

For Dkt #01-D-0064 AND Dkt #01-N-0067

From Consumers for Dental Choice, Inc.:

Request that submissions to Dkt 01-N-0067 be applied to Dkt 01-D 0064

When it issued a press release lauding mercury fillings as being safe, the FDA then announced it would undertake rule making. That the agency has apparently made up its mind appears, on the face of it, to be clear.

Nonetheless, a grassroots movement of consumer, scientific, and environmental, organizations, along with hundreds of consumers, victims of mercury amalgam poisoning, dentists who oppose mercury use, scientists, state legislators, etc., submitted testimony, trying to persuade the agency to change its pre-announced support for mercury.

Only organized dentistry and its economic allies support this rule. Essentially, the rule pits an allied FDA and American Dental Association against the emerging science and scientists, mercury-free dentists, and a broad range of the American public.

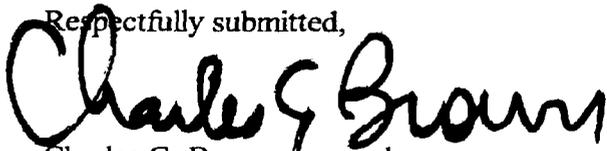
The FDA chose to announce its rule under two dockets. It need not have done so; the two are part of the same topic. The separation into two dockets adds another layer of difficulty to public submissions, ones that already include listing a web site instead of an e-mail address; omitting this regulation from the web site; listing a false zip code in the federal register announcement; refusing to hold public hearings; and setting a deadline in advance of hearings by the Government Reform Committee.

The public comments were generally made only to Docket 01-N-0067. Yet many of them apply to both the labeling and classification. That a less sophisticated public sent in their remarks to one docket should not be grounds for the FDA to maintain an unnecessary wall of separation and not consider them for both.

Thus, we ask the FDA to consider all submissions to one Dkt. 01-N-0067 be considered as comments to Dkt. 01-D-0064 as well as to the docket to which it was sent, and vice versa (Dkt. 01-D-0064 comments considered applicable to Dkt. 01-N-0067).

In the alternative, we ask the FDA to consider all comments made to one docket, but also relevant to the other docket, to be considered in the second one as well.

Respectfully submitted,



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15. The World Health Organization in 1991 reported that dental amalgams constitute the major human exposure to mercury. The World Health Scientific Panel concluded that there is no safe level of mercury exposure. The chairman of the panel, Lars Friberg stated "dental amalgam is not safe for everyone to use."<sup>19 20 21 22</sup>
16. Mercury is a major suspect for AD because most of the proteins /enzymes that are inhibited in AD brain are thiol-sensitive enzymes. Mercury is one of the most potent chemical inhibitors of thiol-sensitive enzymes and mercury vapor easily penetrates into the central nervous system.
17. Dental amalgam is an alloy that contains a mixture of metals in addition to mercury that chemically binds these components into a hard, stable, and a safe substance is totally wrong. The mercury combined with these metals does not change chemical properties and the so called "silver" fillings or dental amalgam continues to emit dangerous levels of mercury and vapors. The ADA refuses to accept this fact and refuses to conduct an objective study, which, if conducted, would support this conclusion.
18. The ADA hides behind the fact that there has not been an epidemiological study to attempt to correlate mercury exposure to any known systemic disease. However the absence of proof is not proof of absence. Of notable interest is why the American Dental Association, the Food and Drug Administration, the National Institute of Dental Craniofacial Research (NIDCR) and the National Institute of Health have refused to push for such a study. These same agencies have refused to scientifically confirm the safe placing into the mouths of Americans, grams of one of the heaviest toxic metals.
19. The United States Food and Drug Administration has not approved the use of dental amalgam. It has approved the two components that make up amalgam i.e., "mercury" and "dental alloy", but has not seen fit to "evaluate" or "classify" "mixed amalgam"

<sup>19</sup> World Health Organization (WHO), 1991, Environmental Health Criteria 118.

Inorganic Mercury, WHO, Geneva: & Envir. H. Crit. 101, Methyl Mercury;

<sup>20</sup> U.S.CDC Toxicology Division, Atlanta, Ga. And WHO, Environmental Health Criteria 101, 1990.

<sup>21</sup> L.T.Friberg, "Status Quo and perspectives of amalgam and other dental materials", International symposium proceedings G. Thieme Verlag Struttgart, 1995

<sup>22</sup> Members of the World Health Organization Scientific Panel (Dr. Lars Friberg-Chairperson, et al. including Dr. Boyd Haley, University of Kentucky)

20. Although mandated by law to evaluate and classify every medical or dental device to be used on or in humans, the FDA has taken the position that mixed amalgam is a "reaction" product manufactured by the dentist when he or she mixes the mercury with the alloy,

\*May 23, 2001 letter from Dr. Boyd Haley to The Honorable Dan Burton

•• Attached are copies of scientific studies with reference to the safety of dental amalgam

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CONSUMERS DENTALCHOICE

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10:00 AM Tuesday  
7/24/99

**Documented High Mercury Exposure Levels from Amalgam and Adverse Health Effects**  
(references published in dental journals only snipped from paper with 1500 peer-reviewed medical studies:  
[www.home.earthlink.net/~berniew1/amalg6.html](http://www.home.earthlink.net/~berniew1/amalg6.html))  
(this is a very incomplete snip from the above paper, which contains a lot more documentation  
including more papers published in dental journals by dental researchers)

Mercury vapor given off by amalgam fillings accumulates in the teeth, tooth roots, gums, jawbone, and oral tissue. Mercury in amalgam fillings, because of its low vapor pressure and galvanic action due to presence of dissimilar metals in the mouth, has been found to be continuously vaporized and released into the body(14,17-19,99,182,183,192,etc.), and has been found to be the number one source of mercury in the majority of people (49,182,183,209,17-19). The level of daily exposure commonly exceeds the U.S. EPA health guideline for daily mercury exposure(2,217). The number of amalgam surfaces has a statistically significant correlation to the level of mercury in oral mucosa and saliva (18,79,182).The average mercury levels in gum tissue near amalgam fillings are often over 100 ppm(192), and levels in oral mucosa removed during oral surgery averaged over 2 ppm(over 20 times controls). Having dissimilar metals in the teeth(e.g.-gold and mercury) causes galvanic action, electrical currents, and much higher mercury vapor levels and levels in tissues. (182,191,192,18,19,30,48) The level of mercury in the gums or jaw bone is often 1000 ppm near a gold cap on an amalgam filling (30,48). The FDA/EPA action level for mercury in food is 1 ppm, and the EPA standard for mercury in drinking water is 2 parts per billion(ppb).

German studies of mercury loss from vapor in unstimulated saliva found the saliva of those with amalgams had at least 5 times as much mercury as for controls(179,etc.). Much mercury in saliva and the brain is also organic, since mouth bacteria convert inorganic mercury to methyl mercury. Oral bacteria streptococcus mitior,S.mutans, and S.sanguis were all found to methylate mercury(51),as well as candida albicans. Methyl mercury, like mercury vapor, crosses the blood-brain barrier, and both forms are converted to very neurotoxic inorganic compounds which have a long half-life in the brain

Some of the oral effects include gingivitis, bleeding gums, bone loss, mouth sores, oral lesions, pain and discomfort, burning mouth, "metal mouth", chronic sore throat, chronic inflammatory response, lichen planus, autoimmune response, oral cancer, bad breath, tender teeth, trigeminal neuralgia, etc. It is well documented in the dental literature that amalgam fillings are a major cause of gingivitis, oral gum tissue inflammation, bleeding gums, metallic taste, mouth sores, tender teeth, bad breath, and bone loss(29,etc.)

Removal of amalgam fillings led to cure or significant improvement for most of such oral health problems (86,87, 90,133,167,168,192) and oral keratosis(pre cancer) (87).

Toxic/allergic reactions to toxic metals such as mercury often result in lichen planus lesions in oral mucosa or gums and play a roll in pathogenesis of periodontal disease. A high percentage of patients with oral mucosal problems along with other autoimmune problems such as CFS have significant immune reactions to mercury, palladium, gold, and nickel. Removal of amalgam fillings usually results in cure of such lesions. [86,87,90,133,167,168].

Teeth are living tissue and have massive communication with the rest of the body via blood, lymph, and nerves. Mercury vapor (and bacteria in teeth) have paths to the rest of the body. (34,etc.) Mercury has direct routes from the teeth and gums to the brain and CNS, where it accumulates to high levels in those with a large number of amalgam fillings(34,etc).

Due to galvanism of mixed metals, amalgam fillings produce electrical currents which increase mercury vapor release and may have other harmful effects(19,28-30,192,etc). These currents are measured in micro amps, with some measured at over 4 micro amps. The central nervous system operates on signals in the range of nano-amps, which is 1000 times less than a micro amp(28). Negatively charged fillings or crowns push electrons into the oral cavity since saliva is a good electrolyte and cause higher mercury vapor losses(192). For these reasons it is important that no new gold dental work be placed in the mouth until at least 6 months after replacement. Some studies have also found persons with chronic exposure to electromagnetic fields(EMF) to have higher levels of mercury exposure and excretion(28).

The component mix in amalgams has also been found to be an important factor in mercury vapor emissions. The level of mercury and copper released from high copper amalgam is as much as 50 times that of low copper amalgams(191). Studies have consistently found modern high copper non gamma-two amalgams have greater

release of mercury vapor than conventional silver amalgams (298). While the non gamma-two amalgams were developed to be less corrosive and less prone to marginal fractures than conventional silver amalgams, they have been found to be unstable in a different mechanism when subjected to wear/polishing/ chewing/ brushing: they form droplets of mercury on the surface of the amalgams(297,182,192). This has been found to be a factor in the much higher release of mercury vapor by the modern non gamma-two amalgams. Recent studies have concluded that because of the high mercury release levels of modern amalgams, mercury levels higher than Government health guidelines are being transferred to the lungs, blood, brain, CNS, kidneys, liver, etc. of large numbers of people with amalgam fillings and widespread neurological, immune system, and endocrine system effects are occurring(34,etc).

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1. Dental Amalgam contains about 50% Mercury.
  2. Mercury has been scientifically demonstrated to be more toxic than Lead, Cadmium, or e Arsenic.
  3. Mercury leaves dental amalgam continuously throughout the lifetime of the filling.(7)
  4. Mercury vapour is the main way that mercury comes out of amalgam.(31)
  5. Mercury vapour is absorbed at a rate of 80% through the lungs into the arterial blood. (31, 55)
  6. Mercury is cytotoxic. Ie. It kills cells
  - ⑦ There is NO harmless level of Mercury Vapour Exposure. (63)
  8. Mercury from amalgam binds to -SH (sulphydryl) groups. These exist in almost every enzymatic process in the body. Mercury from amalgam will thus have the potential of disturbing all metabolic processes. ( 25, 33,60).
  9. Mercury from amalgam is transported freely via the blood.(19,34,35,)
  10. Mercury vapour is absorbed directly into the brain. (34, 55a)
  11. Mercury from amalgam will result in a slow build up of mercury in body tissues. (20,26, 34)
  12. Mercury crosses the blood brain barrier. (34,55a)
  13. Mercury is implicated in the pathogenesis of Alzheimer's Disease. (67,68)
  14. Mercury from amalgam is stored in the foetus and infant before the mother. (20,61)
  15. Mercury from amalgam is stored in the breast milk and the foetus up to 8 times more than the mother's tissues. (18,19)
  16. Mercury (Mercury Vapour / Methylmercury) crosses the placenta.(18, 31)
  17. Mercury Crosses into breast milk.(18,31,61)
  18. Mercury will severely reduce reproductive function.(2, 3, 4, 20, 22, 24, 31, 37,38, 39, 40, 41, 49)
  19. Mercury rapidly depletes the immune system.(27,34,35,42,43,44,45,46,47,48,60)
  20. Mercury will induce a number of Auto Immune Diseases.(27,34,35,42,43,44,60)
  21. Mercury will cause an increase in number and severity of allergies.(1,34,60)
  22. Mercury from amalgam is stored principally in the kidneys, liver and brain. (1,20,31)
  23. Mercury from amalgam (shown in animal experiments) causes kidney damage.(59)
  24. Mercury from will cause a 50% reduction in Kidney filtration as shown in a study of sheep after amalgam placement.(59)
  25. Methyl Mercury is more toxic than elemental Mercury.
  26. Mercury from amalgam is methylated in the mouth.(51,53,54,)
  27. After chewing, Mercury Vapour levels will remain raised for at least another 90 minutes. (1,15,16,18,47)
  28. Mercury from amalgam will migrate through the tooth.(25,27,30)
  29. This rate of migration is increased if a gold crown is placed over a tooth filled with amalgam. (27,30)
  30. Teeth are living tissue and are a part of our bodies.
  31. Teeth have a massive communication via blood. lvmoh and nerves with the rest of the body.(34)

32. Mercury from amalgam is absorbed into the body at a rate of 3 to 17 mcg / day. ( WHO 1991 Criteria 118)
  33. Mercury release is increased by; increases in temperature, friction & increase in electrical currents.(28,31,56)
  34. Mercury from amalgam will enter the body as; Elemental Mercury, Inorganic Mercury, Vapour, charged Mercury ions.
  35. In the Brain, Mercury from amalgam is stored preferentially in the Pituitary Gland and Hypothalamus. (20,34)
  36. Micro-Mercurialism is principally characterised by Neurological symptoms.(34)
  37. Mercury is transported along the axons of nerve fibres.(33,34,50)
  38. Mercury from amalgam may be stored in every other cell in the body. Each area affected will produce its own set of symptoms.
  39. Mercury binds to haemoglobin in the red blood cell thus reducing oxygen carrying capacity.(1,16,17,21,26,35)
  40. Mercury damages blood vessel reducing blood supply to the tissues (micro-angiopathies).(34)
  41. Amalgam fillings produce electrical currents which might be injurious to health. These currents are measurable in Micro Amps. The Central Nervous System (Brain) operates in the range of Nano-Amps this is One Thousand times less than a Micro Amp.(28)
  - 41A. Dissimilar metals in the mouth [eg Gold & Amalgam] will produce higher electrical currents.(19,30)
  42. Mercury from amalgam (shown in animal experiments) will induce Antibiotic Resistance and Mercury resistance in bacteria in the mouth and Gastrointestinal tract.(58)
  43. Brain levels of mercury are in a direct linear proportion to the number of Surfaces of amalgam fillings in the mouth.(1,19,25)
  - 43A? The level of Mercury, in brain tissue of foetus's, new born, and young children, is proportional to the number of amalgams in the mother's mouth.(61)
  44. Mercury will cause single strand breaks in DNA.(41,42)
  45. Mercury levels in the body can not be assessed by either blood or urine levels. (26)
  46. Mercury from amalgam fillings is the single greatest source of dietary mercury for the general population. (W.H.O. Criteria 118., 1991).
  47. Dental personnel are severely effected by exposure to mercury. (3,13,49)
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# Scientific Facts on the Biological Effects of Mercury Amalgam Implants

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1. Mercury penetrates the blood-brain barrier around the brain, and as little as one part per million can impair this barrier, permitting entry of substances in the blood that would otherwise be excluded. (Chang and Hartman, 1972; Chang and Burkholder, 1974).

2. The effect of mercury on the nervous system selectively inhibits protein and amino acid absorption into brain tissue. (Yoshino et al., 1966; Steinwall, 1969; Steinwall and Snyder, 1969; Cavanagh and Chen, 1971).

3. Mercury inhibits the synaptic uptake of neurotransmitters in the brain and can produce subsequent development of Parkinson's disease.

Ohlson and Hogstedt, "*Parkinsons Disease and Occupational Exposure to Organic Solvents, Agricultural Chemicals and Mercury*" Scandinavian Journal of Work Environment Health Vol 7 No.4 : 252-256, 1981.

4. Mercury is nephrotoxic (toxic to the kidneys) and causes pathological damage.

Nicholson et al, "*Cadmium and Mercury Nephrotoxicity*" Nature Vol 304:633, 1983.

5. Chronic exposure to mercury may cause an excess of serum proteins in the urine which may progress to nephrotic syndrome and peculiar susceptibility to infections that break into and modify the course of any pre-existing disease.

Friberg et al, 1953 "*Kidney Injury after chronic exposure to inorganic mercury*" Archives of Environmental Health Vol 15:64, 1967; Kazantis et al, 1962 "*Albuminuria and the Nephrotic Syndrome Following Exposure to Mercury*" Quarterly Journal of Medicine Vol 31: 403-418, 1962; Joselow and Goldwater, 1967 "*Absorption and Excretion of Mercury in Man and Mercury*

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6. Mercury fillings can contribute to a higher level of mercury in the blood, and can affect the functioning of the heart, change the vascular response to norepinephrine and potassium chloride, and block the entry of calcium ions into the cytoplasm.

Abraham et al, 1984 " *The Effect of Dental Amalgam Restorations on Blood Mercury Levels*" Journal of Dental Research Vol 63 No.1:71-73,1984; Kuntz et al, " *Maternal and Cord Blood Background Mercury Levels: A Longitudinal Surveillance*" American Journal of Obstetrics and Gynecology Vol 143 No. 4: 440-443, 1982; Joselow et al, 1972; Mantyla and Wright, 1976; Trakhtenberg, 1968; Oka et al, 1979.

7. Mercury exposure from amalgams leads to interference with brain catecholamine reactivity levels, has a pronounced effect on the human endocrine system, and accumulates in both the thyroid and pituitary glands, reducing production of important hormones.

Carmignani, Finelli and Boscolo, 1983; Kosta et al, 1975; Trakhtenberg, 1974.

8. Mercury induces the thyroid gland to absorb an increasing amount of nuclear radiation from the environment. (Trakhtenberg, 1974.)

9. Mercury can impair the adrenal and testicular steroid hormone secretions, cause intolerance for stress and decreased sexual ability. In rats, it causes subnormal fertility and sperm production. (Burton and Meikle, 1980; Khera, 1973; Stoewsand et al, 1971; Lee and Dixon, 1975; Thaxton and Parkhurst, 1973.)

10. Mercury in the body can produce contact dermatitis and reduced function of the adrenal glands (Addison's disease), producing progressive anemia, low blood pressure, diarrhea and digestive disturbances. (Alomar et al, 1983.)

11. Mercury has a distinct effect on the human immune system, especially the white blood cells. Mercury ions have been observed to cause chromosomal aberrations and alters the cellular genetic code. Mercury has the ability to induce chromosomal breakage, alter cellular mitosis, cause a drop in T-cell production and kill white blood cells.

Vershaeve et al, 1976; Popescu et al, 1979; Skerfving et al, 1970,1974;  
Fiskesjo, 1970.

12. Mercury has an effect on the fetal nervous system, even at levels far below that considered to be toxic in adults. Background levels of mercury in mothers correlate with incidence of fetal birth defects and still births.

Reuhl and Chang, 1979;Clarkson et al, 1981; Marsh et al, 1980; Tejning, 1968;  
Kuntz, W.D., Pitkin, R.M., Bostrum, A.W., and Hughes M.S., The American Journal of Obstetrics and Gynecology Vol 143 No.4:440-443,1982.

13. Mercury in the human body can contribute to intelligence disturbances, speech difficulties, limb deformity, and hyperkinesia (hyperactivity resulting from brain damage). Abnormally small heads and retardation were present in 60% of cases.

Amin-Zaki and Clarkson, et al, 1979.

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