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Will the US Food and Drug Administration (FDA) Follow the EU's Mercury Dental Amalgam Ban? A Mini-Review

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ABSTRACT

The European Union's comprehensive ban on mercury dental amalgam, effective January 1, 2025, marks a pivotal step toward eliminating a known neurotoxin from dentistry, aligning with the Minamata Convention on Mercury's goal to "Make Mercury History". In contrast, the United States, despite ratifying the treaty in 2013, permits the continued use of mercury dental amalgam, a material deceptively called "silver fillings" despite its approximately 50% mercury content. The U.S. Food and Drug Administration (FDA), a global leader in health policy, maintains a contradictory stance: acknowledging mercury's risks for vulnerable populations while resisting mandatory patient disclosures and a phase-out. This regulatory failure, challenged by legal actions, peer-reviewed studies, and advocacy groups, undermines informed consent, exacerbates health inequities, and hinders global mercury reduction efforts. This mini-review examines the FDA's policies, emphasizing its refusal to mandate disclosures, the health risks of mercury dental amalgam, and the necessity of safe removal protocols. Drawing on recent scientific evidence and international benchmarks, we argue for urgent reform to protect public health, the environment and align with global standards.

Keywords

Mercury dental amalgam, Minamata Convention on Mercury, Food and Drug Administration, Informed consent.

Abbreviations

FDA: Food and Drug Administration; GRAS: Generally Recognized as Safe; POTWs: Publicly Owned Treatment Works; EPA: Environmental Protection Agency; ApoE4: Apolipoprotein E4; CPOX4: Coproporphyrinogen Oxidase; NHANES: National Health and Nutrition Examination Survey; ART: Atraumatic Restorative Treatment; IAOMT: International Academy of Oral Medicine and Toxicology; IABDM: International Academy of Biological Dentistry and Medicine.

Introduction

Mercury dental amalgam, comprising approximately 50% elemental mercury, has been used in restorative dentistry for over 150 years. Often called "silver fillings" due to its metallic appearance, this nomenclature obscures their neurotoxic mercury content, misleading patients and undermining informed consent [1]. The U.S. Food and Drug Administration (FDA), a global benchmark for regulatory oversight, has failed to adequately address these risks, despite mounting incontrovertible scientific evidence and legal challenges. In 1976, the FDA classified mercury dental amalgam as "Generally Recognized as Safe (GRAS)" without the current standard of rigorous safety testing, a decision that continues to shape its permissive stance [2].

The Minamata Convention on Mercury Treaty, effective since 2017, mandates a global phase-down of mercury-containing products, including mercury dental amalgam [3]. In 2021, the US Department of State submitted the first national report from the United States to the Minamata Convention on Mercury Treaty. This report consisted of party measures for mercury-added products in Part II of Annex A, specifically related to mercury dental amalgam, which included:

i. Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental

restoration;

ii. Promoting research and development of quality mercury-free materials for dental restoration;

iii. Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices; and

iv. Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land [4]."

Additionally, the US Environmental Protection Agency (EPA) has identified that dental clinics are "the main source of mercury discharge to publicly owned treatment works (POTWs) [5]. The EPA had implemented mandatory mercury amalgam separators to be installed with the final rule going into effect in 2017. It became compulsory on July 14, 2020, to comply with this rule [6,7]. Over 30 countries, including those with populations exceeding 100 million, have implemented bans, with the European Union enforcing a comprehensive ban on mercury dental amalgam as of January 1, 2025, except in specific medical cases [7]. The United States, the first nation to ratify the treaty, has made no progress toward elimination, perpetuating exposure to a known neurotoxin implanted in tens of millions of patients [4]. Despite these environmental measures, the FDA's endorsement of mercury dental amalgam and refusal to mandate patient disclosures represent a profound regulatory failure, compromising public health and global mercury reduction efforts.

This mini-review evaluates the FDA's policies, focusing on its refusal to mandate patient disclosures, the health risks of mercury dental amalgam, and the critical need for safe removal protocols. By integrating recent peer-reviewed studies, legal critiques, and international benchmarks, it is necessary for immediate reform to align with the Minamata Convention and protect vulnerable populations.

Food and Drug Administration (FDA)

The FDA's mission is to ensure the safety, efficacy, and security of medical devices, including mercury dental amalgam [8]. Until 2009, it classified mercury dental amalgam as a Class I device (low risk), requiring minimal oversight [9]. In response to a citizen's petition submitted by attorney James Love, on behalf of various petitioners, the FDA reclassified amalgam as Class II in 2009, acknowledging risks for vulnerable populations, including pregnant women, children, and individuals with genetic predispositions such as apolipoprotein E4 (ApoE4) or coproporphyrinogen oxidase (CPOX4) variants [7,10-12]. These genetic factors, present in approximately 25% and 28% of the global population, respectively, increase susceptibility to mercury toxicity, with ApoE4 linked to Alzheimer's disease and CPOX4 associated with neurobehavioral deficits. A 2010 Scientific Advisory Panel recommended warnings for these groups, but the FDA took no action, a decision later exposed by a 2015 McClatchy investigation as influenced by a Department of Health and Human Services cost-benefit analysis prioritizing economic factors over health [13].

The US national report to the Minamata Convention cited the updated FDA "Recommendations for Certain High-Risk Groups Regarding Mercury-Containing Dental Amalgam." They remarked that some people may be at higher risk for adverse health effects from mercury exposure. While also stated, "Although the majority of evidence suggests exposure to mercury from dental amalgam does not lead to negative health effects in the general population, little to no information is known about the effect this exposure may have on members of the specific groups who may be at greater risk to potential negative health effects of mercury exposure [4]." This statement is false due to the enormous amount of seminal studies of evidence-based scientific research that have been published on the risks of exposure to mercury dental amalgams going back over a century. For example, a simple keyword search of "risks of mercury dental amalgam" on Google Scholar yielded over 15,000 results in 0.14 seconds [14]. A plethora of peer-reviewed scientific papers on mercury dental amalgam continue to be published and cited worldwide. These papers are irrefutable, demonstrating not only the extensive research on mercury dental amalgam risks but also the negative health effects they cause [15-22].

In 2020, the FDA issued non-binding recommendations acknowledging risks for high-risk groups, including pregnant women, children under six, and those with neurological or renal impairments, but continued to emphasize mercury dental amalgam durability and cost-effectiveness [23,24]. These recommendations fall short of a ban or mandatory disclosures, ignoring safer alternatives like Atraumatic Restorative Treatment (ART) and composite resins [7]. Dr. Anne Summers' 2019 critique (Docket ID: FDA-2019-N-3767) to the FDA's Immunology Devices Panel highlighted critical data gaps in its safety assessment: (1) ignoring epidemiological evidence of elevated mercury levels, (2) overlooking cumulative toxicity in adults and the elderly, (3) underestimating mercury's transformation into toxic forms, and (4) neglecting its role in promoting antibiotic-resistant bacteria [25]. Wiggins et al. linked mercury exposure to multi-antibiotic resistance, a global health crisis costing billions annually [26]. Recent studies, such as Geier et al., further associate mercury dental amalgam with arthritis, with higher incidences in individuals with 4–7 amalgam surfaces, reinforcing the FDA's underestimation of systemic risks [27]. These omissions, coupled with reliance on outdated methodologies, highlight the FDA's regulatory inaction.

FDA's Failure to Mandate Patient Disclosures

The FDA's refusal to mandate patient disclosures about mercury risks in mercury dental amalgam, often misleadingly called "silver fillings," is a critical regulatory failure that undermines informed consent. In its 2009 ruling, the FDA stated:

"FDA believes that the recommended labeling statements in the special controls guidance document will provide dentists with important information that will improve their understanding of the devices and help them make appropriate treatment decisions with their patients. In addition, FDA notes that dental amalgam

is a prescription device and, therefore, patients cannot receive the device without the involvement of a learned intermediary, the dental professional. Based on the reasons described above, FDA has concluded that it is not necessary to require that dentists provide this information to patients in order to provide reasonable assurance of the safety and effectiveness of the device". The FDA further asserts that "after consideration, and based on all available scientific evidence, including evidence submitted in your Petitions, FDA does not believe it is necessary or appropriate to require that dental health care providers provide this information to patients" [28].

This position is scientifically and ethically indefensible. First, the FDA's reliance on dentists as "learned intermediaries" assumes uniform competence, contradicted by studies showing many dental professionals underestimate mercury dental amalgam's risks or prioritize cost-effectiveness due to insurance structures [28-30]. The term "silver fillings" obscures the material's ~50% mercury content, misleading patients about a neurotoxin in their restorations [1]. This violates informed consent, a cornerstone of medical ethics [31].

Second, the FDA's claim that existing evidence does not justify disclosures is untenable. Mercury dental amalgam releases vapor, leading to neurological, immunological, and renal impairments, particularly in vulnerable populations [1,15-22]. Autopsy studies show 2–12 times higher mercury levels in brain and kidney tissues of amalgam bearers, with some exceeding toxic thresholds [32]. Park et al. found elevated urinary mercury levels in women with amalgam fillings, correlating with health risks. Geier et al. linked amalgam surfaces to asthma [33]. The Casa Pia study reported neurobehavioral deficits in children with CPOX4 variants, affecting 28% of the population [7,22]. Over 15,000 published studies on Google Scholar document these risks, contradicting the FDA's dismissal [14].

Third, the FDA's stance diverges from international standards. The EU's 2025 ban, building on 2018 restrictions for children and pregnant women, aligns with the Minamata Convention's precautionary principle, as do bans in Norway, Sweden, and Japan [7,34]. The FDA's inaction, influenced by the American Dental Association (ADA), which defends mercury dental amalgam's economic benefits, raises concerns about industry bias, as seen in the 2015 rejection of warning recommendations [7,13].

Fourth, the failure to mandate disclosures exacerbates health inequities. Underserved communities, with limited access to mercury-free alternatives like Atraumatic Restorative Treatment (ART), face disproportionate risks [7]. The deceptive "silver fillings" label and lack of notifications perpetuate uninformed treatment decisions, particularly for vulnerable groups [1].

Counterarguments from the FDA and ADA claim low mercury release poses minimal risk and dentists are equipped to inform patients [7,16]. These are flawed. Individual variability (e.g., ApoE4, CPOX4) increases risks at low exposures, and disparities in dental care access undermine consistent risk communication [7,11,12,16]. Safer alternatives like ART and composite resins, widely adopted globally, render mercury dental amalgam's use unjustifiable [7]. The FDA's refusal to mandate disclosures violates ethical standards and hinders the Minamata Convention's goals [7,31].

Safe Removal of Mercury Dental Amalgam

As global awareness of mercury dental amalgam's health risks grows, particularly with the European Union's 2025 ban, demand for safe removal is surging [7,34]. This process poses significant health risks due to mercury vapor release, which can result in acute exposure levels far exceeding safe limits, particularly for vulnerable populations such as pregnant women, children, and those with genetic predispositions [7,11,12,17,18,20,25]. Warwick et al. found that mercury vapor concentrations during amalgam removal can reach levels associated with neurological and respiratory harm, necessitating rigorous protocols to protect patients and dental professionals [29]. Zwicker et al. reported reduced urinary mercury levels post-removal, underscoring the need for safe practices to mitigate exposure [37].

Dr. Hal Huggins, a pioneer in mercury-free dentistry, ceased using mercury dental amalgam in the 1970s after learning of its toxicity from Dr. Olympio Faissol Pinto. Huggins developed the "Bubble Operatory," a groundbreaking system incorporating advanced air filtration and protective barriers to minimize exposure [38]. His innovations, driven by early recognition of mercury's neurotoxic effects, set a precedent for safe removal practices and influenced organizations like the International Academy of Oral Medicine and Toxicology (IAOMT) and the International Academy of Biological Dentistry and Medicine (IABDM) [35,36].

The IAOMT and IABDM have established evidence-based guidelines, such as the Safe Mercury Amalgam Removal Technique (SMART) and PROTECT Protocol, to ensure safe mercury dental amalgam removal. These protocols mandate measures like high-volume suction, rubber dams, supplemental oxygen via nasal cannula, and full-body protective coverings to reduce mercury exposure. Additional safeguards include cold water irrigation to minimize vapor release, sectioning amalgams to reduce particle dispersion, and rigorous room ventilation to protect dental staff and patients [35,36]. Adherence to these standards is critical, as improper removal can exacerbate health risks, including neurological and immunological damage, particularly in vulnerable populations [18,20]. The FDA's failure to mandate patient disclosures about mercury dental amalgam's risks, compounded by the deceptive "silver fillings" label, leaves many patients unaware of the need for these specialized protocols, increasing the likelihood of unsafe removal practices [1,35,36].

The global shift toward mercury-free dentistry, exemplified by the EU's ban, underscores the urgency of universal adoption of these safe mercury removal protocols [7]. Non-compliance not only

endangers patients and dental professionals but also undermines the Minamata Convention's goal to "Make Mercury History" [7,39]. The FDA's inaction on promoting safe removal guidelines further highlights its regulatory shortcomings, necessitating immediate reform to align with international standards and protect public health.

Conclusion

The FDA's obstinate defense of mercury dental amalgam, falsely branded as "silver fillings," and its brazen refusal to require patient disclosures expose a shameful betrayal of public health trust. The World Health Organization confirms mercury dental amalgam as the dominant source of human mercury exposure, with NHANES data revealing that over half of Americans aged 15 and older bear these toxic fillings, and 30–40% surpass EPA safety limits, driving such health maladies as neurological, immunological, renal, arthritic, and respiratory harm. These figures likely understate the crisis, as NHANES excludes children with amalgam fillings. Mercury dental amalgam's role in fueling antibiotic-resistant bacteria escalates a global health emergency, threatening the efficacy of critical medical interventions. Dental professionals endure relentless mercury exposure, with evidence of these professionals' heightened health risks, while dental clinics account for roughly 50% of U.S. wastewater mercury, poisoning ecosystems. The FDA's feeble Class II classification dismisses thousands of peer-reviewed studies, including autopsy data revealing toxic mercury in tissues and heightened risks for those with genetic vulnerabilities like ApoE4 or CPOX4. By endorsing the deceptive "silver fillings" label and discouraging mercury disclosure, the FDA obfuscates informed consent, defying ethical mandates like the American Medical Association has recommended. Proven alternatives such as Atraumatic Restorative Treatment (ART) and composite resins, embraced worldwide, render mercury dental amalgam archaic and unjustifiable. The EU's 2025 ban proves mercury-free dentistry is not only feasible but essential, aligning with the Minamata Convention's urgent call to eradicate mercury use. Legal challenges, advocacy critiques, and recent studies highlight the FDA's transparency deficits and potential industry bias. The FDA's obstinacy sabotages global mercury reduction efforts and endangers millions. It must enact mandatory disclosures, enforce stringent safe removal protocols, and ban mercury dental amalgam outright to honor the Minamata Convention, rebuild public trust, and safeguard humanity from this preventable scourge. The FDA must act to "Make Mercury History."

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