

July 22, 2019

Norman E. Sharpless, M.D.
Acting Commissioner
Food and Drug Administration

Dear Acting Commissioner Sharpless,

We are writing to request the FDA's assistance in removing barriers that prevent some people in the United States from accepting immunizations for their children or for themselves. A key step the FDA can take in this regard is to use its authority to facilitate the availability of vaccines in the U.S. market that do not utilize cell lines derived from the tissue of aborted babies. Currently, several vaccines are produced using aborted fetal cell lines, including those for polio, rabies, hepatitis-A, shingles, measles, mumps, rubella (MMR), and varicella/chickenpox (Varivax).

Along with millions of Americans, we consider the use of aborted fetal tissue to be morally problematic for several reasons. First, we are concerned that seeking to benefit from the destruction of even one human being incentivizes the evil of abortion and lessens opposition to it. We also have moral concerns about how the tissue was obtained, the large number of abortions which were used to develop fetal cell lines, and the utilization of medicines derived from their bodies. We are also concerned that new cell lines have been, and will continue to be, derived from aborted fetal cells and that additional research and medical applications are continuing to be pursued. We strenuously object to abortion and any attempt to justify or to benefit from it.

While alternative vaccines exist in the United States for polio, rabies, and shingles, there are no ethically-produced alternatives for the Hepatitis-A, MMR and Varivax vaccines. Specifically, the rubella portion of the MMR uses RA27/3 virus which was cultivated on the WI-38 cell line, both of which involved nearly 100 elective abortions in the research and development. Likewise, the Varivax (chickenpox) vaccine also uses both WI-38 and yet another aborted fetal cell line, MRC-5, which was developed in the UK and is also used in Hepatitis-A.

While there is no ethically-produced alternative for the Varivax vaccine anywhere in the world, there are alternative vaccines in the United States for measles and mumps and in Japan for rubella, measles, and mumps. Prior to 2010, parents had the option of using Merck's separate doses of measles (Attenuvax) and mumps (Mumpsvax) vaccines which were produced using chicken eggs.¹ In 2010 Merck stopped providing these vaccines, stating it was not "economical" to do so. With the

¹ Right now, some people are avoiding getting the MMR precisely because of the fact that the rubella vaccine, whether given combined or separately, uses aborted fetal cell lines. Providing ethically-produced mumps and measles vaccines separate from the rubella vaccine would at least avoid people refusing these vaccines. Furthermore, data on rubella shows we have not had a native case since 2002 and less than 10 cases per year since then (all of which were imported with no spread of the disease to others), so this is not the primary concern for parents. See: https://www.paho.org/hq/index.php?option=com_content&view=article&id=10798:2015-americas-free-of-rubella&Itemid=1926&lang=en and https://wwwnc.cdc.gov/eid/article/24/4/17-1540_article. In addition, in the rare case of pregnant women who are not immune to rubella, they do have the option of using Immune Globulin which provides temporary immunity if needed.

encouragement of the FDA, perhaps Merck would again produce these vaccines or outsource the storage and distribution of them to another company.

Japan has two ethically-produced measles-rubella vaccines (MR) as well as a separate mumps vaccine, but they are not licensed in the United States. Parents cannot feasibly request personal import for one or two doses of these vaccines due to the high cost of shipping at specific temperature control, but those costs could be shared among several hundred users at a time. Personal import could be granted for the Japanese MR + mumps on an ongoing basis as needed. The FDA has allowed such personal import in the past for the Takahashi rubella from Japan. (see attached)

Based on our concerns and on the barriers to accessing potentially available alternative vaccines, we request the FDA to consider the following actions:

- 1) Urge Merck to provide the separate doses of Attenuvax and MumpsVax again so that parents can protect their children in good conscience or, as an alternative, allow another biotech company to outsource the product.
- 2) Request Merck to provide these vaccines in 3-packs, not 10-packs so that more physicians (or another company) can stock them.
- 3) Consider FDA allowance for import of several hundred morally-produced MR (measles + rubella) and separate mumps vaccines from Japan through a network of pro-life health care providers associated with some of the signatories to this letter. This would ensure safety of storage and distribution and defray high cost of shipping due to controlled temperature shipping and storage requirements.
- 4) Investigate the authority of HHS, under Sections 317(m) and 340 of the Public Health Service Act, to make bulk purchases of the morally-produced MR and separate mumps vaccines from Japan.
- 5) Urge other pharmaceutical companies to develop their own morally-produced MMR and varicella vaccines.
- 6) Take steps to promote and encourage the production of vaccines and other medicines which do not utilize aborted fetal cell lines.

While we are aware that people have differing views on vaccines and not all objections will be resolved with moral alternatives, these actions would significantly improve the status quo for Catholic, pro-life, and other concerned parents. As a case in point, the recent lawsuit in Kentucky arose not because the student and his family objected to all vaccines, but specifically to those derived from aborted fetal tissue.² The Pontifical Academy for Life did conclude that such vaccines may be used by Catholics under certain conditions—including the obligation to use alternative vaccines whenever possible and to advocate for vaccines not linked to aborted fetal cell lines.—nonetheless, the vaccines remain morally problematic in the eyes of many.

² <https://www.cincinnati.com/story/news/2019/03/21/taking-chickenpox-vaccine-violates-my-conscience-says-kentucky-student-who-sued/3235012002/>

We remain committed both to public health and to the protection and non-commercialization of unborn children. Taking the steps listed above will go a long way in promoting the health of our nation through the use of ethically-produced vaccines. Thank you for considering our requests and for your service to our nation. Please address any responses to Greg Schleppenbach at 3211 4th Street, NE, Washington, DC, 20017-1194 or gschleppenbach@usccb.org.

Sincerely,

Most Reverend Joseph F. Naumann
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Chairman, USCCB Committee on Pro-Life Activities

Most Reverend John F. Doerfler
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CC: Alex M. Azar II, Secretary of Health and Human Services
Admiral Brett P. Giroir, M.D., Assistant Secretary for Health
Jerome Adams, MD, Surgeon General