FLORIDA CATHOLIC CONFERENCE
201 WEST PARK AVENUE
TALLAHASSEE, FLORIDA 32301-7715

PHONE (850) 222-3803
FAX (850) 681-9548
www.flacathconf.org

D. MICHAEL MCCARRON, PH.D.
EXECUTIVE DIRECTOR

December 22, 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I am writing on behalf of the Florida Catholic Conference to provide comment on the *Draft Guidance (Guidance) for Industry on Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral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.*

Recognizing Scope of this Work & Importance of Immunizations

We specifically wish to comment on the recommendations that the Food and Drug Administration (FDA) is providing to manufacturers of viral vaccines. We recognize the intent of the *Guidance* is to assure purity of the vaccines produced and the important individual and public health benefits provided through the use of vaccines for the prevention and treatment of infectious diseases. Within the Catholic community, there is almost a moral imperative to be immunized from infectious diseases, for the well being of one's self, one's family, one's community, and 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.

Our Main Concern

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, particularly those specifications for the use of human substrates derived from destroyed embryos and directly aborted fetuses. The desired good end – development of health promoting vaccines – is not justified by the direct destruction of human beings, especially when other avenues can be utilized in the development of vaccines.

Dilemma Some Vaccine Development Sources Present

There is a dilemma that has been raised by the current posture of the FDA regarding vaccine production with directly aborted fetuses and destroyed human embryos. It means that the American people have no real choices as to the vaccinations provided to us. We have two options: we either may be forced to become complicit – to some degree – with a violation of the integrity of human life, (despite the fact that protection of human life is codified in elements of current federal law), or to refuse to allow ourselves, and those for whom we are responsible, to receive vaccinations that could be protective of our own health and the public good.

We Urge Revision to Draft Guidelines

We strongly urge revision of the *Guidance* 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 individual humans, 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 the inherent dignity in each human life.

Sincerely,

Michael B. Sheedy

Michael B. Sheedy
Associate for Health