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NON-PROMULGATION OF MANDATORY COVID-19 VACCINATION IN THE REPUBLIC OF SERBIA**

Abstract: *The first COVID-19 case in the Republic of Serbia was registered on 6th March 2020. The World Health Organization declared the COVID-19 pandemic five days later. In the circumstances of the ongoing pandemic, the Republic of Serbia clearly faced, and is still facing, serious challenges. Once the infection began spreading, the state introduced various economic, legal, and medical measures to lessen the negative effects of the pandemic, constantly modifying them to adjust the rigidity of state response to the intensity of different waves of infection. Both individual and overall effects produced by the adopted measures are a highly interesting study topic. Yet, the available measures which were not introduced seem to be as interesting to research. This particularly refers to mandatory vaccination. In that context, two questions arise: what is the rationale for the authorities' decision not to introduce mandatory vaccination, and what it actually means from legal perspective. This paper focuses on the later question. Specifically, the paper aims to provide a possible interpretation of the recommended (non-mandatory) COVID-19 vaccination, and discuss the roles of participants and possible civil liability. In this pursuit, the author relies on the normative method and different analytical techniques, with due respect for theoretical achievements in medical law.*

Keywords: *mandatory vaccination, recommended vaccination, informed consent, civil liability, medical experiment, COVID-19, SARS-CoV-2.*

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1. Introduction

On 10th March 2020, the Government of Republic of Serbia declared COVID-19 a contagious disease¹ and introduced a cluster of measures, including a temporary ban for foreign citizens from countries with a high infection rate to enter Serbia, a temporary ban on export of essential goods important for the Serbian citizens,² as well as a change in the structure, organization and *modus operandi* of the Crisis Management Team.³ On 15th March 2020, the President of the Republic, together with the President of the National Assembly and the Prime Minister⁴, declared the state of emergency^{5,6}. Consequently, the previously introduced measures were complemented with a set of restrictive and incentive measures declared by the National Assembly, the Government, the Crisis Management Team, and the Serbian Central Bank.

Once the Serbian National Assembly lifted the state of emergency on 6th May 2020⁷, the implemented measures remained the subject of constant analysis. Apparently, going back to the routine that existed before imposing the state of emergency was neither possible nor recommended. It was crucial to adjust the rigidity of implemented measures to the current epidemiological assessment; thus, certain measures were suspended, new measures were introduced, but most of them were modified over time. The overall effects of implemented measures will be the subject matter of future scientific research. Yet, one measure that was not introduced is worth elaborating on.

As of the end of 2020, as many as five COVID-19 vaccines were available in the Republic of Serbia. Yet, mandatory Covid-19 vaccination has never been introduced to date. This raises various medical but also legal and ethical questions. In this article, we try to clarify the complex legal nature of what is called “recommended” Covid-19 vaccination, with specific reference to the roles of health care providers and the key constituents of well-founded informed consent.

1 Article 1, the Decision of the Government of the Republic of Serbia on declaring COVID-19 disease caused by SARS-CoV-2 virus a contagious disease, *Official Gazette RS*, 23/2020.

2 Article 1, The Decision on temporary ban on export of essential goods of importance for the population, *Official Gazette RS*, 28/2020.

3 Articles 1-23, The Regulatory Act on the composition, operating procedures and organization of crisis management teams in emergency situations, *Official Gazette RS*, 27/2020.

4 Article 200, para. 5 in relation to paragraph 1, Constitution of the Republic of Serbia, *Official Gazette RS*, 98/06.

5 The Decision on the State of Emergency, *Official Gazette RS*, 29/2020.

6 As already noted (Nastić, 2020: 71), it was possible to select a different legal route by resorting to the Act on decreasing the risks of disaster and mitigating state of emergency, *Official Gazette RS*, 87/2018.

7 The Decision on lifting the State of Emergency, *Official Gazette RS*, 65/2020.

2. Introducing mandatory Covid-19 vaccination?

The promotion of patients' rights, as the youngest group of widely recognized human rights, was initiated during the 20th century (Драшкић, 2018: 9). Namely, during the Major War Criminal Trial, a number of standards was formulated on the subject of standard medical behavior⁸. These were summarized and included in the Universal Declaration of Human Rights (UDHR). Among other universally recognized "standards of achievements for all people and all nations"⁹, it is resolutely stated that no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment (Article 5, UDHR), and the concept of informed consent has become the international norm which is not restricted to any single jurisdiction (Beran, 2016: 110). In the International Covenant on Civil and Political Rights (ICCPR),¹⁰ it is stated not only that cruel, inhuman or degrading treatment or punishment is forbidden but also that no one shall be subjected to any sort of medical or scientific experimentation without his/her free consent (Article 7, ICCPR). This initiated a paradigm shift from "paternalistic" to "autonomy"-based medical practice. Simply, medical personnel are expected not only to take care of one's health but also to fully respect the patient's integrity and his/her human rights in the process. A patient is no longer a protégé of medical experts but an equal (contractual) partner whose consent is the key factor in deciding whether the intervention will be undertaken (Драшкић, 2018: 10-11).

The Republic of Serbia recognizes both of these documents¹¹. The Constitution of the Republic of Serbia is built on the aforesaid principles and installs a novel *voluntas aegroti suprema lex est* paradigm into its legal system¹². Further, the Patients' Rights Act of the Republic of Serbia promotes the idea of partnership between a doctor and a patient,¹³ based on the patient's right to be informed¹⁴, the freedom of choice in selecting medical services, the right to informed consent

8 These standards were elaborated during Subsequent Nuremberg Trials and incorporated into a document later known as the Nuremberg Code.

9 Preamble, The Universal Declaration of Human Rights, 1948. [Electronic version]. Retrieved 28.01.2022, from <https://www.un.org/sites/un2.un.org/files/udhr.pdf>

10 The International Covenant on Civil and Political Rights (1976). Retrieved 29.01.2022 from <https://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx>

11 Serbia recognizes the former one as a member state of the United Nations, and the latter on the basis of the Act on Ratification of the International Covenant on Civil and Political Rights, *Official Gazette SFRJ*, 7/71.

12 Article 25, the Constitution of the Republic of Serbia (2006).

13 Article 3, paragraph 5, the Patients' Rights Act, *Official Gazette RS*, 45/13 and 25/19.

14 Article 7, the Patients' Rights Act.

in deciding on anything concerning his/her health¹⁵, the right to complaint¹⁶, as well as the right to be fully compensated for sustained damage resulting from non-compliance with any of these principles¹⁷.

Vaccines are the most successful and cost-effective medical technology ever developed. They are the reason why most people have not experienced commonly recognized vaccine-preventable infection (Lantos, Jackson, Harrison, 2012: 132). It is well known that vaccination plays a significant role in controlling preventable diseases, that there is an indisputable link between exemptors and the disease transmission, and that immunization linked to fines may successfully establish a sustainable preventive system (Opel, Diekema, 2012: 141-142). Yet, a considerable part of world population questions mandatory vaccination¹⁸, especially of children, and many people believe that mandatory vaccination constitutes a violation of the fundamental legal principles.

Ample concerns come from sensationalistic media reports¹⁹, rumors, prejudices, and non-credible sources in general (Драшкић, 2018: 26). Concerns about the vaccine safety essentially stem from the fear of counter-indications,²⁰ but there is also a wide-spread opinion that mandatory vaccination is a form of inhumane treatment, even an attack to one's physical integrity. Making vaccination mandatory (and eliminating personal exemptions) may actually hinder the efforts to promote vaccination among the anti-vaccination groups; it may also anger those who are vaccine-hesitant and activate those people who do get vaccinated but who also support the freedom of choice (Opel, Diekema, 2012: 143).

15 Articles 12 and 15, the Patients' Rights Act.

16 Article 30, the Patients' Rights Act.

17 Article 31, the Patients' Rights Act.

18 Vaccination strategies come with different degree of coercion which varies from "forced vaccination" as the most coercive act to "persuasion" as the least coercive act (Yeh, 2022: 258). The European Court of Human Rights (ECtHR) has brought some clarity regarding this terminology. Mandatory immunization secures compliance through established duty, and it is a form of lawful interference with the right to respect for private and/or family life, but also the freedom of thought. As such, it should be distinguished from compulsory immunization which is considered to be forced medical treatment in a strict sense which, therefore, implies unlawful interference (Case 47621/13 and 5 others *Vavrička and Others V. The Czech Republic* [2021]). See: An interesting analogy to mandatory voting (Wang *et al.*, 2021: 165).

19 See: A brief retrospective on how media headlines based on entirely wrong interpretation of the European Court of Justice (CJ EU) decision about liability for vaccine as a defective product can make public confusion (Караникић Мирић, 2017: 138-140).

20 As a matter of fact, none of the vaccines and none of the medicines are 100 percent safe *per se*. However, when compared to most medical interventions necessary to cure any vaccine-preventable disease, vaccines are incomparably safer (Lantos, Jackson, Harrison, 2012: 132).

The conclusion that mandatory vaccination is a form of violation of some fundamental human rights is not the wrong one *per se*. However, contrary to the libertarian ideology, the guarantee for both human and minority rights is never unconditional, with the exception of absolute human rights²¹. It is impossible to give an abstract response to the conflict between the claims of individual autonomy and public interests (Wang, Moribe, Arruda, 2021: 165) but, in general, whenever there is a tension between individual rights and public interests, the latter prevails. In the context of an ongoing pandemic, freedom cannot be absolute when choices of individual make him/her a potential vector of illness (Wang, *et al*, 2021: 164). Public interests are considered to outweigh individual ones; in order to protect them, if solidarity cannot be achieved otherwise, individual rights can be limited²². Human rights can even be restricted. So, the major ethical question is not if but to what extent state could adopt any form of coercive vaccination policy (Yeh, 2002: 255).

A general rule that promotes free will, including the rule that no medical intervention shall be performed without previously attained consent, may as well be subject to restriction. The introduction of mandatory immunization is one way to limit these rights. The question is whether this is permissible under the conditions specified in Article 20 of the Serbian Constitution²³.

First, the Act on Protection of the Population from Infectious Diseases declares immunization as mandatory, depending on the circumstances, either as a preventive or as a post-exposition measure.²⁴ The imperative nature of the norm

21 Article 202 in conjunction with Articles 23, 24, 25, 26, 28, 32, 34, 37, 38, 43, 45, 47, 49, 62, 63, 64 and 78 of the Constitution of the Republic of Serbia (2006); Article 4 in conjunction with Articles 6, 7, 8, 11, 15, 16 and 18 of the International Covenant on Civil and Political Rights (1976).

22 There is an interesting point regarding solidarity in the COVID-19 vaccination process or vaccination process in general. Namely, the entire Social Health Insurance system is mandatory and there are pretty much no opt-out options, and “similarity test” implies the acceptable degree of coercion on mandatory vaccination, which is also grounded on solidarity (Yeh, 2022: 258).

23 When interpreting the constitutional norms on this matter, it is important to do so in the spirit of the so-called Oviedo Convention and its narrower frame for possible restriction of human rights (in comparison to Article 8 paragraph 2 and Article 15 of the European Convention on Human Rights). See: Article 26 of the Act on the ratification of 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, *Official Gazette RS*, 12/2010; Act on the ratification of the European Convention on Human Rights (with Protocols 4, 6, 7, 11, 12 and 13), *Official Gazette SMN*, 9/03, 5/05 and 7/05 and *Official Gazette RS*, 12/10 and 10/15.

24 Articles 32 and 33, Act on Protection of the Population from Infectious Diseases, *Official Gazette RS*, 15/16, 68/20 and 136/20.

is confirmed by the prescribed sanction for non-compliance with the primary rule (ranging from 50.000 RSD to 100.000 RSD).²⁵ The number of cases when immunization is mandatory, clusters of individuals “compelled” to be immunized, as well as exceptional circumstances²⁶ are strictly specified.

This Act also states that, in the event of an outbreak of an epidemic of an infectious disease, recommended or mandatory immunization may be proclaimed for all individuals, or for certain categories.²⁷ Both mandatory and recommended immunization may be ordered by an act issued by the Minister of Health.²⁸ Therefore, considering that the permission to restrict the basic constitutional right comes from the Act as a hierarchically adequate legal act, it is prudent to say that the first condition is met.

Second, according to the Serbian Constitution, the protection of both mental and physical health of the population is of the highest priority²⁹. An entire set of human rights and freedoms³⁰ may be restricted if it is necessary to protect these values. In that context, the need to protect human lives, public health and public safety are the objectives acknowledged by the Constitution; therefore, restrictions of human rights and freedoms are allowed if any of them is compromised.³¹ When it comes to vaccination, considering that vaccination generally offers a benefit not only to the person who is immunized but also to the community (Wang, *et al.* 2021: 167), such a restriction makes absolute sense.

25 Article 85, paragraph 1, point 6, Act on Protection of the Population from Infectious Diseases.

26 Exceptional circumstances are reduced to confirmed medical counterindications of a specific vaccine. The Serbian legislation does not recognize other reasons but there are nonmedical exceptions worth considering. For example, personal beliefs could be recognized as a valid reason to refuse vaccination. Moreover, there is strong case that protecting the right to refuse vaccination on the basis of personal convictions in a way that minimizes unfairness may have a counterintuitive effect, as it would actually decrease resistance to vaccination which is definitely on the rise (Opel, Diekema, 2012: 142-145).

27 Similarly, it applies to restrictions of mobility rights. Article 52, 53, 53a of the Act on Protection of the Population from Infectious Diseases.

28 Article 33 para. 3 in relation to Article 6 para. 1, Article 7 para. 3, and Article 11 para. 1 of the Act on Protection of the Population from Infectious Diseases.

29 Article 68 of the Constitution of the Republic of Serbia.

30 Article 43, paragraph 4; Article 44, paragraph 3; Article 46, paragraph 2; Article 54, paragraph 4; Article 83, paragraph 2 of the Constitution of the Republic of Serbia.

31 As the Constitutional Court of Republic of Croatia ironically states in the decision on same issue, the need to protect children’s lives, but also public health and safety in general, has absolute priority over anyone’s “right to make (a wrong) choice” (the Decision of the Constitutional Court of the Republic of Croatia n U-I-5418/2008, U-I-4386/2011, U-I-4631/2011).

Further, the Serbian Constitution allows for the restriction of human right only if the limitation can be introduced in such a manner that the substance of the right is not compromised. The Serbian Constitutional Court states that it is necessary to differentiate between “the attained human and minority rights” which cannot be reduced even through amending the Constitution, and the “level” of these rights³². In that context, the level refers to the manner in which these human rights are exercised, whereby the established manner is not immutable.

In a later decision on the merits,³³ the Serbian Constitutional Court explicitly stated that the introduction of recommended or mandatory vaccination entails a change in how the right to health protection is exercised.³⁴ Although this situation may be subject to different interpretations, the Constitutional Court established that the introduction of recommended or mandatory immunization does not threaten the substance of any constitutionally proclaimed human right.

Finally, pursuant to the Serbian Constitution, competent authorities are expected to constantly (re)evaluate whether the restriction is proportional to the purpose of restriction in a democratic society (Article 20). It means that the legitimate aim has to be firmly established, that there is a rational connection between the restrictive measure and the legitimate aim, but also that there is no other available less restrictive measure to achieve the same goal. The so-called proportionality test, performed by constitutional courts all over the world, aims to guarantee the greatest protection of individual rights with the least restriction on another (Wang, *et al.*, 2021: 168). In the context of the ongoing pandemic, any restriction on individual freedom needs to be justified and proportional to the desired public health gains (Wang, *et al.*, 2021: 164-165).

The constitutional right to health protection of individuals is correlated with the obligation of the state to take protective and preventive measures for the entire population, but it also entails the obligation of each individual to comply with a measure so that other people can exercise their right to health protection. The right to refuse medical treatment can be restricted if such a restriction is necessary (*inter alia*) for the protection of public health or rights or freedoms of others (Yeh, 2002: 256). Bearing in mind the provision of the Patients’ Rights

32 The Decision of the Constitutional Court of the Republic of Serbia IY3-479/2014.

33 The Decision of the Constitutional Court of the Republic of Serbia IY3-48/2016.

34 In legal theory, it has been correctly noted that the Court challenged all the arguments of the constitutional review initiators, which is quite unusual. The scope of the normative assessment and the content of the Court decision raise suspicion on whether the nature of the decision-making process has been intentionally tempered in order to avoid public discussion on the initiators’ arguments in front of all judges (Ristivojević, 2017: 484).

Act³⁵, the Serbian Constitutional Court stated that mandatory immunization may be a necessary measure to preserve the collective immunity and to eradicate infectious disease; if that is the case, proclaiming mandatory immunization is not contrary to any human right.³⁶

The very fact that the Republic of Serbia coped with tens of thousands of newly infected patients on a daily basis suggests that previously introduced less rigid measures were not effective. Thus, it seems that the introduction of mandatory vaccination might have been a legitimate way to fight COVID-19. It also seems that shift from *voluntas aegroti suprema lex est* to *salus populi suprema lex est* might have been both logical and necessary.

Indeed, we see the logic of legal experts dealing with this issue who criticize any influence of Criminal Policy into Healthcare (Ристивојевић, Самарџић, 2018: 548-549). We also agree that it is highly questionable whether mandatory immunization was rightfully introduced in legal system of Republic of Serbia in the first place³⁷. But even though health experts do not fully agree, at least in some phases of the pandemic, the introduction of mandatory COVID-19 vaccination had met both “proportional” and “subsidiary” criteria.³⁸ The introduction of such a measure would have been the example of the state’s determination to promote the principle of lawfulness in a critical emergency situation.

Yet, the authorities in the Republic of Serbia chose a different route by introducing recommended instead of mandatory vaccination. This approach would seem logical, and would thus remain out of the focus of this research, if the authorities conduct had been more consistent and less contradictory. On the one hand, the active pro-vaccination campaign was entirely based on fear: fear of death, hospitalization, long-term negative effects of infection (especially for elderly citizens), loss of employment, etc. It was constantly emphasized that the undisciplined (unvaccinated) people were the ones to blame for the occurrence of any negative effects (Милутиновић, 2020: 257-258). If so, we have no doubt that the introduction of mandatory vaccination would have been an absolutely

35 Article 15 para. 1 of the Patients’ Rights Act specifically states that the patient is entitled to autonomously decide on every issue concerning his/her life and health, except when it directly endangers the life and health of others.

36 Decision of the Constitutional Court of the Republic of Serbia IVз-48/2016.

37 For a detailed critique of the Constitutional Courts standpoint regarding the initiative to investigate whether the constitutional requirements were met when deciding on the proclamation of mandatory immunization and other restrictive measures in specific cases, see: Ristivojević, 2017: 485-497.

38 In this context, proportionality implies that the extent of restriction corresponds to and is equivalent to the projected legitimate goal, and subsidiarity means that there is no less rigid means available to achieve the same goal (Ristivojević, 2017: 493).

legitimate way to respond. However, state authorities had failed to introduce this measure; moreover, they had bluntly left the choice to individuals, not only in terms of citizens' consent to vaccination but also in terms of selecting one of the available vaccines which a citizen would receive if he/she decided to get vaccinated. Thus, the authorities actually renounced liability for any negative effects of the vaccination. Apparently, it calls for a comprehensive legal analysis of this situation. The next part of this paper offers the starting point for further research and debate.

3. On true legal nature of recommended vaccination against COVID-19 in the Republic of Serbia

From December 2020, as many as five different vaccines were successively available to citizens in the Republic of Serbia³⁹. Bearing in mind the level of threat that nations worldwide had encountered during the pandemic and the limited access to vaccines, considering that the production capacity was unable to meet the global demand (Wang, *et al.*, 2021: 164), it may be said that the Republic of Serbia was among the few privileged nations which had access to several vaccines in early phases of the COVID-19 pandemic.

In the previous part of this paper, we noted that there was a possibility to introduce mandatory vaccination by making one or more of the available COVID-19 vaccines mandatory. While this issue may be subject to different interpretations, the prevailing understanding is based on the stance that the Serbian Constitution allows for restrictions of individual rights. Yet, the term "restriction", particularly if it can be equated to a physical attack on one's integrity, should be used very cautiously. This mainly refers to possible outcomes of such an intrusive action. It implies that the overall consequences of restriction (in this case, the effects of mandatory vaccination) must be positive. In other words, mandatory vaccination against COVID-19 is constitutional in general but the actual mandate may still be unlawful, depending on the concrete elements of mandate policy (Wang, *et al.*, 2021: 168).

Any time new medical procedure is included into a medical protocol, it is necessary to secure a high level of certainty, especially when it comes to negative effects of procedure in question. Ideally, when providing information necessary for patient to legally consent, medical experts should be able to inform them about the level of necessity or even certainty of whether and when specific damaging effects will occur.

³⁹ The available vaccines were: Pfizer-BioNTech and Moderna mRNA vaccines; Gamaleya Research Center (Sputnik V) and AstraZeneca (viral vector vaccines); and Sinopharm (a more traditional inactivated vaccine).

Even today, human body obviously remains a secret. All mechanisms in human body have not been examined completely, which makes this ideal difficult to achieve. In clinical practice, medical professionals are expected to deal with specific situations involving a lower level of certainty. Yet, even in regular circumstances, it is unacceptable to deal with all or most of the vital information only on level of possibility or probability, let alone in a situation when the procedure is imposed as mandatory. On the other hand, when intervention is imposed as mandatory, it is necessary for the “knowns” to significantly outweigh the “unknowns” in terms of the positive but especially damaging effects of intervention.

The overall value of vaccination, particularly the mandatory vaccination, has to be positive. Mandatory immunization policies are more ethically defensible and politically acceptable when the disease is deadly, highly contagious and/or difficult to treat, but primarily if the vaccines are safe (Lantos, Jackson, Harrison, 2012: 136). It seems that it might be easier to introduce mandatory vaccination if the requirement is limited to a certain subpopulation.⁴⁰ The ethical justification for any coercive state action, such as mandatory vaccination without the option of a “personal belief exemption” (especially if refers to all citizens), must be predominantly based on the “no harm” principle (Opel, Diekema, 2012: 143-144).

We agree that urgent need to alleviate the crisis caused by COVID-19 demands a departure from traditional vaccine regulatory pathways, but certainly not at the expense of vaccine safety, efficacy and quality (Smith, Forman, Parker, Perehudoff, Rawson, Sekalala, 2021: 147). In other words, shifting from the *primum non nocere* to *salus aegroti suprema lex est* paradigm is neither ethically nor legally acceptable.

The COVID-19 pandemic is ongoing for more than two years now, but there is still no consensus in the scientific community even on the most basic questions. To name just a few: the origin of the virus is unknown, or unconfirmed at best; the spreading methods, especially the asymptomatic ones, are not precisely described; we are not certain whether this will be a permanent or a periodic threat; another unresolved question is whether all people are susceptible to the virus to the same degree, and whether all people are predisposed to develop severe symptoms, or just specific groups of people; there is an ongoing debate on whether COVID-19 is a pulmonary disease or a cardiovascular disease; scientists are still researching the variants of the virus (when and how they emerge, the expected transmission rate of a specific variant, and how they will affect people); there are highly speculative claims about the long-term effects

40 Although it is not undisputable, truly mandatory vaccination is an effective disease control strategy that has been widely practiced for tackling infectious diseases among different subpopulations such as children, people of specific age groups, health care workers, and employees in other sectors running a higher risk of infection (Yeh, 2002: 255).

for those who were previously infected once or even multiple times, based on viral interplay with the immune system; scientists still have to examine whether available testing methods (especially the PCR method) are reliable for detecting the virus in the conditions other than a laboratory. These and many other questions remain open, which implies that the virus is still a huge unknown *per se*. As there is insufficient data to properly assess the “material risk” of vaccination against COVID-19,⁴¹ we are unlikely to have definite and repeatedly confirmed answers for a long time.

Yet, a number of vaccines against COVID-19 were developed in less than nine months since the pandemic outbreak; furthermore, their use was shortly approved by relevant medical organizations. There is still an ongoing debate on whether one or more COVID-19 vaccines should be considered as “essential” under the WHO standards.⁴² Not surprisingly, it raises suspicions, particularly when the idea of making those vaccines mandatory is presented by state officials, medical or legal experts⁴³. In other words, significant scientific uncertainties remain and indeed underpin the debate on whether to put a mandatory vaccination policy in place (Yeh, 2022: 256)⁴⁴.

In the ideal situation, if the goal is to increase adherence to vaccine mandates, the focus should be more on understanding how to improve citizens’ confidence in vaccines, rather than removing the ability to opt out. In other words, by endorsing programs that address vaccine safety concerns, promote transparency in the vaccine development process, and improve provider-patient communication

41 In ‘material risk’, the understanding how an intervention might impact the patient (either positively or negatively) may influence the patient to accept or reject a proposed treatment option (Beran, 2016: 109).

42 Introducing COVID-19 vaccine(s) as essential medicine under the WHO standards would invoke special “core” human rights duties for governments to provide the vaccine as a matter of priority regardless of resource constraints in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at an affordable price (Smith *et al.*, 2021: 146-147).

43 Some countries have already introduced some of the available COVID-19 vaccines mandatory. Most countries made vaccination mandatory for specific groups (e.g. elderly people, health care providers, or government officials). Different variations of this “semi-mandatory” system are accepted in Australia, Canada, Croatia, Czech Republic, Denmark, France, Greece, Hungary, Italy, Poland, Russia, Saudi Arabia, Turkey and Ukraine. Yet, there are countries that made vaccination mandatory for all adults (Austria, Germany, Indonesia, Turkmenistan, Tajikistan).

44 For example, the US FDA issued and later revoked “Emergency use approval” for a number of drugs for COVID-19 infection, which shows that a medical product safety or efficacy profile may no longer support its emergency, let alone mandatory use (Smith *et al.*, 2021: 148).

about vaccines, it is likely to achieve a more acceptable and sustainable path to increased compliance with vaccine mandates (Opel, Diekema, 2012: 143).

As we see it, this is not the case. Even if we assume that all the research results completely coincide, which is unlikely at this point, none of this makes the entire process more transparent. After all, it is not up to the general public to study and interpret data. The vast majority of people are not medical experts; we are not expected to understand any of the available data. Therefore, it is up to medical professionals to ensure that the provided information is understood, even if they cannot fully guarantee the trustworthiness of such information (Beran, 2016: 110). It is up to medical professionals to convince us that *they* fully understand both the virus and vaccines mechanisms. Even more importantly, it is up to them to convince the general public that they agree on achieved level of safety for different vaccines that are available, and that any negative effects are actually the result of certain specificities of an individual organism rather than the result of typical vaccine defect.⁴⁵ What we know so far for certain is that some COVID-19 vaccines offer “promising safety” (Smith *et al.*, 2021: 147) but that none of the drugs meet the traditional standards of safety and efficiency (Smith *et al.*, 2021: 147).

The most important tool for providing relevant and up-to-date information to public is proper and objective media coverage. In extraordinary circumstances, the importance of the media in informing and educating the public is even greater but, proportionally, there is an additional danger if the quality of information decreases (Јефтовић, Бајић, 2020: 535). In practice, it has been shown not only that media coverage of these issues does not foster trust but that further undermines it. Namely, at the peak of the pandemic, journalists were not allowed to attend Crisis Management Team meetings, nor did they have an opportunity to ask questions via video-link at least (Милутиновић, 2020: 256).⁴⁶ In most media, speed is favored over truth, and “journalism of claim” is favored over “journalism of verification” (Јефтовић, Бајић, 2020: 535).

In the Republic of Serbia, individuals were expected to get vaccinated; in spite of not being medical experts, individuals were also expected to decide whether they should be vaccinated; yet, they were not provided clear instructions on the

45 It certainly does not mean that the court is not allowed to investigate causality questions. Precisely, as the medical science has not yet confirmed or refuted the causal link between the vaccine and the disease, the court is allowed to, freely assess (on the basis of known facts) whether it would be well-founded, precise and uncontroversial enough to assume that there is defect in the vaccine that caused the victim's illness (Караникић Мирић, 2017: 142-144).

46 Moreover, even medical experts who were not members of the Crisis Management Staff were not allowed to share and discuss their own experiences in fighting COVID-19 (Милутиновић, 2020: 253-254).

effects of each vaccine, and whether and how the vaccination is related to their preexisting health problems, the presence of antibodies during post-COVID-19 recovery, or their previous travel to exotic destination and mandatory immunization requirements during travel or after return. Individuals were further expected to decide on their own which of the five available vaccines they would receive. Moreover, they were expected to decide how many doses they would receive and whether they would receive only one type of vaccine or they would mix different ones, which was actually suggested at some point. Finally, individuals (who are on average completely incompetent on medical matters) were expected to take full responsibility for any consequences of their own choice by waiving in advance the right to claim compensation for damage.⁴⁷ Their decision-making processes were further aggravated by dissonant messages coming from medical experts; some of them promoted mask-wearing and physical (social) distancing, while others advocated that the only solution was full exposure to achieve herd immunity; while the leading medical experts promoted wearing face masks and medical gloves, others found that practice ridiculous (Милутиновић, 2020: 257). On top of that, it was difficult to make the correct choice in a situation where the medical community was almost equally divided into those who promoted vaccination as a most effective form of prevention against COVID-19 and those who refused to get vaccinated, even at the cost of being discharged, because there were more “unknowns” than “knowns”.

4. Instead of conclusion: Contribution to the discussion

Considering all the above, it is almost impossible to fully accept the idea that vaccination is the best possible choice, not only for legal but also for practical reasons. If we set the negative media influence aside for a moment,⁴⁸ we may summarize the collected material as follows: a) both COVID-19 as a disease and SARS-CoV-2 virus with its variants are new and unresearched phenomenon; b) various vaccines became available in less than ten months since the virus was successfully isolated (even though in standard multiphase clinical trials just a

47 Neither the state nor the manufacturer is expected to guarantee that the vaccine or any medicine is absolutely safe and that there are no negative effects. However, in case the vaccination is mandatory, the state is expected to guarantee the compensation of damage if damage occurs as a result of mandatory vaccination. For a thorough interpretation of the decision of the Constitutional Court of Slovenia on that matter, see: Драшкић, 2018: 23-25.

48 The perception of reality primarily depends on the ways in which media create images, which are mostly colored with life-threatening colors and contents that feed suspicion, unrest and confusion; the closeness of events and the knowledge that illness is really happening to the loved ones encourages emotional inclusion, anxiety and isolation of individuals (Јефтовић, Бајић, 2020: 536). So, the main reason for general mistrust lies in the sensationalistic approach of mostly tabloid media (Јефтовић, Бајић, 2020: 538).

single phase of testing typically lasts double or triple that time)⁴⁹; thus, they are by nature less safe (Smith *et al.*, 2021: 148); in some countries, vaccines began to be applied before phase III clinical trials were concluded, and most countries started their campaigns with vaccines which had gone through phase III trials but which were approved for emergency use only (Wang, *et al.*, 2021: 169); c) in Serbia, a total of five different vaccines were available but it was almost entirely up to individuals whether they would get vaccinated, when they would do it, how many doses they would get, and whether they would mix different types of vaccines; d) individuals who decide to get vaccinated are obliged to waive in advance the right to claim compensation for any damage that occurs as a result of vaccination because they were fully medically examined (which was never the case in practice) and informed about positive or negative consequences of vaccination (which was impossible because the vaccines are still under research); e) at one point, Serbia provided a simple but quite effective monetary incentive program to motivate individuals to receive the first or the booster dose.

After all, what does such a vaccination process remind us of? Is it really vaccination as a preventive procedure, or is it something entirely different from the legal standpoint? Judging by the way the COVID-19 vaccination has been conducted in the Republic of Serbia, the entire process strongly resembles a medical experiment. In fact, when the disease is uncommon, when the suggested preventive method is still under research and when new data are yet to be collected in this process, such a situation resembles a medical experiment. If there is any doubt whether it is a proper way to interpret the given circumstances, we may refer to the scenario where the state, the medical institution where vaccination is performed, or even the vaccine manufacturers transfer the entire burden of possible outcomes of vaccination to individual citizens (who waived in advance their right to seek compensation for damage); moreover, instead of taking responsibility for the negative effects of vaccination, the state offers monetary incentives for individuals to take a part in the vaccination process. In that context, we firmly believe that vaccination is not the proper term. The proper legal category is a medical experiment.

The author of this article has no doubts that a vaccine, as a simple yet exceptionally effective piece of medical technology, is the single most important tool available in the new era of medicine. In that sense, the author is entirely pro-vaccination oriented, and fully agrees that the development of effective vaccines for COVID-19 offers the main route out of the present tragic bind (Wang, *et al.*, 2021: 164). However, the author also believes that “no harm” standard must remain

49 There are different (more optimistic) estimates but, on average, it takes two to four decades of research to resolve all or most of the doubts and uncertainties about the effects of vaccination (Матејић, Кесић, 2013: 129).

uncompromised as the ultimate principle and that standard testing procedures should be fully respected. The author is also aware that medical experiments are a necessary and even an inevitable part of the process of attaining knowledge in medical sciences, that the role of all participants is particularly important and highly stressful in cases when disease is novel, deadly, and spreads rapidly, and that ethical components of the actual medical experiment must be assessed with due consideration to the degree of vulnerability of the population, particularly in cases where the speed of response is crucial. In the author's opinion, the policy that is designed to provide monetary or other incentives to get vaccinated is a legitimate way to address the problem of growing distrust in the vaccination process. There are good reasons for encouraging people to voluntarily receive vaccines whose efficacy and safety are still uncertain; yet, the argument for making vaccination mandatory is weaker without solid evidence that a vaccine is effective and safe (Wang, *et al.*, 2021: 169).

Therefore, when saying that COVID-19 recommended vaccination process is a medical experiment rather than a true (actual) vaccination process, it is said with absolute respect for medical science, medical and pharmaceutical experts all over the world and their efforts to protect our most important assets (life and health). The author's interpretation of the recommended vaccination against COVID-19 by no means diminishes those efforts, nor does it lessen the danger of the novel Corona virus and its variants. Calling it experimental does not even mean *per se* that this process should be terminated. On the contrary, although not a medical expert, the author believes that the herd immunity cannot be achieved, or at least it is highly unlikely to be achieved if the process is not "catalyzed" through vaccination. However, there is absolutely no reason and no excuse not to name and categorize things properly from the legal standpoint, especially because consent to a scientifically verified medical treatment and consent to participate in a medical experiment have different meanings, and the legal consequences are not the same. Thus, once we have established the basic premises in this article, the legal specifics of this subject matter will be addressed in the next one.

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НЕУВОЂЕЊЕ ОБАВЕЗНЕ ВАКЦИНАЦИЈЕ ПРОТИВ КОВИДА-19 У РЕПУБЛИЦИ СРБИЈИ

Резиме

Први случај ковид-19 забележен је у Србији 06.03.2020. године. Светска здравствена организација прогласила пандемију пет дана касније. Како је пандемија и даље у пуном јеку, јасно је да се Република Србија суочила и суочава се са озбиљним изазовом.

Као одговор на ширење инфекције, држава је представила низ економских, правних и медицинских мера које за циљ имају ублажавање негативних ефеката пандемије, уз стално кориговање истих како би се строгост одговора прилагодила интензитету појединачних таласа пандемије. Појединачни и укупни ефекти уведених мера, свакако, изузетно су интересантни за проучавање. Ипак, чини се како је неувођење мера које су биле на располагању најмање подједнако интересантно за проучавање. Јасно је, ово се нарочито односи на обавезну вакцинацију.

Два питања следе. Прво је који су разлози превагнули за овакву одлуку надлежних институција. Друго питање, које је иначе у фокусу овог рада, је шта то тачно значи са становишта права. Конкретно, у раду желимо да представимо могућу интерпретацију препоручене, дакле не обавезне, вакцинације против ковида-19, улоге учесника у овој медицинској интервенцији, те потенцијалне одговорности за штету, све то уз ослонац на нормативни метод, аналитичке технике и уз уважавање теоријских достигнућа медицинског права.

Кључне речи: *обавезна вакцинација, препоручена вакцинација, престанак пацијента, грађанска одговорност, медицински експеримент, ковид-19, SARS-CoV-2.*