

# MedCon, Inc.

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Documents Management Division  
Food and Drug Administration  
Dept. of Health and Human Services  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

October 25, 2004

**RE: FDA Docket #2004P-0349**

To Whom It May Concern:

These comments are being submitted in support of the Citizen Petition dated July 30, 2004, filed by Coalition for Mercury-Free Drugs with the FDA Dockets Management Division on August 4, 2004, and subsequently assigned FDA Public Docket number 2004P-0349.

In the months since the submission of the Citizen Petition by the Coalition for Mercury-Free Drugs, there a number of further developments supporting that Thimerosal/mercury should be removed from all products injected/applied/administered to children under the age of 3 and to pregnant women.

On August 7, 2004, the British Broadcasting Corporation (BBC) announced that the British Government was going to rapidly remove Thimerosal from its childhood vaccinations amid fears that Thimerosal (also known as Thiomersal in England and Europe) was linked to childhood autism.<sup>1</sup> Specifically, it was reported, "A vaccine containing mercury given to babies when they are eight weeks old is to be scrapped amid fears of a link with autism. The move follows recent research in America that suggests a connection between the mercury used to preserve the whooping cough vaccine and autism." [Note: This removal was effected by a change in the vaccines to be administered on September 27, 2004.]

On September 28, 2004, Governor Arnold Schwarzenegger of California signed Assembly Bill No. 2943 into law.<sup>2</sup> This bill, similarly to the Citizen Petition (2004P-0349), states, "This bill, with certain exemptions, would prohibit, on and after July 1, 2006, a person who is knowingly pregnant or who is under 3 years of age from being vaccinated with a mercury-containing vaccine or injected with a mercury-containing products that contains more than a specified amount of mercury.... Except for an influenza vaccine described in subdivision (b), on and after July 1, 2006, a person who is knowingly pregnant or who is under three years of age shall not be vaccinated with a mercury-containing vaccine or injected with a mercury-containing product that contains more than 0.5 micrograms of mercury per 0.5 milliliter dose. (b) On and after July 1, 2006, a

<sup>1</sup> Autism Scrapped Over Autism Fear. BBC News – UK Edition, August 7, 2004.

<sup>2</sup> <http://www.assembly.ca.gov/acs/acsframeset2text.htm>

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person who is knowingly pregnant or who is under three years of age shall not be vaccinated with a mercury-containing influenza vaccine that contains more than 1.0 microgram of mercury per 0.5 milliliter dose.”

The following are some abstracts from discussions/debates concerning Assembly Bill No. 2943 that occurred in the California Assembly and Senate from April through August 2004:

According to the author, this bill was introduced to respond to growing concerns that Thimerosal, a preservative containing approximately 50% ethylmercury (actually 57 % ethylmercury, 49.55 % mercury), could be contributing to increasing rates of neurodevelopment disorders, including autism, in children. New information, presented in a June 2004 study funded by the UC Davis Mind Institute and conducted by the University of Columbia, indicates that Thimerosal can increase the risk of autism-like damage in autoimmune disease susceptible mice. This is the first study to demonstrate that a low dose of ethylmercury, coupled with a genetic predisposition, can lead to behavioral and neurological changes in the developing brain. Though the medical and scientific community is still discussing the significance of this study and others, this bill is a precautionary measure that would reduce infants' and children's overall exposure to mercury during critical developmental years.

Mercury is a persistent toxin that accumulates in the environment and in the food chain. If ingested by humans, mercury can damage the central nervous system, kidneys, and liver even at very low levels. It is especially hazardous to children and pregnant women... Research has shown that developing fetuses and young children are very sensitive to the toxic effects of mercury, and that fetuses may be more prone to mercury exposure than previously thought. While mercury as a heavy metal is a toxin, combined with other chemicals or metals into different mercuric compounds, it may be more or less toxic to the human body depending on how the compounds are metabolized. Additionally, the impact of a compound on infants and children may differ from the effects on adults. Studies and guidelines are, for the most part, based on data taken on methylmercury as it has been more prevalently used in products and found as a contaminant in the environment. The impacts to the human body of ethylmercury, which is an ingredient of the vaccine preservative, are still not fully known.

In February 2004, the California Environmental Protection Agency's (CalEPA) Office of Environmental Health Hazard Assessment (OEHHA) issued a decision on Bayer Corporation's petition request to remove Thimerosal from the Proposition 65 list of chemicals known to cause cancer or reproductive toxicity. The decision stated: "...there are a number of studies providing direct evidence of developmental toxicity for Thimerosal, ethylmercury and related mercury compounds... In humans, accidental exposure to ethylmercury produced severe mental retardation in offspring, growth retardation, and decreased muscle tone...In addition, human and animal data show the interconversion of ethylmercury to inorganic mercury; (and) inorganic mercury has been clearly shown to cause developmental toxicity. Ethylmercury has also been shown, like methylmercury, to accumulate in the brain and cause tissue damage..."

After a three year investigation, the U.S. House of Representative's Subcommittee on Human Rights and Wellness of the Committee on Government Reform found that the

available studies on ethylmercury indicate that ethylmercury is just as toxic as methylmercury. Their report found that the FDA failed to require that product manufacturers prove Thimerosal was safe before it was introduced on the market. They also stated that the introduction of thimerosal appeared to be based on a single, uncontrolled and poorly reported human study in the 1920s, possibly in combination with animal and laboratory studies. However, the report stated that this study was not a true safety study and produced a faulty foundation for the vaccine program, in which young children are injected with multiple doses of ethylmercury [generated in vivo from the Thimerosal injected].

A 2003 report published by the *Journal of American Physicians and Surgeons*, conducted by Drs. Mark Geier and David Geier, asserts strong epidemiological evidence for a link between mercury exposure from Thimerosal-preserved childhood vaccines and neurodevelopment disorders...

The Sierra Club asserts that, "A recent analysis by the U.S. Environmental Protection Agency nearly doubled - to 630,000 - the number of children born annually in the U.S. with unsafe levels of mercury in their blood. To continue injecting pregnant women and children with a potent neurotoxin [i.e. Thimerosal], when safer alternatives are available, would be irresponsible."

Supporters also argue that, "In the 70 years since Thimerosal was first used in vaccines, science has made great strides in understanding the danger of exposure to even minute levels of mercury. We have succeeded in removing mercury in many items such as paints and thermometers; and warnings are routinely issued about mercury in fish. Thimerosal, once marketed as the topical ointment Mercurochrome, was banned specifically due to recognition that exposures to mercury could be harmful yet we continue to inject infants and young children with vaccines that contain mercury because government officials which regulate the national vaccine program claim mercury is safe in trace amounts – this makes no sense."

It is imperative that the FDA, which began to recommend removal of mercury from medicinal products over two decades ago, now finally mandate the reduction of mercury levels to trace amounts in all drugs, including vaccines, administered/injected/applied to children under the age of 3 and to pregnant women. Concomitant with this reduction, the FDA and the industry need to prove that the trace levels remaining in a given vaccine are truly safe or, if the trace level cannot or is not proven safe, require the removal of all mercury from all such vaccines by the end of 2007.

Thank you,



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