

Celebrating 35 Yean: HLI was established in 1972 by Fr. Paul Marx, OSB, as the "Human Life Center" in Collegeville, MN; in 1981 it was officially founded as Human Life International.

2007

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December 20, 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

To Whom It May Concern:

On behalf of Human Life International I would like to offer an opinion on the *Industry Guidelines* for development of cell-based viral vaccines which have been opened up for public comment by your Department. Thank you for the opportunity to give input on such a serious matter. For the record, Human Life International is a federation of pro-life and pro-family organizations with affiliates in seventy-five countries and a long track record of responding to public issues to uphold universally-held norms of conscience. The issue that the FDA has placed before the public at **this** time is undoubtedly one of grave concern for people of **conscience**, and **for** that **reason** it is important for us to raise our **voice**.

The use of cell lines derived from tissues of aborted children presents one of the greatest moral concerns of our time, and the possibility that this practice could be expanded through the **FDA's** endorsement of further aborted fetal cell lines for new vaccines is alarming. At the **Nuremburg** War Trials the principle of *the inviolability of the human person* was considered a fundamental principle of *justice* in the treatment of other human beings. Those who tried to use the argument that they were simply obeying military orders to commit crimes against humanity were found guilty on the basis of this principle: the right to life is inviolable and intrinsically **knowable** by every human being, not because a government makes a law to prohibit its destruction, but because it is written on the human heart. There was considered no excuse for anyone of any stripe to kill innocents and to benefit from that killing.

In our day, certain cell lines were **created**—**current** research indicates **deliberately** from the tissues of aborted babies. Human diploid cell lines such as MRC-5, WI-38, HEK-293, IMR-90, PER C6 are among the cell lines that are known to have been created in this way. Nor does it concern any person of conscience whether those abortions were legal or illegal.

The concern is that the tissues used to create the cell lines were the "fruits of the poisoned tree" of abortion and are morally objectionable to use even for noble purposes. The use of vaccines derived from these cell lines creates a significant dilemma of conscience above all for those parents who wish their children to be vaccinated with untainted vaccines and also at the same time show concern for public health.

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Our own Catholic religious authority on these issues, the Vatican's Pontifical Academy for Life, has warned us that the use of such vaccines constitutes a certain cooperation in evil, sometimes remote and sometimes proximate, and that we as individuals should strive in every way to avoid such cooperation and to work for morally acceptable alternatives. We know that even today there are ethical alternative vaccines that may be used when the political and economic will is there. The Vatican also reminds us that public policy cannot legitimately base its decisions for the common good of society on unethical actions or institutions. When at all **possible** — and it is indeed possible in this instance — we must develop policies which safeguard the moral integrity of society and universal ethical norms.

In the case of further tainted cell lines that the FDA is considering authorizing, we object to their use for several reasons:

First, the principle of the inviolability of human life is dangerously cast aside and the endorsement of the federal government of practices that institutionalize such callous disregard for human life would allow others to justify further abuses of human dignity.

Second, when human life is allowed to be treated as a commodity for the cure of diseases, a utilitarian mind-set toward healthcare becomes the norm and leads both business and society down an ever-darkening path of human rights abuses; it also absolves us of the responsibility to make the sacrifice to find moral responses to human problems.

Third, there is no need for further tainted vaccines; while public health and herd immunity are of the highest priorities for any society, rights of conscience cannot be sacrificed to the lack of economic will to find ethical alternatives to our public health needs. We already know that ethical alternatives exist and can find a way into our public policy for the good of our people.

Finally, the United States is a moral and cultural force of nature for the world. Policies and actions of the US government, whether agreed with or not by other countries, exert an enormous amount of influence around the world; and if the US should publicly ignore the concerns of conscience in this fundamental matter, the effect on other countries could be catastrophic especially given the multi-national nature of the pharmaceutical companies who promote their products globally.

For these and many other concerns, we, the multi-national family of Human Life International, urge the FDA to accept no compromise on the issue of tainted cell lines and use every possible means in the future to endorse and promote ethical vaccines for the population whose conscientious concerns deserve to be heard, not only from the US but from the entire world.

Sincerely, Rev. Thomas J. Extensuer

Rev. Thomas J. Euteneder, President/CEO Human Life International

Cc: Julie L. Gerberding, Director, CDC Michael O. Leavitt, Secretary, HHS