

MEASURABLY **Misleading**

Evidence the FDA and Dental Industry are Deliberately Deceiving American Families about Mercury Dental Fillings and Why That Now Has International Consequences



A SPECIAL REPORT BY



**CONSUMERS for
DENTAL CHOICE**

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Based on a new national poll by

**Zogby
Analytics**

With findings supported by

Mercury Policy Project

Organic Consumers Association

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BY ANY MEASURE, AN INFORMED POLICY ABOUT MERCURY DENTAL FILLINGS STARTS WITH THIS PREMISE: *Americans have a right to know what their dentists are putting in their mouth.*

Mercury began being used as a principal component of dental fillings more than 150 years ago. Because mercury is a known neurotoxin, controversy surrounding its use in dentistry began almost immediately. Early on, the dental industry tried to circumvent the controversy about dental mercury by calling it something else. Terms like “amalgam” and “silver fillings” became the new name for a product that’s primarily mercury.¹

The controversy over the health impact of mercury dental fillings continues. But Consumers for Dental Choice believes that Americans – whatever their views on dental mercury – have a right to know exactly what their dentists are putting in their mouths so they can make informed healthcare decisions for themselves and their families.

The purpose of this report is to demonstrate that Americans – after decades of false labeling by the dental industry – have been “measurably misled” about dental mercury and what that means both here at home and internationally.

The impact is big

According to the United Nations Environment Programme, the use of mercury in tooth fillings represents 10% of global mercury consumption, making it one of the largest consumer uses of mercury in the world.² In the United States, amalgam constitutes the largest amount of mercury used in products, accounting for between 35% and 57% in 2010.³ An estimated 28.5 tons of amalgam were released into the environment in the United States in 2009.⁴

As a way to bring global focus to mercury issues, last year the United States signed and ratified the Minamata Convention on Mercury, which among other mandates requires the phase down of mercury dental fillings to protect human health and the environment.⁵

If Americans don’t know about the mercury content in their dental fillings, that creates a serious obstacle to fulfilling this commitment, because experience shows that countries which have successfully phased down mercury dental fillings begin by assuring transparency in the marketplace.⁶

Consumers for Dental Choice asked Zogby Analytics to poll 1500 Americans to learn exactly what they know and don’t know about mercury dental fillings.

Zogby asked these questions:

- Amalgam is a common dental filling material. What is the primary metal in amalgam fillings?
- Dental amalgam fillings, also called “silver fillings,” contain 50% mercury. Do you feel “silver” fillings is a misleading term for a material that is mainly mercury?
- The American Dental Association has long called amalgam “silver fillings” or “silver-colored fillings.” Did your dentist ever tell you that these fillings are mainly made of mercury?
- Do you think a government agency, or a court of law, should stop companies and dentists from promoting mercury amalgam as “silver fillings”?
- Do you feel your dentist provided you with enough information on alternatives to mercury amalgam to enable you to make a truly informed decision about the procedure?

This report summarizes what we learned from that poll and shows how the dental industry and the U.S. Food and Drug Administration (FDA) keep consumers unaware of amalgam’s mercury content and why the FDA needs to raise consumer awareness now in order to actively promote the phase down of amalgam.

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EYE-OPENING INSIGHTS:

What the New Consumers for Dental Choice / Zogby Analytics Poll Shows

- **KEY ZOGBY FINDING** A significant majority of Americans **DO NOT KNOW** that mercury is the main component of “silver” or amalgam dental fillings.

When asked to name the primary metal in amalgam dental fillings, a clear majority (57%) of respondents are unable to name mercury. The most common incorrect answer (23%) is, not surprisingly, “silver”

- **KEY ZOGBY FINDING** Only about 1-out-of-10 Americans (11%) **ARE EVER TOLD** by their dentists that amalgam or “silver” fillings contain mostly mercury.

And it gets worse. Americans making under \$50,000/year are three times less likely to be told by their dentist that their amalgam fillings contain mercury. And a miniscule 6% of African-Americans report getting this critical information.

- **KEY ZOGBY FINDING** Nearly two-thirds (63%) of Americans **DO NOT BELIEVE** their dentist provides them with enough information on alternatives to mercury dental fillings to help them make informed decisions.

Women – including mothers – are far less likely than men (19% vs 28%) to say their dentists are giving them enough information on what’s in their dental fillings.

So, not surprisingly....

- **KEY ZOGBY FINDING** About 2-out-of-3 Americans (63%) consider the term “silver fillings” **MISLEADING**.

Only 16% believe the term isn’t misleading, and remaining 21% are “unsure.”

Leading to this...

- **KEY ZOGBY FINDING** Regardless of their politics, region or demographics, a strong majority of Americans (55%) **WANT GOVERNMENT ACTION** that stops the marketing of mercury dental fillings using misleading terms like “silver.”

Americans believe a government agency or court of law should stop companies and dentists from promoting mercury fillings using the term “silver.” Only 17% of Americans disagree. Conservatives – normally a group less likely to call for additional regulation – are about as likely as liberals to want government action – 53% and 55%, respectively.



THE FDA AND DENTAL INDUSTRY ARE MEASURABLY MISLEADING AMERICANS ABOUT MERCURY DENTAL FILLINGS

Findings from a new national Consumers for Dental Choice / Zogby Analytics poll of 1,508 Americans (June 2014)

A significant majority of Americans

(57%)

do not know that mercury is the main component of dental amalgam

Possibly because

ONLY about 1 out of 10

(11%)

of Americans report being told by their dentists that "amalgam" fillings are mostly mercury

In addition

Nearly 2 out of 3 Americans

(66%)

believe their dentists do not provide them with enough information on alternatives to mercury to make informed decisions

And, when they learn that so-called "silver fillings" or amalgam are, in fact, mostly mercury...

About two-thirds of Americans

(63%)

call the term "silver fillings" **MISLEADING**

Given all these facts...

A strong majority (55%)

of Americans across all demographics, regions and political beliefs support government action to stop the deceptive practice of marketing mercury dental fillings using misleading terms like "silver."



NOT SURPRISINGLY, YEARS OF DELIBERATELY MISLEADING INFORMATION LEADS TO DELIBERATELY CONFUSED CONSUMERS

The right of dental consumers to the information they need to make decisions about their health care should be paramount. But the poll results indicate that many consumers are not given the most basic information about amalgam: its mercury content.

This deliberate void in consumer awareness has three main causes:

The central deception: calling mercury fillings “silver” or “amalgam” has a long, disreputable history

It is no accident that the marketing term “silver fillings” misleads dental consumers about amalgam’s mercury content – that was its original purpose. This deception goes back a long way. As a doctor observed in 1896, “Certain dentists are themselves aware of the popular dread of mercury and hence the false term of ‘silver filling,’ which is a deliberate swindle and a disgrace to the dental occupation.”⁷

By the twentieth century, the FDA was cracking down on marketing tactics that misled consumers about the alcohol content in patent medicines, the narcotic content in tonics for women, and even the grass seed content in “fruit” jams.⁸ But the FDA never stopped the dental industry from misleading consumers about the mercury content in “silver fillings.”

Instead, the FDA did just the opposite. As recently as 2009, the FDA announced, “Dental amalgam fillings are also known as ‘silver fillings’ because of their silver-like appearance.”⁹

In light of this century-long industry campaign to market the substance that’s primarily mercury as “silver,” and the FDA’s willingness to go along, it’s understandable that **57% of Americans do not know that amalgam is mainly mercury – and 23% say it is mainly silver.** So, not surprisingly, with the FDA’s endorsement of the term “silver fillings,” many consumers believe their fillings really are made of silver.



The dental industry is all in

Consumers are not likely to learn about amalgam’s mercury content from their dentists, either. Dentists are discouraged from educating the public about the mercury in amalgam at every stage of their professional careers.

It starts in dental school: Many dental schools and dental licensing exams required future dentists to demonstrate competency in amalgam placement on live patients. So as dental students, many dentists had to convince patients to accept mercury-made fillings – and the easiest way to do that was to avoid using the term mercury at all.

State dental boards are also a key reason Americans are so confused about their dental fillings. It’s safe to say these boards look unfavorably on dentists who initiate discussions about amalgam’s mercury content with dental consumers.¹⁰ As one dentist explains, “Many dentists are still reluctant to talk about amalgam issues for fear of jeopardizing their licenses...there still remains an overall restrictive environment for dentists and patients to exchange needed information to make adequate treatment decisions.”¹¹

Driving much of the effort to mislead Americans is the American Dental Association (ADA). This politically powerful association has long lobbied against laws requiring amalgam fact sheets for consumers,¹² while distributing patient brochures referring to mercury-based amalgam as “silver fillings.”¹³ With dentists’ speech effectively chilled, it is not surprising that only 11% of polled consumers report being told by their dentists that amalgam is mainly mercury.





The FDA: Regulator or enabler?

Most Americans do not believe they are getting enough information from their dentists – and **55% agree that the government should stop companies and dentists from promoting amalgam as “silver fillings.”** As the federal agency charged with “helping the public get the accurate, science-based information” it needs,¹⁴ the FDA is responsible for informing the public about amalgam’s mercury content.

“I have always thought that mercury, in any form, is bad for humans and the environment. So why is this only coming out now?”

— Zogby Poll Respondent

THE FDA HAS FAILED TO HEED ITS OWN EXPERTS ON MERCURY-BASED FILLINGS.

The FDA’s own Dental Products Advisory Panel has repeatedly alerted FDA officials to the need for patient information about amalgam on more than one occasion. As one of the FDA’s key consultants on the issue has said:

“I think the major thread, or the take-home message that I have, is that the Federal Government and the agencies need to force dentists to provide informed consent to the patient, and make sure that the patient is going to be well-informed and able to make the appropriate decision regarding the use of this material.”¹⁵

And:

“... it’s very important to have informed consent, and I think there should be a change in the labeling of these amalgams to, if you will, ‘silver mercury,’ or ‘mercury silver amalgams,’ so people really understand what is being put in their mouths.”¹⁶

Leading to this recommendation:

“A very simple thing. The consumer needs to know the risks and benefits of both products [mercury amalgam and mercury-free materials] and they should be given the choice as to which product they want to use.”¹⁷

But the FDA has chosen to ignore its own expert advisors and deny labeling that would alert Americans to the mercury content in their dental fillings.





IT'S TIME FOR THE FDA TO STOP MISLEADING AND START LEADING

The data from the Consumers for Dental Choice/Zogby Analytics poll are clear and convincing. The FDA's willingness to allow the dental industry to use the term "silver fillings" and blatantly misrepresent a product that's primarily mercury has **measurably misled** Americans. As a policy, it flies in the face of one of the agency's primary reasons for being: to protect consumers by preventing companies from misbranding and mislabeling health care products.

Clear labeling and an aggressive patient education program will help Americans make informed choices on dental fillings for themselves and their families. It's the FDA's job. It's the least they can do. And they need to start doing it now for these critical reasons:

To protect Americans from mercury

Most critically, the FDA must require patient labeling and consumer education to prevent unsafe use of mercury-based dental fillings.

In a recent ruling on the subject, the FDA "concludes that existing data indicate that certain individuals with a pre-existing hypersensitivity or allergy to mercury may be at risk for adverse health effects from mercury vapor released from dental amalgam."¹⁸ But the Consumers for Dental Choice/Zogby Analytics thought the analytics poll makes clear that most dentists do not talk about amalgam's mercury content with their patients. Since most consumers do not, by design, know that "silver fillings" are mainly mercury, they are not likely to volunteer information about their mercury hypersensitivities or mercury allergies in the absence of patient labeling and education.

To protect the long-term oral health of America's families

The FDA must require patient labeling and education in order to protect consumers' oral health. The poll indicates that most Americans do not believe that their dentists provide them with enough information on



mercury-free alternatives to make informed decisions. But consumers need to know that mercury-free alternatives – such as composites and glass ionomers – offer important oral health benefits over amalgam. Mercury-based fillings placement requires the removal of a significant amount of healthy tooth matter, which can weaken tooth structure, shorten the life of the tooth, and lead to more expensive dental care in the long-run. In

stark contrast, the World Health Organization¹⁹ found mercury-free materials "allow for less tooth destruction and, as a result, a longer survival of the tooth itself."

To protect America's environment

The FDA must do its job by requiring patient labeling and education in order to protect our planet. After mercury amalgam is released into the environment, certain microorganisms can change into methylmercury, a highly toxic form of the substance that builds up in fish, shellfish, and animals that eat fish.²⁰ **Methylmercury has been proven to damage children's developing brains and nervous systems even before birth.**²¹

Norway, Denmark and Sweden have significantly reduced or virtually phased out mercury-based dental fillings in order to protect their people's health and environment. And their governments learned by experience during this phase out process that strong public awareness about mercury-based fillings and their alternatives was critical to the policy's success.²²

By comparison, most Americans are not aware that high amalgam use continues to pose significant risks to their environment.





A DOMESTIC MANDATE. AN INTERNATIONAL COMMITMENT: *Consumers for Dental Choice Calls on The Secretaries of State and Health & Human Services to make certain the FDA provides American consumers the truth about dental mercury*



Awareness of amalgam’s mercury is not only an issue for the FDA – the U.S. State Department and other government agencies need to take action too, in light of the Obama Administration’s policy against mercury content and the new Minamata Convention on Mercury.

The Obama Administration’s fractured policy on mercury

The Obama Administration embarked on an aggressive campaign to, in the President’s words, “keep our kids from being exposed to mercury.”²³ Administration policies and regulations focusing on reducing mercury emissions from power plants are clear examples. But the FDA essentially has been going the wrong direction when it comes to mercury. A *Huffington Post* headline characterized it this way: “As Obama Warns of Hazards, The FDA Approves Mercury Dental Fillings.”²⁴

Consumers for Dental Choice believe it’s time for the Secretary of Health and Human Services to insist that the FDA support the Obama Administration position to reduce mercury use by raising consumer awareness of dental mercury.

A global game changer: The Minamata Convention on Mercury

Under President Obama, the United States was a leader in negotiating the first major international convention on toxins in this century. In Nairobi in February 2009, Daniel Reifsnyder of the State Department announced that the United States was changing its position from opposition to full support of an international agreement on mercury – a dramatic event that kick-started the international negotiations.

During the ensuing four years’ work on the agreement, the U.S. government took the initiative to propose the “eventual phase out” of mercury-based dental fillings.²⁵ America’s leadership continued through the signing of the new Minamata Convention in 2013, when in November, the U.S. became the first nation in the world to ratify the Convention. Among its provisions, the Minamata Convention calls for each ratifying nation to “phase down the use of dental amalgam.”²⁶

“ I think it should be ended all together, people don’t even know what is being put in their mouth, or what the dangers are — I was one of them until a short time ago.”

— Zogby Poll Respondent



- **The Minamata Convention will require the phase down of amalgam use – contrary to FDA policy:** Contrary to the Minamata Convention, the FDA's official position is to actually phase up the use of mercury-based dental fillings. An FDA rule states unequivocally that: “any change away from use of dental amalgam is likely to result in negative public health outcomes.” ²⁷

To be in full support of the Obama Administration's mercury phase down, FDA must immediately change its rule to support the phase down of amalgam use and raise public awareness about non-mercury dental alternatives through patient labeling and education.

- **The Minamata Convention will require public information about mercury-added products and mercury-free alternatives – contrary to FDA policy:** The Minamata Convention requires the phase down of amalgam use, but also mandates patient information and education about mercury-free alternatives.

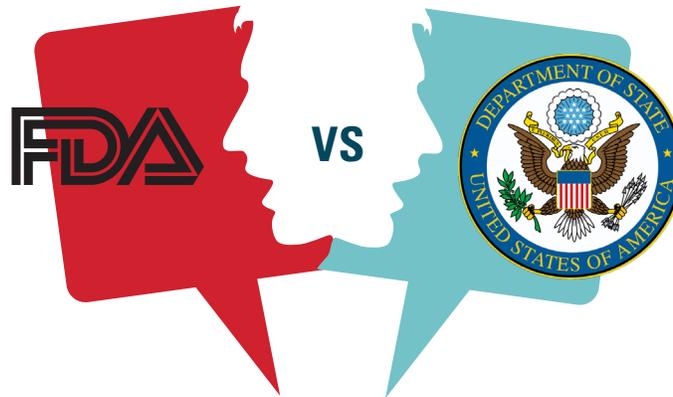
Under the FDA, none of this is happening, or can happen, due to consumers don't even know they're buying mercury because of misleading terms like “silver” and “amalgam.”

COMPETING U.S. POLICIES ON MERCURY DENTAL FILLINGS ARE A BIG PROBLEM FOR AMERICAN CONSUMERS AND THE WORLD

When it Comes to Mercury-Based Dental Fillings, the Government is Talking Out of Both Sides of its Mouth.

FDA POLICY:

Deliberately conceal the mercury in Americans' dental fillings by calling them “silver” or “amalgam” and scale up their use.



State Department Policy:

Meet the critical environmental goals of the Minamata Convention on Mercury, a key U.S.-led global initiative, by scaling down mercury-based dental fillings.

THE RESULT:



Misled American consumers and missed opportunities to lower mercury's dangers in the U.S. and around the world.





TO EMPOWER AMERICAN CONSUMERS AND DEMONSTRATE THE US. COMMITMENT TO SCALING DOWN DENTAL MERCURY, CONSUMERS FOR DENTAL CHOICE CALLS FOR THESE IMMEDIATE CHANGES IN U.S. POLICY

Americans have a right to know what's in their dental fillings, and the Obama Administration has made an international commitment to phase down dental mercury.

These important goals are coherent, urgent and right, and they should be fully aligned.

But, right now, as this report has shown, rules and actions by the FDA make it impossible to meet either of these important and mutually supportive goals.

That's why Consumers for Dental Choice calls on the State Department, which signed the Minamata Convention, and the Department of Health & Human Services, which oversees the FDA, to work together with urgency to assure that President Obama's clear directive to lower Americans' exposure to mercury has a real chance of success.

State and Health & Human Services need to work collaboratively to craft a proactive and coherent government-wide policy that provides consumer awareness and transparency on dental mercury while aggressively scaling down its use. We're calling for administration-wide accountability on this critical issue and leadership from the top to deliver results.

Specifically, we call on Secretary of State Kerry and Secretary of Health and Human Services Burill to ensure that the U.S. keeps its promises to its citizens and the rest of the world, by doing the following:

- **Convene:** Work with a diverse and representative group of government agencies, nonprofit organizations and advocacy organizations to develop an ambitious and accountable national action plan to set clear objectives aimed at minimizing dental mercury's use, as committed to by the Obama Administration when it signed the Minamata Convention.
- **Regulate:** Rewrite the FDA amalgam rule to remove language encouraging the phase up of amalgam use and replace it with language and action supporting the effective reduction of amalgam use of as called for by the Minamata Convention.
- **Educate:** Launch a consumer education campaign to undo the damage wrought by the FDA who for decades has steadfastly refused to order disclosure of amalgam's mercury content.
- **Prohibit:** Stop the use of the misleading marketing term "silver fillings," including legal action to stop it and removal of the sentence condoning this term from the FDA's website.
- **Demand:** Require amalgam manufacturers, such as Dentsply and Danaher/Kerr, to provide patient labeling that includes at least specific information regarding (a) amalgam's mercury content, (b) the effects of mercury, and (c) the benefits of mercury-free alternatives.
- **And, deliver:** The United States, as a major provider of dental services, needs to begin the switch to non-mercury dental filling alternatives at the Department of Defense, the Veterans Administration, the Bureau of Prisons, the Indian Health Service and other agencies.

“ You [this poll] are the ones that made me aware of the mercury being used in fillings.”

— Zogby Poll Respondent





CONSUMERS for DENTAL CHOICE

M E M O R A N D U M

TO: The FDA

FROM: Consumers for Dental Choice

RE: **You can't solve the problem when you're the root of the problem.**

Section 502 of the Federal Food, Drug and Cosmetic Act (FFDCA) is quite clear: The FDA's job is to stop companies from misbranding or mislabeling healthcare products and punish them when they do.

This law defines mislabeling as "incorrect, inadequate or incomplete identification."

But because you've been unwilling to require consumer labeling and education for mercury-based dental fillings, the consumer protections afforded under Section 502, and other sections of the FFDCA, don't apply to this product. So, most don't know that the chief component of "amalgam" is mercury, a neurotoxin.

If those critical consumer protections under Section 502 were in place for dental fillings, your Agency and the dental industry certainly would no longer be permitted to call mercury-based dental fillings something as incorrect as "silver," or as inadequate and incomplete as "amalgam."

Our recent Zogby Analytics poll found that because of this misbranding, Americans have been deliberately misled, and are consequently quite confused about what their dentists are putting in their mouths.

Please fix the problem. Immediately extend the FDA's basic protections against misbranding and mislabeling to mercury-based dental fillings so Americans can have correct, adequate and complete information with which to make informed decisions for themselves and their families when they visit their dentists.





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