.harvard.edu/flash/2014/crispr-a-game-changing-genetic-engineering-technique/ [2021-06-06]
[16] Cyranoski, D. *The Crspr-baby scandal: what next for human gene-editing?* In: Nature, 26.2.2019. See: https://www.nature.com/articles/d41586-019-00673-1 [2021-06-06]

doctors, but mainly among ethicists and lawyers [17]. A born of child with hereditary immune to HIV virus after use of CRISPR/CaS9 method made the future of humane genome editing cntroversial.

That genetic manipulations was so far new in the world, as they always ended with the death of the individual and did not transfer to descendants. The problem is that this new mechanism doesn't work at 100 percent, however i tis not only problem, but in some cases the fortune as well. In our evolution the mankind was lucky that not all spontaneously arisen DNA mutations were corrected, therefore, there were various genetic variants that allowed humanity to survive under changing conditions. Always was there some part of humanity whose genetic composition suited the changing environmental conditions and survived. An example are blood diseases such as sickle cell anemia or thalassemia, which arose from mutations of genes for hemoglobin. They were diseases, but in the malaria regions of Africa or Asia they allowed the affected individuals to survive [18].

The using of the mentioned CRISPR/CaS9 method could be seen as illegal, ethically controversial, and has a number of shortcomings. Some scientist however defended the procedure used in China, in particular, by saying that the father of twins was HIV positive and there was a risk that children could get sick with AIDS. On the other hand, parts of their DNA are more susceptible to other viral infections. Finally, the method CRISP / Cas9 does not work quite precisely and can also hit other places in the genome. For those reasons most of the scientific world community condemned that step. Many considered it to be a dangerous path that goes to eugenics. Implantation of genetically altered human embryos, is a red line that must not be crossed. WHO has already set up an ethics panel that will deal with genome editing [19].

[17] See: Deutscher Ethikrat: *Eingriffe in die menschliche Keimbahn. Stellungnahme*. Berlin: DEutscher Ethikrat, 2019. In: https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/deutsch/stellungnahme-eingriffe-in-die-menschliche-keimbahn.pdf [2021-06-06]

[18] Fábryová, V., Božek, P., Drakulová, M. et al. *Care for haemoglobinopathy patients in Slovakia.* In: Central European Journal of Public Health 2017, 25 (1), p. 67.

[19] World Health Organisation. *WHO expert panel paves way for strong international governance on human genome editing.* See: https://www.who.int/news/item/19-03-2019-who-expert-panel-paves-way-for-strong-international-governance-on-human-genome-editing [2021-06-06]

The path the genetics is taking in 21st century may also use some arguments based on the viral threat. In the future, the pandemics may arise conditions that were huge threat to human life on Earth. If there is a genetic method, able to „correct" the gene in the embryos and so prevent the spread of pandemics, the prevention of the devastating effect should be taken into account. It is possible that genome editing will be an active option for groups of people to survive. On the other hand, nowadays it is dangerous to put it in the hands of a man the power to take control of his evolution. There are real dangers as editing genetic material can get to the criminal level. Trading the human future, creating "genetic aristocracy" and, conversely, "slave class" need no longer be just a science fiction topic[20].

## Limits of legal regulation

In the times of pandemics and rapid development of biotechnology the world faces not only genome editing, but many other legal and ethical challenges that will need to be addressed in the future. Decades have passed since World War II and today we have legal binding Oviedo Convention[21]. Article 13 of the Convention prohibits changes in human genes that would be transmitted to future offspring: „An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants." Like all new groundbreaking discoveries of mankind, even the technique of genome editing can be equally used for the benefit of mankind (treatment of genetic diseases), as well as misused (deepening of social differences between people) and in terms of changing natural conditions once can save mankind.

One of the frequent problems in relation to Bioethics causes the ideologisation of biomedicine. Topics such as origin of life or human genome are fundamental and very complex. It is almost impossible to create biomedical

[20] Gardocka T, Kowalski P. Genom ludzki jako dziedzictwo ludzkości. In Ury E, ed, Potrzeby jako współczesny determinant treści praw człowieka. WSGE, Józefów; 2017:57-70.

[21] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, opened for signature on 4 April 1997 in Oviedo

law that wouldn't be tied to ideology. Experience shows that ideology in the regulation of biomedical issues interferes in a fundamental way [22]. This trend will obviously continue, and it is clear that constitutional discussions on biomedical issues can't avoid ideological influences. In addition, the legal order contains not only a growing number of provisions that are essentially based on ethical standards, but also those that point to ethical standards (e.g. professional codes of ethics).

Another problem in regulation in the field of biomedicine, in particular biomedical research, is the fact, that there have always been areas of life that were not regulated by law, respectively there were no restrictions, and legal norms for the area appeared only gradually. The number of areas insufficiently regulated by law can include, in particular, new areas of human activity, which law "domesticates" quite slowly. Such problems include the question of the human genome and cloning, which may directly question the substance of man's existing legal status. As an example, that may be threaten due to editing and interference in the human genome, is equality of subjects, one the leading principles of the rule of law.

The law should certainly act for the future, but it cannot respond to all the bioethical challenges that will soon arise. This is especially true for biomedical research. Of course, when it comes to the law made for the future, the legislator can predict certain situation, even in the field of biomedicine, but the huge technological progress makes it impossible to predict all, and especially in the field of human genome research, the number of unforeseen situations will remain high.

The answer to problems of technological development shouldn't be seen in retroactive rules as well. Even retroactivity will not provide answers to the new bioethical challenges; moreover, it also poses a threat to the principle of legal certainty. It's difficult to comply with standards that aren't known in advance by the subjects of duty and the use of retroactivity could also have an impact on biomedical research. Legal certainty is important so that scientists do not have to worry that their research, prepared in good faith in accordance with the law, will lead to criminal sanctions in the future.Legal uncertainty can

[22] Fábry, B. *Argumentáácia v bioetike – špecifiká právnych argumetntov*. In: HRKÚT, J. Argumentácia v bioetke (vyd.). Ružomberok: Katolícka univerzita, Filozofická fakulta, 2009, 91-116, p. 114.

also lead to the departure of grioup of scientists, even to exodus, especially to the countries that are not so much concerned with human rights issues.

Research in the field of biomedicine is technically very difficult and i tis not surprising that the legislator – layman largely doesn't understand the risks. On the other hand, everyone who aspires to the application of law has his own idea of how the law should work in society. Professional, ideological and political disputes usually arise about draft laws, especially about laws in the field of bioethics, and these often affect the legislator as well. It is an important question, how far is it possible to protect the bioethics from these influences. The question is also how many risks can be caused by unpredictable development of biomedicine It usually causes an increase in normative regulation. In the legislative process, there is also need for the ability to find normative solutions for practical cases and to translate these solutions into an appropriate form. Legislative activity imposes extremely large demands on the legislator. It is very important, however, that the law is not only well-intentioned, but that it is effective in reality. Some legal theorists believed that the law should be proposed in such a way that we imagine the worst possible situations and consider how they would fit in with the new law [23]. It would be particularly important to think how the laws will be changed in the light of new scientific knowledge. However, the above method used by the legislator will not exclude the unpredictable impact of biotechnology.

## Human Dignity

The contemporrary legal systems recognise the value of human dignity as upmost imprtant for all the legal regulations. Oviedo Convention confirms its imoportance in the art. 1: „Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine." Charter of fundamental rights of the Euroean Union is also confirming the value as fundamtnal (art. 1): „Human dignity is inviolable. It must be respected

[23] Fábry, B. *Teoretické problémy tvorby práva.* Bratislava: A – medi, 2018, p. 118.

and protected." Important emphasis on the human dignity will be made in the Preamble of the Universal Declaration of Bioethics and Human Rights (UDBHR)[24]: „Recognizing that ethical issues…should be examined with due respect to the dignity of the human person and universal respect for, and observance of human rights and fundamental freedoms." Art.2 of UDBHR also aims "to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundament freedoms, consistent with international human rights law". Fundamental role of human dignity and rights in the bioethis could be seen in the art. 28 of UNBHR: "Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity".

European bodies also declare key importance of human dignity. The European Group on Ethics in Science and new Technologies (EGE) took position on Genome Editing[25] with emphasizing the human dignity as basis: „The EGE considers that deliberation regarding the acceptability and desirability of gene editing will require inclusive debate which extends to civil society where diverse perspectives and those with different expertise and values can be heard. This cannot be left to select countries, social groups or disciplines alone. The EGE cautions against reducing the debate to safety issues and the potential health risks or health benefits of gene editing technologies. Other ethical principles such as human dignity, justice, equity, proportionality and autonomy are clearly at stake and should be part of this necessary reflection towards the international governance of gene editing."

All mentioned authorities confirm, there is no value that will be considered superior and will be seen as more fundamental ethical criterion than human dignity.

The human dignity indicates certain orientation in dispute about medical ethics and human genetics. Thus, for the treatment of human life, human dignity is a key value. It must be however analyzed not only in legal, but also in social and economic terms. However, there is the already mentioned

[24] Unversal Declaration on BIoethics and Human Rights, adopted by General Conference of UNESCO on 19 October 2005

[25] 9. *Statement on Gene Editing*. See: https://ec.europa.eu/info/sites/default/files/research_and_innovation/ege/gene_editing_ege_statement.pdf [2021-06-06]

problem of anthropocentrism, that may lead to reckless treatment of nature, which may be the reason for many enviromental threats and pandemics are one of them. It can only be concluded that legal responses to existing problems of pandemics, biomedical research and human dignity must be sought in coopoeration between different groups of experts. Bioethical topics can't be limited by the borders of the state, since it is not a problem to transfer all research to a neighboring country. This is typical in the case of the Slovak Republic, where biomedical research is regulated very restrictively, but in the neighboring Czech Republic there is a much more permissive regulation of the topics concerning human genome research [26]. However, the same is reality at the intercontinental level. Scientists in Europe may be more carefull, because of technoscepticism or restrictive legal and ethical regulations. They didn't dare to practise editing of human genome, but a scientist in China did it. At present, it is necessary to abandon the image that the West may determine the rules for the rest of the world in the new technologies. We have to search for legal answers together with different legal cultures.

In addition to the fact that scientific progress can not only not be limited by the borders of the state, it is also true that strict regulation alone is not wroking as well. The method like CRISPR / CA9 can also be performed in simpler laboratories and at lower costs. Monitoring all those laboratories would require an extremely sophisticated control system. It is therefore necessary, in addition to legal regulation, to create moral standards for dealing with unethical practice in biology and medicine. There is also a need to focus more on education in field of Bioethis, which is lacking especially in less developed countries. It is necessary to involve the public in the debate on the results of biotechnology, since this is a key tool that will determine new trends in politics and legal regulation, especially in times of pandemics.

[26] Criminal Code of the Slovak Republic (no. 300/2005 Z.z.) defines crime of „Unauthorized experiment on human and clonig of human being" (§ 161), making no difference between therapuetic and reproductive cloning. Czech Republic regulates the topic with law. No. 227/2006 Sb. on Research on Human Embryonic Stem Cells and Related Activities