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DEMOCRATIC SENIOR WHIP

CHAIR, Congressional Entertainment
Industries Caucus

May 14, 2009

Dr. Joshua Sharfstein
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue, Room 2200
Silver Spring, MD 20903

Dear Acting Commissioner Dr. Joshua Sharfstein:

As a result of *Moms against Mercury vs. von Eschenbach*, the Food and Drug Administration must classify mercury amalgam as a device by July 28, 2009. As this date approaches, we urge you to consider the many ill effects of mercury amalgam in reaching your decision. Though we commend the efforts of FDA to clarify the effects of mercury by updating the FDA website, we must stress the importance of imposing more stringent regulations on this toxic device.

Once mercury is placed in the body in the form of a "silver" filling, it is released in the form of vapors as a result of chewing, as noted on the FDA website. These odorless and colorless vapors travel from the mouth and eventually into the body where they can possibly attack numerous vital organs and key body functions.

Vapors from mercury can also traverse the placenta of pregnant women and threaten the development of the fetus. Studies have shown that the level of mercury in fetus' liver, kidney and brain tissues were proportionate to the number of fillings in the mother's mouth. Mercury is also known to pass into breast milk of lactating mothers, increasing the amount of mercury in the infant during formative months.

Mercury is a known neurotoxin; the third most known toxic element as listed by the CERCLA Priority List of Hazardous Substances. Also, mercury is regulated by the Environmental Protection Agency as a toxic element in certain fish found along the Western Coast of the United States. The FDA currently recommends that pregnant women limit their consumption of fish because of the high level of mercury. Even though dental amalgam is the predominant source of human exposure to mercury, it is not regulated by FDA.

As FDA classifies mercury amalgam and determines the labeling, FDA should first require the industry to correctly label 'silver' fillings to reflect their predominate

Acting Commissioner Dr. Joshua Sharfstein

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component, mercury. The FDA should also require all parents of children under the age of 18 years old to sign a written consent form indicating that they are fully aware of the potential negative effects of mercury. The FDA should also require a verbal warning given by dentists to patients over the age of 18 years noting the high toxicity of mercury and the potential of neurological problems.

It is imperative that we protect the women and children from the harmful effects of mercury fillings. We look forward to your response and working with you regarding this important issue.

Sincerely,



Diane E. Watson
Member of Congress



Dan Burton
Member of Congress



Corrine Brown
Member of Congress



Yvette Clarke
Member of Congress



Emanuel Cleaver
Member of Congress



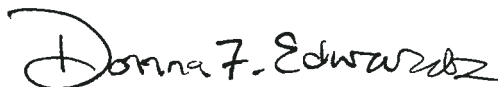
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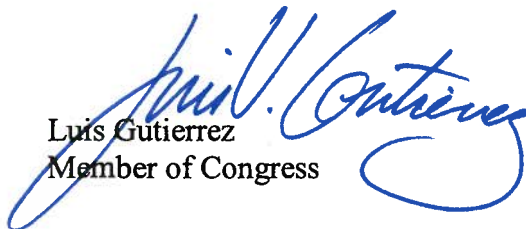
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Member of Congress



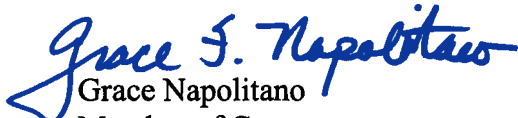
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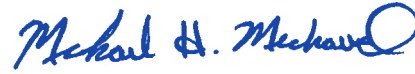

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