THE NATIONAL CATHOLIC BIOETHICS CENTER
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December 18, 2006

U.S. Department of Health and Human Services
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852.

Re.: Docket No. 2006D-0383

Dear Sir/Madam:

I am writing on behalf of the National Catholic Bioethics Center to provide comment on the *Draft Guidance (Guidance) for Industry on Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases*. The National Catholic Bioethics Center *(Center) is a non-profit 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 Center provides consultations to institutions and individuals seeking its opinion on the appropriate application of Catholic moral teachings to these ethical issues.*

The Center specifically wishes to comment on the recommendations that the Food and Drug Administration (FDA) is providing to manufacturers of viral vaccines. Of particular concern are the recommendations for the characterization and qualification of cell substrates and biological raw materials used for the production of viral vaccines for human use. The Center recognizes the intent of the *Guidance*, which is to assure purity of the vaccines produced. The Center also recognizes the important individual and public health benefits provided through the use of vaccines for the prevention and treatment of infectious diseases. One could even say there is a moral imperative to be immunized from infectious diseases, for the well being of one's self, one's family, one's community, and the society at large. We also recognize that the *Guidance* is not explicitly creating new ethical standards in terms of the use of human tissue, but commenting on various existing methods and tissue sources used in vaccine production. However, these recommendations include specifications for the use of human substrates which are derived from destroyed embryos and directly aborted fetuses.

In the definition of terms in the *Guidance*, there appears to be tacit approval for the use of tissue from destroyed embryos: "VI. GLOSSARY, 26. PRIMARY CELLS: Cells placed into culture immediately after an embryo, tissue, or organ is removed from an animal or human and homogenized, minced, or otherwise separated into a suspension of cells. Primary cells may be maintained in medium, but are not passaged (split)." Herein the most serious ethical dilemma is forced upon people of conscience, through the creation of vaccines using tissues that might be derived from directly destroyed human embryos. Basic embryology makes it clear that from fertilization a new human being exists, as a composite unity, with his or her own internal principle directed toward continuing organismic development and growth towards adulthood. Each of us was that embryo and fetus at one point in time. Each human being has an immeasurable and intrinsic moral significance, which outweighs any utilitarian consideration. Providing a regulatory framework to allow for the use of cells and tissues obtained through the destruction of human beings, especially at their most vulnerable stages, is an affront to the dignity of all persons. This commodification and reduction of the human embryo to "raw material" is among the gravest of bioethical concerns. As C.S. Lewis, in *The Abolition of Man*, has stated, "If man chooses to treat himself as raw material, raw material he will be." (1943). This, in summary, is the first and most serious concern, namely, the destruction of living embryonic human beings as the starting point for cell or tissue procurement.

A second, related concern involves the use of fetal cadaveric material derived from elective abortions, where the abortions occurred for other reasons independent of tissue procurement, such as limiting family size. The use of tissue for research and vaccine development, from human beings whose lives have been previously terminated by elective abortion, is an offensive misuse of human remains and an affront to human life. It poses serious questions of conscience among those who wish to honor and respect the sanctity of human life, and has the practical effect of discouraging universal immunization.

These provisions of the draft *Guidance* appear to be strongly inconsistent with the intent of existing federal law, promulgated to protect the humanity of the American people. Laws governing funding of current federal research, passed by Congress, provide the same protection to the embryo and fetus as is provided to an infant. Since 1975, when the federal government first established federal regulations for the protection of human subjects in medical research, human embryos from the time of implantation in the womb (about a week after fertilization) have been included under the federal definition of "fetus" and hence treated as "human subjects," deserving of protection from harmful research. In 1985 Congress further clarified this standard by amending the National Institutes of Health reauthorization act: for research involving live fetuses *in utero*, protection from risk must be "the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term" (42 USC §289g).

No matter what fate may be planned for the developing human being by others, the government must still maintain a posture of respect towards human life -- it cannot single out certain lives as disposable, or as uniquely fit for harmful research, simply because someone else plans to destroy those lives. In 1996 Congress passed legislation to provide the same protections to the embryo. The 1996 Dickey Amendment states that federal funds are not to be used for the creation of human embryos for research purposes or for research in which embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C. F. R. 46.208(a) (2) and 42 U. S. C. § 289g (b). The ban defined "human embryo or embryos" as including any organism, not protected as a human subject under 45 C. F. R. 46 (Human Subject Protection regulations) that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes (sperm or egg.).

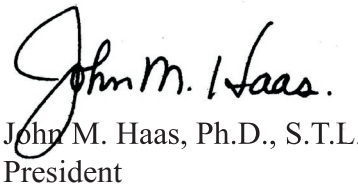
The Center has attached an Appendix page of examples within the *Guidance* which would appear to give approval for the use of tissue from destroyed embryos or directly aborted fetuses. The Center notes the lack of moral coherence in the drafting of the *Guidance* in the face of existing federal law, which has afforded protections for both the embryo and fetus for over ten years

The dilemma raised by the unduly permissive moral posture of the FDA regarding vaccine production means that the American people will have no real choices as to the vaccinations provided to them. Thus, they will have two options: they either may be forced to become complicit with a violation of the integrity of human life, (despite the fact that protection of human life is codified in current federal law), or to refuse to allow themselves, and those for whom they are responsible, to receive a vaccination that could be protective of their own health and the public good.

We urge revision of the *Guidance (Guidance) for Industry on Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases*, as drafted. We ask that the FDA explicitly prohibit the use of tissue from directly aborted fetuses and destroyed embryos in the future, in the development of vaccines to be approved by the Federal Drug Administration. We also urge the FDA to encourage and approve the development of cell lines not derived from tissue taken from directly aborted fetuses and the approval of the importation of safe vaccines which have been manufactured without using cell lines from aborted fetuses or destroyed embryos. When we allow the most vulnerable human beings to be exploited and destroyed, we not only destroy human life, but in the process diminish ourselves as persons and as a society.

We ask that you amend the draft *Guidance* to provide the requisite precautions necessary for the protection of human life. In particular, we most urgently ask that in the future the word "embryo" be removed from the VI. Glossary, 2b, Primary Cells" since it would countenance the direct killing and mincing of living human beings.

Sincerely yours,



John M. Haas, Ph.D., S.T.L.
President

APPENDIX

- *Section II. OVERVIEW: CHARACTERIZATION AND QUALIFICATION OF CELL SUBSTRATES, BACKGROUND (Page 2) states, in part:*

> *The number of different cell substrates used in currently licensed vaccines is limited. The emergence of new infectious diseases necessitates the need for development of new vaccines for agents such as human immunodeficiency virus (HIV), pandemic influenza virus strains, severe acute respiratory syndrome (SARS) virus, and agents of bioterrorism. In some cases, novel human and animal cell substrates might be needed to manufacture certain vaccines, including live attenuated viruses, live viral vectors expressing vaccine antigens, inactivated whole or subunit virions, purified recombinant proteins, and virus-like particles.*

Novel human cell substrates include such substrates as 293 cells and PER.C6 cells. These cell lines were developed from human embryonic kidney cells (293) and human embryonic retinal cells (PER.C6) from directly aborted fetuses. For the FDA to recommend the use of such tissue is inconsistent with the understanding of the rights and dignity legally attributed to the fetus under United States federal law.

- *Section III. CHARACTERIZATION AND QUALIFICATION OF CELL SUBSTRATES, VIRAL SEEDS, BIOLOGICAL RAW MATERIALS AND VACCINE PRODUCTION, A. PROPERTIES OF THE CELL SUBSTRATE, 3. History (including identifying characteristics) and other important characteristics (Page 7).*

This section requires the identification of the sources of human substrates, without any limitations on such sources. This opens the door to a myriad of human abuses in obtaining such cells:

> *documentation of the history of human-derived and animal-derived materials used during passage of the cells;*

- *Section III. CHARACTERIZATION AND QUALIFICATION OF CELL SUBSTRATES, VIRAL SEEDS, BIOLOGICAL RAW MATERIALS AND VACCINE PRODUCTION, B. CELL BANKING, 6. Additional considerations for cell lines that are tumorigenic or tumor-derived (Page 15).*

This section gives approbation to the use of fetal tissue (293 cells), from a direct abortion, as a source of a cell for transformation into a cell line:

> *…to transform a primary human cell to produce a cell line (e.g., 293 cells),….*

- *Section III. CHARACTERIZATION AND QUALIFICATION OF CELL SUBSTRATES, VIRAL SEEDS, BIOLOGICAL RAW MATERIALS AND VACCINE PRODUCTION, D. BIOLOGICAL RAW MATERIALS AND ANCILLARY REAGENTS (Page 17).*

This section labels all human-derived cell substrates, which in the *Guidance* includes tissue from directly aborted fetuses, as "Biological Raw Material," an affront to the dignity that should be afforded tissue from human beings.

- *Section IV. DESCRIPTION OF QUALITY-CONTROL TEST METHODS, C. OTHER TESTS, 2. Testing for Residual Cellular DNA (Page 39).*

This section specifically acknowledges, and affirms, the use of tissue from directly aborted fetuses for the production of vaccines:

> *You should measure the amount and size distribution of residual DNA in your final product. For widely used human diploid cell strains, such as MRC-5 and WI-38 cells, measurement of residual DNA might be unnecessary because we do not consider residual DNA from these human diploid cells to be a safety issue.*

The MRC-5 cell line was developed in September 1966 from lung tissue taken from a 14 week old directly aborted fetus. The WI-38 cell line was developed in July 1962 from lung tissue taken from a directly aborted fetus of approximately 3 months gestational age.