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DAVE WELDON, M.D.
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Congress of the United States
House of Representatives
Washington, DC 20515
September 25, 2007

The Honorable David Obey
Chairman
Appropriations Committee
H-218 The Capitol
Washington, D.C. 20515

Dear Chairman Obey,

Shortly after and in the weeks following the adoption of my amendment to prohibit federal funds from being used to provide mercury-containing vaccines to children under age three, a handful of arguments have been leveled against the amendment from several public health organizations, many of which receive funding from the pharmaceutical industry or the CDC. I want to assure you and my colleagues that the proposal adopted by the Appropriations Committee is based on sound science, puts the safety of our children first, and is an achievable goal given the facts regarding the current and future supply of pediatric, thimerosal-free influenza vaccine for the U.S. market. I have carefully examined current and future sources of thimerosal-free flu vaccine and have established that current supplies are almost certainly adequate to fully vaccinate all children covered by the amendment, and future sources of thimerosal-free flu vaccine will be sufficient to vaccinate all U.S. children ages 6-36 months. I would like to share with you the basis for my assessment.

When evaluating whether or not to vaccinate their children against influenza, parents should not be forced to choose between the risk of the mercury containing preservative thimerosal—whether real or perceived—and the risk of contracting influenza. Although many have argued to the contrary, I firmly believe that the uptake rates for influenza vaccination among children, currently at less than 50%, will rise when the thimerosal risk calculation is removed from the equation.¹

July 16 letter to the committee signed by more than two-dozen organizations who opposed my amendment assert that my amendment “will send the message that the federal government has determined that thimerosal-containing flu vaccine is unsafe [and that] ... it may increase the confusion about the safety of vaccines, resulting in an erosion of the public’s trust, causing the deaths of untold numbers of children.” However, in 1999, many of these groups adopted the position that thimerosal should be removed from vaccines “as soon as possible” for among other reasons, “public concern about the use of mercury of any sort...”

¹ <http://www.cdc.gov/flu/professionals/vaccination/pdf/targetpopchart.pdf>

Public concern about mercury has not abated since 1999. In 1999, the CDC, AAP, USPHS, FDA and the manufacturers worked together and totally eliminated mercury from all routinely recommended childhood vaccines. This was a wise response to shore up public confidence in vaccines, and appropriately, vaccination rates have increased since 1999. Somehow the absurd argument that taking thimerosal out of the pediatric flu vaccine – which became routinely recommended in April 2004 – will “erode the public’s trust” rings hollow. If anything, the public’s trust will build as those parents who are concerned about the potential adverse effects of mercury in their children’s flu vaccines see the public health community and manufacturers going the extra mile to put safety first.

Because I believe in the value of vaccinating children against influenza, I have made every effort to establish, with as much certainty as is possible given the vagaries of the influenza vaccine manufacturing process, that there will be adequate supply of thimerosal-free flu vaccine for the 2008-09 flu season to satisfy the demands of the amendment.

To cover every child under the age of 3, at least 10 million full doses of influenza vaccine are necessary each flu season. Approximately 54% of the nation’s children are eligible for the Vaccines for Children Program (VFC), the program most directly impacted by the amendment. Given the other programs funded in the Labor, Health and Human Services Appropriations bill, at most 70% of the nations children will be impacted by the amendment, requiring roughly 7 million thimerosal-free influenza vaccine doses to give every eligible child the opportunity to get vaccinated with a thimerosal-free flu vaccine.

In the last flu season, Sanofi-Pasteur produced approximately 8-9 million doses of thimerosal-free flu vaccine indicated for the pediatric population, which was able to cover at least 4-5 million children under the age of 3. In fact, for the 2006-2007 flu season, the CDC website states:

“thimerosal-free vaccine supplies will be adequate for children ages 6-23 months. Thimerosal-free vaccine doses licensed for three year olds, however, are limited in supply and CDC anticipates that there will be insufficient vaccine for this age group. Thimerosal-containing vaccine can also be used to vaccinate children if the product’s age indication is appropriate.”²

Thus, according to CDC, even in the last flu season, enough thimerosal-free flu vaccine was produced to meet the demand for children ages 6-23 months. My amendment applies to children under the age of three.

For the 2007-08 flu season, MedImmune, the manufacturer of the live, attenuated nasal flu vaccine *FluMist*, recently received FDA approval for this vaccine for ages 2-49. (Previously, the vaccine is licensed for ages 5-49).³ This vaccine does not contain

² <http://www.cdc.gov/flu/about/qa/vaxprioritygroups.htm>

³ <http://www.baltimoresun.com/business/bal-bz.flumist20sep20,0,5227993.story>

thimerosal. Studies, including one published in the prestigious *New England Journal of Medicine (NEJM)*, have shown that the nasal flu vaccine is 55% more effective for children than the traditional, injectable flu vaccine produced by Sanofi-Pasteur and purchased by the VFC.⁴ MedImmune has the capacity to manufacture approximately 30 million doses of the trivalent seasonal influenza vaccine, but has traditionally manufactured much less due to poor demand, including low levels of purchase through the VFC program. MedImmune expects to ship 4.4 million doses of FluMist with the expanded age indication. Even this season, this amount would cover ALL children ages 2-3.

Clearly, MedImmune has the capacity to supply additional thimerosal-free vaccine to satisfy the requirements of the amendment for 2-3 year olds for the 2008-09 flu season. In fact, some public health professionals have argued that since FluMist is a nasal vaccine, more widespread use of *FluMist* would actually increase vaccine uptake rates among children, who hate getting shots.⁵ Since this vaccine is also more effective at protecting healthy children from influenza, increased use of *FluMist*, which may occur as a result of my amendment, may actually result in INCREASED protection against flu for this age group, contrary to the assertions of my critics.

If Sanofi-Pasteur and MedImmune can meet the 7 million doses required even for the 2007-08 flu season, we have every reason to believe that sufficient quantities of thimerosal-free vaccine will be available even to cover children (ages 6 months to 3 years) not impacted by the amendment during the 2008-09 flu season. Yet the CDC's most recent estimate of vaccination rates among children ages 6 months to 5 years demonstrated that only 3.1 million doses of influenza vaccine were given in 2006, with an uptake rate for ages 6-23 months of only 47%.⁶ Even if CDC successfully encourages more children to get vaccinated, demand will likely not reach 7 million doses.

There are a number of other flu vaccine manufacturers that currently supply millions of doses of thimerosal-free flu vaccine in the U.S. for the adult market (over 18 years of age). Indeed, some of these manufacturers are providing this very same vaccine for children in Europe as young as 6 months of age. According to my conversations with these manufacturers, some are pursuing approval from the FDA to market their thimerosal-free flu vaccine for children 6 months and older in the U.S., while others see no financial incentive to do so.

If currently available sources of thimerosal-free flu vaccine prove inadequate to meet demand, the FDA could work with these manufacturers to expedite expanded approval of a thimerosal-free flu vaccine for children 6 months and older that has been demonstrated safe and effective in the pediatric population in Europe where it has been used routinely for years. There are two recent models for how the CDC, FDA, and vaccine manufacturers have worked together to meet critical vaccine demand. First,

⁴ Belshe, R.B., et al., *NEJM*, 2007. 356:685-696

⁵ <http://www.cidrap.umn.edu/cidrap/content/influenza/general/news/may1707flumist.html>

⁶ <http://www.cdc.gov/flu/professionals/vaccination/pdf/targetpopchart.pdf>

during the 2004-05 flu season, when the unexpected problems at the Chiron manufacturing facility threatened the supply of flu vaccine for the U.S. market, the FDA worked with Glaxo-Smith-Kline (GSK) to expedite U.S. approval of the flu vaccine they were already manufacturing for the European market. In fact, last year GSK supplied approximately 12 million doses of thimerosal-free flu vaccine for the U.S. adult market. Second, as I noted before, in 1999, the FDA, CDC and manufacturers worked in an expedited manner to remove all thimerosal from routinely administered pediatric vaccines. Clearly, the FDA, CDC and manufactures have the ability to meet this safety requirement. The FDA has the resources at its disposal should current supply prove insufficient. It really boils down to a question of, do they have the will.

Each season, the CDC has expanded their recommendation of who should get vaccinated against influenza, steadily moving towards a universal vaccine recommendation. This accomplishes two purposes: expanding the market for seasonal flu vaccine so that the supply remains secure, and preparing both the market and the public for the possibility of pandemic flu. As we have seen in the past few years, manufacturers are willing to enter the U.S. market as CDC works to increase demand. The result is an unprecedented increase in the number of flu vaccine doses available to the U.S. market. Current CDC estimates for the 2007-08 season project that over 130 million doses of flu vaccine will be available.

My amendment accomplishes a similar purpose: expanding demand for thimerosal-free pediatric flu vaccine creates additional financial incentive for manufacturers who already have the capacity to produce thimerosal-free flu vaccine to pursue pediatric licensure for their vaccines in the U.S. I would also note that the fact that the availability of only 130 million doses of flu vaccine for the 2007-08 flu season has not made CDC shy away from expanding their recommendation to include 218 million Americans – almost 100 million more than current supplies can meet.

My critics argue that amendments such as mine “send the message that the federal government has determined that thimerosal-containing flu vaccine is unsafe.” But the federal government has already made a prudent decision to remove thimerosal from all other childhood vaccines (1999), while never conceding that thimerosal posed a risk to children. In my professional opinion, the data on the safety of thimerosal is, as yet, inconclusive. Yet mercury is a known neurotoxin, and children are exposed to mercury in various forms through sources that are difficult, if not impossible, to control. The EPA has estimated that one-in-six infants is born with mercury levels higher than those deemed safe by the EPA. My amendment offers a straightforward way to reduce a direct source of mercury exposure for children while still allowing all children to get vaccinated against flu. Rarely are politicians offered such win-win proposals.

CDC and FDA have made a valiant effort to shore up the nation’s influenza vaccine supply to prepare manufacturing capacity for a universal seasonal flu vaccination recommendation and for a possible pandemic flu situation. Thus, in only three years after the problems at Chiron threatened the U.S influenza vaccine supply, there are now five manufacturers producing vaccine for the U.S. market. The same effort can be easily

directed toward shoring up the thimerosal-free influenza vaccine supply for our nation's children.

As a physician, I know the tremendous benefit vaccines have provided in reducing or eliminating death and hospitalization from disease, and I am supportive of vaccinating children against influenza. Yet, the public health community must confront the real and widespread concerns many parents have about injecting their children with mercury by removing thimerosal from childhood influenza vaccines. I firmly believe that more parents will choose influenza vaccination for their children when thimerosal is removed from the equation. Eliminating thimerosal from pediatric influenza vaccines would aid in the effort of rebuilding public confidence in our nation's vaccine program. This amendment is common sense, it is feasible, and is in the best interest of our most vulnerable children.

Sincerely,

A handwritten signature in black ink, appearing to read "Dave Weldon". The signature is fluid and cursive, with a large initial "D" and "W".

Dave Weldon
Member of Congress

cc: Ranking Member Jim Walsh