CoMeD Sues FDA to Force Mercury Out of Medicine

Press Release **Contact:**

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Washington, DC – On Friday, October 27, 2006, the Coalition for Mercury-free Drugs (CoMeD) filed an amended complaint in U.S. Federal Court, disputing the FDA response it received on September 26, 2006.

CoMeD is asking the court to compel the FDA to: comply with the law, follow existing regulations, and provide proof of the safety and efficacy of mercury in drugs.

This lawsuit was originally filed in August 2006 because the FDA had failed to answer the issues raised in a CoMeD citizen petition (FDA Docket: 2004P-0349), filed on Wednesday, August 4, 2004, by representatives from CoMeD.

Of concern is that mercury, which is second only to plutonium in toxicity, remains in at least 45 different prescribed and over-the-counter drugs (according to the FDA), including various eye ointments, ear solutions, nasal sprays, vaccines, biologics, and perhaps most importantly, in flu vaccines currently being administered to millions of pregnant women, children, and the elderly.

Mercury is toxic to all human systems. Infants and children are especially susceptible to mercury poisoning. Mercury has been implicated in a long list of human chronic disorders including Alzheimer's disease, asthma, attention-deficit disorder, autism, diabetes, and multiple sclerosis, among many others.

In a letter sent to the CoMeD and made public on September 27th, Dr. Jeffrey Shuren, the FDA Acting Assistant Commissioner for Policy, denied the CoMeD petition, but his admission that the FDA had no substantive evidence confirming the safety of mercury in medicine was stunning.

FDA also acknowledged that mercury in drugs could easily be eliminated.

Plaintiffs' lead attorney, Clifford Shoemaker stated, "*In its response, the FDA refused to address the merits of the complaint. It is not the responsibility of consumers to prove drugs 'unsafe'; it is the FDA's duty to prove drugs are safe. The FDA has ignored a mountain of scientific evidence and its responsibility to the public, specifically to protect our children. ... It has failed to follow its own statutes and regulations. ... Just as we witnessed with Vioxx, the FDA has turned a blind eye to the danger of mercury in medicine. To the detriment of multiple generations, industry influence over the FDA has again compromised drug safety.*"

In a 1999 internal email, obtained under a Freedom of Information Act (FOIA) request, an FDA official admitted that the agency's failure to evaluate the cumulative amount of mercury in medicine, "*...will raise questions about FDA being 'asleep at the switch' for decades by allowing a potentially hazardous compound to remain…and not forcing manufacturers to exclude it from new products…"*
(**See:** http://www.putchildrenfirst.org/media/1.6.pdf.)

In a second email, the same FDA official wrote, *"... the greatest point of vulnerability on this issue is that the systematic review …by the FDA could have been done years ago and on an ongoing basis*."
(**See:** http://www.putchildrenfirst.org/media/1.7.pdf.)

In May of 2003, the U.S. House of Representatives, Government Reform Committee released a report, "Mercury in Medicine – Taking Unnecessary Risks" following a three-year investigation into mercury. The report found, "*Mercury is hazardous to humans. Its use in medicinal products is undesirable, unnecessary and should be minimized or eliminated entirely...The FDA has never required manufacturers to conduct adequate safety testing on thimerosal and ethylmercury compounds…Studies and papers documenting the hyperallergenicity and toxicity of thimerosal (ethylmercury) have existed for decades.*" Furthermore, it concluded, "*...the Committee…did find evidence that thimerosal did pose a risk…Thimerosal used as a preservative in vaccines in* [sic; is] *likely related to the autism epidemic...Our public health agencies' failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry.*" (For the published Congressional report, **See:** http://frwebgate.access.gpo.gov/cgi-bin/multidb.cgi?WAIStemplate=multidb_results.html&WAISqueryRule=%24WAISqueryString&WAISdbName=2003_record+Congressional+Record%2C+Volume+149+%282003%29&WAISqueryString=%22Mercury+In+Medicine+Report%22&Submit.=Submit&WAISmaxHits=200&WrapperTemplate=crecord_wrapper.html

In February, 2004 the California Environmental Protection Agency Office of Environmental Health Hazard Assessment found "*the scientific evidence that PMA (phenylmercuric acetate) and thimerosal cause reproductive toxicity is clear and voluminous…The evidence for its reproductive toxicity includes severe mental retardation or malformations in human offspring who were poisoned when their mothers were exposed to ethyl mercury or thimerosal while pregnant, studies in animals demonstrating developmental toxicity after exposure to either ethyl mercury or thimerosal, and data showing interconversion to other forms of mercury that also clearly cause reproductive toxicity*".
(**See** page 3 of: *http://www.oehha.ca.gov/prop65/CRNR_notices/pdf_zip/hgbayer1.pdf.)*

To view CoMeD's petition to remove mercury from medicine, and all the subsequent documents, including the FDA responses: http://www.fda.gov/ohrms/dockets/dockets/04p0349/04p0349.htm

To view CBS News Report on CoMeD's delivery of the petition to the FDA:
http://www.cbsnews.com/htdocs/videoplayer/newVid/small_player/cbsnews_videoplayer.shtml?clip=/media/2004/08/21/video637597.wmv&sec=undefined&vidId=undefined&hitboxMLC=undefined&CMP=ILC-SearchVideos