

September 18, 2020

Advisory Committee on Immunization Practices Centers for Disease Control and Prevention (CDC) Department of Health and Human Services (HHS) 1600 Clifton Road Atlanta, GA 30329-4027

Dear Advisory Committee Members:

Re: COVID-19 Immunization Practices - Docket No. CDC-2020-0093

The National Catholic Bioethics Center (NCBC) is a nonprofit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences. The Catholic Church is the largest non-governmental, non-profit sponsor of health care in the United States. Many of these sponsors are NCBC members. NCBC has over 2100 members throughout the United States, many of whom employ and/or serve thousands of persons, and thus its collective membership is significant. The NCBC provides ethical consultation to thousands of institutions and individuals seeking its opinion on the appropriate application of Catholic moral teaching to these ethical issues. With the realities on interagency collaboration, impacted by funding sources, the issue of providing funding for abortion, abortifacients, and contraception has far-reaching negative implications for our membership who regularly seek our ethical advice on the moral quandaries in which such provisions place them.

The Catholic Medical Association (CMA) has over 2,200 physicians and hundreds of allied health members nationwide. CMA members seek to uphold the principles of the Catholic faith in the science and practice of medicine—including the belief that every person's conscience and religious freedoms should be protected. The CMA's mission includes defending its members' right to follow their conscience and Catholic teaching in their professional work.

The NCBC and CMA submit the following comments for the September 22, 2020 meeting of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

Re: Importance and ethical concerns with COVID-19 immunization

We support and encourage the rapid development of an effective, safe, and widely available vaccine to combat COVID-19. Safe and effective immunizations following appropriate ethical guidelines are an important part of sound health care and, in the context of a pandemic, can serve the common good in an even more critical way. However, even a pandemic does not justify forgetting or violating the fundamental moral principles that guide ethical action: human life is sacred and should never be exploited. As the bishop chairmen of the United States Conference of Catholic Bishops aptly note in their statement on rationing, "Every crisis produces fear, and the COVID-19 pandemic is no exception. However, this is not a time to sideline our ethical and moral principles. It is a time to uphold them ever more strongly, for they will critically assist us in steering through these trying times." With this it mind, we note that the development and deployment of a vaccine for COVID-19 raise several major ethical concerns.

Re: Development using abortion-derived cell lines

Calling to mind the teachings of the Catholic Church in the 2008 instruction *Dignitas personae*, we firmly oppose the efforts of organizations and researchers to use cell lines derived from elective abortions—such as HEK-293 and PER.C6—to develop a vaccine against COVID-19. The use of the cell lines cannot be justified by the historical separation that exists between the deliberate abortions that gave rise to the lines and the current decisions of researchers to continue to use this biological material. The Congregation for the Doctrine of the Faith made this clear:

Therefore, it needs to be stated that there is a duty to refuse to use such "biological material" even when there is no close connection between the researcher and the actions of those who performed . . . [the abortion]. This duty springs from the necessity to remove oneself, within the area of one's own research, from a gravely unjust legal situation and to affirm with clarity the value of human life.²

In addition, the use of these cell lines, even for the laudable purpose of a COVID-19 vaccine, is a cause of serious theological scandal. Appealing to good aims and an "urgent need" will foster the deeper penetration of unethical research and development into medicine, politics, law, and culture. *Dignitas personae* warns against this: "Any appearance of acceptance would in fact contribute to the growing indifference to, if not the approval of, such actions in certain medical and political circles."³

In union with the moral tradition and teaching of the Catholic Church, we affirm the dignity of human life and strongly request the development and deployment of immunizations developed without any use of abortion-derived human fetal cell lines.

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¹ United States Catholic Conference of Bishops Public Affairs Office, "Bishop Chairmen Issue Statement on Rationing Protocols by Health Care Professionals in Response to COVID-19," April 3, 2020, https://www.usccb.org/news/2020/bishop-chairmen-issue-statement-rationing-protocols-health-care-professionals-response.

² Congregation for the Doctrine of the Faith, Instruction *Dignitas personae* (2008), n. 35, emphasis original. https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html.

³ Ibid.

It is critical to consider that many Christians and others who value human life at every stage, while not opposed to immunization and earnestly praying for one, may choose to conscientiously object to a COVID-19 vaccine developed using abortion-derived cell lines as a way of giving witness to the dignity of unborn human persons. This right to object must be respected yet may create difficulties reaching adequate vaccination levels for herd immunity.

A morally sound vaccine, with no ties to abortion-derived cell lines, could be firmly embraced by all.

Re: Informed Consent, safety, and efficacy

One of the cornerstones of modern medical ethics is informed consent—the principle that patients need to understand all the relevant information, including the risks and benefits of procedures or drugs, and give their consent before any action is taken. Vaccination decisions demand consideration of the facts to make an informed judgment.

A major concern with novel and perhaps "fast-tracked" COVID-19 vaccines is the quality, availability, and effective communication to the public of information concerning effectiveness and risks—the very facts essential to informed consent. A person always has the right to know the expected benefits and burdens of a treatment. Will the vaccine be 50% effective or only 10%? Will it be expected to elicit immunity, or simply to reduce symptoms? How extensive was the testing to rule out adverse side effects? How will this information be conveyed to potential recipients?

No coronavirus vaccine has ever been approved, so a COVID-19 vaccine would be a historic first for this family of viruses. This novelty, including the novel mRNA and DNA technologies being used in some cases, create additional reasons to question the reliability of initial assessments of safety and efficacy.

Transparency and completeness of information regarding mode of action, manner of production, any differences with respect to typical approval processes, and expected safety and efficacy of any vaccine approved and proposed to the public is ethically essential for proper informed consent.

Re: Government mandates

A universal vaccine mandate applied to all citizens at the federal or state level is morally unacceptable and would feed a lack of public trust, which is an essential component of any effort to accomplish the common good of a society.

Expected population health benefits from widespread vaccination do not automatically create a moral obligation for each individual to be vaccinated. Experimental or novel treatments with only limited knowledge of side effects, adverse events, efficacy, and long-term consequences are never morally obligatory for an individual. As such, they cannot be mandated by the state and any form of coercion would be unethical. The decisions remain personal, accounting for circumstances and respecting conscience, with appropriate medical and public health information for consent.

If information about the risks, burdens, and expected benefits of vaccination are clearly communicated without undue coercion, many may be willing to be vaccinated on an ethically solid footing without need of mandates or coercion and without compromising public trust.

Re: Exemptions for immunization requirements

If requirements for immunizations are implemented at a targeted level, such as in health care, nursing homes, or schools, it is ethically critical to ensure a right to refusal for reasons of deeply held moral, religious, philosophical, or other conscience convictions. We understand that with the right of such refusal comes the obligation to respect very limited legally imposed public safety restrictions, for example, the need to agree to alternative modes of education for children, or types of employment for adults. However, such restrictions cannot violate civil rights or be arbitrary, and must be scientifically defensible.

Re: Allocation of immunizations with initial limited availability

We recommend that any immunization allocation framework exclude discrimination on the basis of age, race, sex, religion, and any other criterion likewise unrelated to individual clinical benefit or the rapid and effective mitigation of COVID-related morbidity and mortality at a population level. We recommend tiers or categories that would prioritize immunization access with a view to rapidly ending the spread of COVID-19 while protecting those most vulnerable. For example, prioritization could be based on factors such as infection risk by geographic area (e.g., prioritize higher population density with higher transmission rates over lower population density with lower transmission rates), infection risk by type of work (e.g., health care workers prioritized over workers in other low-risk fields), infection risk by clinical profile (e.g., the immunocompromised prioritized over those with healthy immune systems), and risk of severe disease (e.g., persons with preexisting respiratory conditions, diabetes, etc.).

Conclusion

NCBC and CMA support efforts to develop an effective vaccine against COVID-19 for the protection of all members of society. However, to achieve compliance requires that the vaccine be morally acceptable and not developed using cell lines from aborted fetuses. This will greatly enhance the development of herd immunity. However, as important as it is to achieve herd immunity, it cannot be achieved at the risk of violating the right to informed consent, and even the right to refuse the vaccine, with the understanding that there could be ethically defensible consequences of such refusal. Furthermore, we understand that certain populations, based on risk factors, may be assigned non-discriminatory priority for receipt of the vaccine. We ask that all of these aforementioned ethical principles be respected in the development of COVID-19 immunization policies

Sincerely yours,

ELECRONICALLY SIGNED

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