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Filed Electronically

February 9, 2021

Office of the Secretary
Department of Health and Human Services
Washington, D.C.

Re: Proposed Rule on Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue, RIN 0991-AC15

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops ("Conference"), we respectfully submit the following comments on the proposed rule to clarify and improve regulations governing federally funded research involving human fetal tissue, including tissue obtained after abortions, published at 86 Fed. Reg. 2615 (Jan. 13, 2021) ("Proposal").

Interest of the United States Conference of Catholic Bishops

The Conference is a nonprofit corporation organized under the laws of the District of Columbia. All active Catholic bishops in the United States are members of the Conference. The Catholic Church, the largest religious denomination in the United States, has about 70 million adherents in over 16,000 parishes throughout the country. The Conference advocates and promotes the pastoral teaching of the bishops in such diverse areas as education, family life, health care, social welfare, immigration, civil rights, and the economy. The Conference participates in rulemaking proceedings of importance to the Catholic Church and its people in the United States. Rulemaking that concerns the protection of unborn human life and the ethical integrity of medicine and medical research is of paramount concern to the Conference.

In the Conference's view, the dignity and inviolability of human life at every stage of development is a foundational principle of any truly civilized society. The core ethical norms

protecting human research subjects, affirmed in the Nuremberg Code and many subsequent documents, reflect this principle.

Current Federal Law's Respect for the Unborn Child as a Human Subject

The care shown in this Proposal for the ethical and moral dimension of fetal tissue research is amply supported by longstanding statutory and regulatory enactments. These precedents recognize the child in the womb as a protectable human subject in medical research, deserving protection comparable to that afforded to the newborn child.

The regulations that govern federally funded research involving human subjects were prompted especially by news of two abuses in this field that shocked consciences throughout our nation: The Tuskegee syphilis experiments, in which Black sharecroppers were deliberately deprived of treatment for their illness to study the progress of the untreated disease over decades; and horrific experiments exploiting the victims of abortion, including children who were alive after being aborted at later stages of pregnancy.[1] Abuses of both kinds had received federal funding. Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974 to recommend regulations addressing such violations of human dignity.[2]

In the meantime, Congress barred the Department of Health, Education and Welfare from conducting or supporting "research in the United States or abroad on a living human fetus, before or after the induced abortion of such fetus, unless such research is done for the purpose of assuring the survival of such fetus."[3] Therefore it is by statutory mandate that the regulations for protection of human subjects, codified at 45 C.F.R. part 46, include Subpart C, "Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research."

Congress acted again in 1985 to correct deficiencies or possible loopholes in these regulations, by requiring two clarifications. First, the child who leaves the womb but may not survive (whether or not due to an abortion) may be subjected only to research that may (a) meet that child's health needs or enhance his or her chances of survival or (b) pose no added risk of suffering, injury or death. Second, regarding the living child in the womb, protection from

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[1] For reports of some of these experiments see: *Fetal Research, 1974: Hearing Before the Subcommittee on Health of the Committee on Labor and Public Welfare, United States Senate* (July 19, 1974), at #9 - Fetal research, 1974: hearing before the Subcommittee on Health ... - Full View | HathiTrust Digital Library | HathiTrust Digital Library, especially pp. 65-76. One such experiment that received NIH funding was P. Adam et al., "Oxidation of Glucose and D-B-OH-Butyrate by the Early Human Fetal Brain," *Acta Paediatr. Scand.* 64 (1975) 17-24, at Oxidation of glucose and D-B-OH-butyrate by the early human fetal brain - PubMed (nih.gov).

[2] See Title II of the National Research Act of 1974 (Public Law 93-348). The Act required the Commission to conduct "an investigation and study of the nature and extent of research involving living fetuses, the purposes for which such research has been undertaken, and alternative means for achieving such purposes." *Id*., Sec. 202(b).

[3] *Id*., Sec. 213.

research risks must "be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term."[4]

Two principles emerge from this history. First, the unborn child is a human subject with rights and interests that are distinct from those of the pregnant woman. Second, the fact that private parties, including the pregnant woman, may be legally allowed to take that child's life through abortion has no bearing on the respect due to the child in research funded by the federal government. In short, the government will not add insult to injury by treating the innocent abortion victim as a convenient laboratory animal for research protocols deemed unethical when applied to other members of the human family.

Two statutory provisions enacted in 1993 provide more specific guidance on use of human fetal tissue. One of them governs "research on the transplantation of human fetal tissue for therapeutic purposes" that is conducted or supported by the Department of Health and Human Services. It seeks to ensure, among other things, that a woman's decision about donating such tissue from an abortion is sought only after she has consented to the abortion, and that "no alteration of the timing, method, or procedures" for the abortion is done for the purpose of obtaining the tissue. There is no logical reason why these requirements, seeking to maintain some separation between the practice of abortion and the donation and use of fetal tissue, should not be equally applicable to donation of tissue for medical research other than transplantation research. Moreover, the abovementioned 42 U.S.C. § 289g, on federally funded researchers' respect for the child intended by others for abortion, applies regardless of the kind of research involved. The Proposal is fully justified in applying these safeguards against incentivizing abortion more broadly.[5]

The other statutory provision enacted in 1993 makes it a federal crime, punishable by up to ten years in prison, for anyone "to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."[6] Under this provision it is also a crime knowingly to receive fetal tissue "knowing that a human pregnancy was deliberately initiated to provide such tissue." These prohibitions are not confined to fetal tissue used for transplantation. The Proposal is fully warranted, to say the least, in taking extra care to ensure that federally funded researchers have no part in activities that would be

[4] Sec. 498 of the Health Research Extension Act of 1985 (Public Law 99-158), codified at 42 U.S.C. § 289g. While it is not the focus of the immediate Proposal, the fact that these important requirements, affirmed in statutory law for 35 years, have never been incorporated into the regulations themselves is cause for serious concern.

[5] Sec. 111 of the National Institutes of Health Revitalization Act of 1993 (Public Law 103-43), codified at 42 USC §289g-1. Some other aspects of this provision, like its safeguard against the pregnant woman selecting (or knowing the identity of) the person receiving this tissue, are specifically focused on the transplantation context, but are still based on the principle that federally funded research must not influence, or be influenced by, decisions by the pregnant woman or the abortion practitioner about the abortion itself.

[6] *Id*., Sec. 112, codified at 42 U.S.C. § 289g-2.

criminal for any researcher. The Proposal's exclusion of for-profit companies from this process is very much in accord with this statutory guidance.

Finally, a provision enacted into law in 1984 forbids any person "to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce." The penalty is a fine of up to $50,000 and/or a prison term of up to five years. Through a 1988 amendment the term "human organ" is here defined to mean, at a minimum, "the human (*including fetal*) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin *or any subpart thereof*." Therefore this prohibition is applicable to fetal tissue, albeit only in the context of transplantation.[7] Here as well, a federal statute recognizes that protections against any financial incentive for retrieving organs or tissue – or for hastening a donor's death to retrieve these – apply equally to the born and the unborn.

These current laws provide additional strong support for the Proposal's effort to eliminate use of financial incentives in this area of law, and to prevent the prospect of tissue donation from influencing a decision to undergo or perform an abortion.

Limitations of the Proposal

While the Proposal's clarifications are very welcome, it should be noted that they are unlikely to fully achieve their purpose as long as fetal tissue from abortion victims is seen as a standard tool of medical research. This was persuasively argued by some members of the federal Human Fetal Tissue Transplantation Research Panel studying this issue in 1988. They pointed to indications that some women change their mind about undergoing an abortion *after* signing the abortion consent form, and these women may be dissuaded from reconsidering their choice by the offer of tissue donation. They added that public attention to the alleged use of fetal tissue for medically beneficial purposes may influence women's choice of abortion.[8] The latter problem may be alleviated to some extent by requiring facilities that supply fetal tissue for federally funded research not to advertise this fact to the public.

These panelists also raised a more fundamental question. Parents are generally seen as the most appropriate decision makers regarding research involving their children because they will act in their child's best interests. Even after a child's death, parents are seen as the best decision makers to give consent to the disposition of a child's remains, because they will ensure that this process fully respects the humanity and dignity of the child. How can these assumptions apply, and how can such consent be valid, when the parent has decided on the premature death of that

[7] Sec. 301 of the National Organ Transplant Act of 1984 (Public Law 98-507) as amended by Sec. 407 of the Health Omnibus Extension of 1988 (Public Law 100-607), codified at 42 U.S.C. § 274e (emphasis added).

[8] J. Bopp and J. Burtchaell, "Statement of Dissent," in Consultants to the Advisory Committee to the Director, National Institutes of Health, *Report of the Human Fetal Tissue Transplantation Research Panel* (December 1988), at Fetal Tissue Panel Volume 1.pdf (georgetown.edu), pp. 52-63.

child? To raise this question is not to cast blame, or to ignore the pressures and ambivalent emotions that may be involved in a woman's choice of abortion. It is simply to recognize that the usual presumption about parental decision making, based on a harmony of interests between mother and child, does not seem to apply here, where those interests are in conflict.[9]

To be sure, a majority of the panel members did claim that fetal tissue research could be insulated from the morality of abortion through procedural safeguards. But most of these members proceeded to undermine that claim, by endorsing an additional statement that if elective abortions ultimately do not provide enough tissue to meet researchers' demand, the government should consider approving *abortions specifically performed for the purpose of providing such tissue*.[10]

This is not to belittle the Proposal, which makes very significant improvements in current federal regulations. It is to suggest that federally funded researchers' use of fetal tissue from abortion victims will never be fully isolated from the moral problem of abortion itself, until as a society we move away from use of such tissue. Last year the federal Human Fetal Tissue Research Ethics Advisory Board charted a path toward this positive outcome. It recommended disapproval of research projects that fail to demonstrate the need for such tissue, and approval of a project that will use alternative models alongside fetal tissue to determine whether the latter is necessary for the research.[11]

A Case in Point: Vaccines

The COVID-19 pandemic and the rapid development of vaccines to address this crisis provide a clear example of the current problem as well as a reasonable solution.

Catholic moral teaching opposes decisions to exploit abortion victims by using their remains for research, and we have been among those urging the federal government to develop much-needed vaccines in other ways.[12] At the same time, our teaching recognizes that adults requiring vaccination to protect their health and that of their children are at the end of a long process in which decisions were made by others, without their consent, about the use of fetal tissue to develop cell lines for research. Therefore we have said that in situations where a serious health danger exists, Catholics do not act immorally when they accept vaccines cultured using such cell lines if a vaccine with no connection to abortion is not available.[13]

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[9] *Id*., pp. 47-50.

[10] *Id*., Additional statement by J. Robertson et al., p. 38.

[11] National Institutes of Health, *Report of the Human Fetal Tissue Research Ethics Advisory Board- FY2020*, at Report of the Human Fetal Tissue Research Ethics Advisory Board- FY2020 (nih.gov).

[12] *See* "Coalition letter to FDA (2020) urging ethical COVID vaccine" at Letter to FDA urging ethical COVID vaccines_0.pdf (usccb.org).

[13] For documentation see Biomedical Research | USCCB.

However, many Catholics and other pro-life Americans have continued to express serious conscientious objections to making use of a product that relies on tissue from abortion victims, and this has contributed to public suspicion of the vaccination program. At times that suspicion has extended to vaccines developed without use of fetal tissue, if during the pre-clinical stage they were tested for effectiveness on a fetal cell line alongside other models. Continued reliance on these cell lines can therefore compromise much-needed efforts to protect the public health from an outbreak of infectious disease.

We are encouraged that some major vaccines now in circulation were developed using new technology that does not rely on culturing dead or disabled virus in any cell line, and that some were neither developed nor tested using abortion-derived cell lines.[14] This trend is good news for the ethical integrity of medical research as well as for future public health campaigns.

We are aware that the current Proposal does not apply to "established human fetal cell lines (including immortalized cell lines…)." Previous NIH guidance had been more specific, referring to "already-established (as of June 5, 2019) human fetal cell lines."[15] We recommend that the final Rule include a date certain such as this. It should also state explicitly that the use of fetal tissue from abortions to establish *new* "immortalized" cell lines is included under these regulations, or ideally that *such projects should not be pursued at all* using federal funds. This will encourage the salutary trend, already begun, of developing research and treatment protocols that do not rely on fetal tissue from abortions at all.

Conclusion

In short, we welcome the Proposal, and we suggest that a Final Rule should:

- Cite the full range of statutory enactments on live fetal research and fetal tissue research in support of the Proposal's policies;

- Enhance the safeguard against abortion decisions being influenced by the prospect of tissue donation, by preventing abortion facilities from advertising the latter prospect to clients or the general public;

- Serve the ethical integrity of medical research and the effectiveness of public health efforts by discouraging the use of federal funds for creation of new cell lines using fetal tissue from abortion victims, thereby advancing ethically sound alternatives that make no use of such tissue.

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[14] For an overview of COVID vaccines, see Charlotte Lozier Institute, "Update: COVID-19 Vaccine Candidates and Abortion-Derived Cell Lines" at COVID-19-Vaccine-Candidates-and-Abortion-Derived-Cell-Lines.pdf (pcdn.co).

[15] Proposal at 2620.

Thank you for this opportunity to comment.

Respectfully submitted,

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