

4240 '03 JUL -2 P1:28

FDA  
Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, room 1061  
Rockville, MD 20852.

Re: Docket No. 03N-0169

June 27, 2003

Enclosed are (2) copies of the book MERCURY-FREE...The wisdom behind the global consumer movement to ban "silver" dental fillings, written by Dr. Hardy for submittal to the FDA for review to evaluate risks of mercury toxicity from dental amalgam.

Dr. Hardy has devoted his entire career as a dentist of 20 years to informing people of the hazards of silver amalgam fillings. MERCURY-FREE...The wisdom behind the global consumer movement to ban "silver" dental fillings is fully supported by more than 350 scientific references, with testimonies from people who have gone from sickness to health by becoming mercury-free. These improvements came after their "silver" mercury dental fillings were replaced by composite fillings, which are safer, stronger and more attractive. MERCURY-FREE is endorsed by many prominent scientists and physicians, including Bernie Siegel M.D., author of Love, Medicine and Miracles and Neal Barnard M.D., author of Eat Right Live Longer.

The major ingredient both by weight and volume in a "silver" dental filling is mercury, which is one of the most toxic substances known to man. These very common "silver" dental fillings contaminates our bodies, water, soil and the air we breathe.

The U.S. Food and Drug Administration (FDA), allows only 1 ppm mercury in tuna fish. Mercury has been declared a hazardous air pollutant under the Clean Air Act of 1987, a toxic pollutant under the Clean Water Act of 1988, and the EPA in 1988 declared mercury amalgams a hazardous substance under the Superfund Law.

Approximately 100 million amalgams are placed in the United States each year. The World Health Organization (WHO) concluded that the largest source of mercury exposure in the general population is by far, dental amalgams. There is a great deal of scientific evidence conclusively showing that mercury constantly leaks out of amalgams, lodging in vital organs where it can cause great harm. One is tempted to wonder what role this continual mercury exposure has on disease processes in large populations. It is estimated that 50% of Americans have mercury dental fillings.

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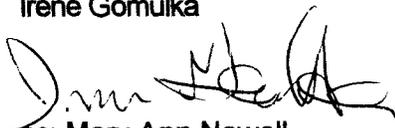
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Because the symptoms of mercury poisoning mimic other disease conditions, it is very hard to diagnose. Mercury is tasteless, odorless and invisible. Its effects can be slow, progressive and cumulative. It crosses the placental barrier in pregnant women and concentrates in fetal tissue. Most physicians are not even aware of the problem because the American Dental Association (ADA) has been so insistent on the safety of "silver" mercury dental fillings. However the ADA does warn its members not to handle the mercury amalgam unless absolutely necessary; wearing gloves and using extreme caution. Amalgam fillings removed from human mouths must be disposed of as hazardous waste regulated by the U.S. Environmental Protection Agency (EPA).

Sincerely,

Irene Gomulka



cc: Mary Ann Newell

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