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Division of Dockets Management, Food and Drug Administration
Department of Health and Human Services, rm. 1-23
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Petition for Reconsideration

Docket No. FDA-2008-N-0163 (formerly Docket No. 2001N-0067)

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. FDA-2008-N-0163 (formerly Docket No. 2001N-0067).

A. Decision involved

The decision is the Final Rule for Dental Amalgam. The rule classified dental amalgam as a class II device. The rule did not contraindicate dental amalgam for children under age six, pregnant women, nursing mothers, and persons who may have a health condition that makes them more sensitive to mercury exposure, including individuals with existing high levels of mercury bioburden. The rule did not require that patients be provided with any sort of warnings. The rule did not require the disclosure of amalgam's mercury content to patients. The announcement of the rule also resulted in a revised consumer website.

B. Action requested

Petitioners request that the Principal Deputy Commissioner carry out the following upon reconsideration:

- (1) Contraindicate mercury amalgam for children under age six, pregnant women, nursing mothers, and persons who may have a health condition that makes them more sensitive to mercury exposure, including individuals with existing high levels of mercury bioburden.
- (2) Require warnings to all dental patients or their parents that amalgam contains mercury, which is bioaccumulative and is associated with adverse effects in the brain and kidneys.
- (3) Require warnings to all parents of minor dental patients that "the developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor."

- (4) Revise the consumer website associated with this rule in order to
- (a) include in the Potential Risks section the warning that “the developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor”
 - (b) delete the reference to mercury amalgam as “silver fillings”
 - (c) explain the concept of bioaccumulation to consumers
 - (d) change the description of the clinical information on “pregnant women and their developing fetuses, and on children under the age of 6, including breastfed infants” from “limited clinical information” to the Final Rule’s description which was “very limited to no clinical information”
 - (e) explain that amalgam’s primary component is mercury on the introductory page of the consumer website

C. Statement of grounds

INTRODUCTION

While a boon to the dental products industry, FDA’s amalgam rule permits amalgam sales with no consumer disclosures, a denial of consumers’ fundamental right to know that a neurotoxin is being placed in their bodies. Despite overwhelming evidence on the record that consumers do not know that amalgam is mainly mercury, despite decades of deceptive marketing as “silver fillings,” despite the agency’s concession that its rule will impede a trend of decreasing human exposure to mercury, FDA inexplicably fails to require that consumers be informed of amalgam’s mercury content or warned about its potential effects, including the neurological risk that it poses to children and the unborn.

That FDA would go to such extreme lengths to avoid informing consumers of anything even though scientific evidence indicates the potential harm for children and the unborn suggests that other factors entered the regulatory equation. At least two factors have tainted this rule beyond the bounds that ethical standards would allow – the intertwining of Commissioner Margaret Hamburg with her corporate benefactor Henry Schein, Inc. and former Center Director Daniel Schultz’s track record of approving unsafe devices. Dr. Hamburg, coming through the revolving door from a highly-paid corporate directorship with foremost amalgam distributor Henry Schein, Inc. failed to actually cut her ties with the corporation until the day before the rule was announced. She claims to have recused herself, but stonewalls all questions regarding the date of her recusal – a date the public is entitled to know. Her delayed exit not only biased the process of this rulemaking, but denied Deputy Commissioner Sharfstein the opportunity to fully vet the rule that came from Center Director Schultz and his staff.

The questionable ethical issues and the ties to industry are clearly reflected in FDA's evaluation of the science and its decision to reject alternatives that would have required patients to receive direct information regarding dental amalgam's mercury content, its safety, and other filling materials. The agency's rationale for denying the public's demand (92% have stated that they want to be informed before mercury amalgam is implanted in their mouths) is not even comprehensible, much less supported by evidence from the administrative record.

Only inappropriate industry influence can explain a rule that is so inconsistent with not only FDA's mission, but our national policies and values. The decision distorts FDA's mission beyond recognition as FDA decides to allow industry to sell amalgam for young children, pregnant women, and nursing mothers while also indicating that this mercury exposure puts children, nursing infants, and the unborn at risk for neurological harm. Such callous gambling with the next generation's health inexplicably defies the anti-mercury public record and campaign promises of the President of the United States who appointed Margaret Hamburg and Joshua Sharfstein to their current positions.

To make matters worse, FDA is confusing both dentists and patients with this rule. The decision is a regulatory disaster for dentists who will face the befuddling task of deciphering their duties and their legal liability risks under this rule. For instance, the rule says they are placing young children at risk by exposing their developing neurological systems to mercury, but it does not contraindicate its use. Then the rule says, the dentists are responsible for deciding whether to put children at this increased risk, but a few pages later it implies that this is really for the parent to decide. And that does not even cover half of the scientific questions raised by the rule that dentists with no training in toxicology and neurology will be left to navigate on their own. The patient is kept even more in the dark than the dentist. FDA's efforts to use this rule to ensure public ignorance went so far as to remove accurate statements contained in the pre-rule consumer website and bury them in the special controls intended only for dentists and FDA staff.

Under these circumstances and for the following specific reasons, FDA must reconsider this rule in order to protect the interests of children and the unborn.

COMMISSIONER HAMBURG'S INVOLVEMENT WHILE STILL ASSOCIATED WITH HENRY SCHEIN INC. TAINTED THE RULE'S CONSIDERATION

#1: Commissioner Hamburg had an ethical problem that should have prevented her from being involved in the amalgam rule

Not until mid-July, after being pressed by a trade news reporter, did Commissioner Hamburg admit that she had to recuse herself from the amalgam rule "based on the requirements of federal ethics laws and the standard of ethical conduct."¹ She still refuses to explain what led to her recusal, but it was believed to have been her intertwining relationship with dental products colossus Henry Schein Inc.,² a connection that began in 2003, existed until the day before the rule was announced on July 28, 2009, and gave Schein's CEO a reason to boast the morning after the rule was published on August 4.

Between stints in the Clinton Administration and the Obama Administration, Dr. Margaret Hamburg served on the board of directors for Henry Schein, Inc., receiving, for example, \$282,365 in 2006 and \$249,151 in 2007 for the handful of hours generally involved in being a corporate director. With a court settlement requiring FDA to classify amalgam within the first 75 days of her taking office,³ Dr. Hamburg's remaining interest in Schein – including stock options held until July 27, just 24 hours before the rule was announced – should have resulted in her immediate public recusal from the amalgam rulemaking.

Because Commissioner Hamburg was not supposed to be involved in the rule at all due to her ethical issue, she could not possibly have adequately considered it.

#2: Hamburg's involvement in the rulemaking despite her ethical problem tainted the rule

Dr. Hamburg denies participating in the decision making for the amalgam rule, but consumers have three reasons for believing she was nonetheless involved in the rulemaking that denied them any protections.

First, when Senator Enzi asked Dr. Hamburg two written questions about the amalgam rulemaking during the confirmation process, she failed to disqualify herself or disclose her conflict even though she had been briefed on the issue enough that the conflict should have been apparent. Instead, she expressed her intention to review the amalgam rule and to work on it with staff.⁴

Second, Dr. Hamburg failed to publicly recuse herself upon taking office, and in fact did not announce her recusal until two months later, even though the issue was raised at the start of her tenure. Consumers for Dental Choice wrote Dr. Hamburg to notify her of a possible conflict in early June. That letter was ignored. In response to a second letter, she said she “decided not to participate,” however, the legal meaning of such terminology is unclear. Two weeks after a third letter, FDA's Chief Counsel, just four days before the rule was due, notified the organization that Dr. Hamburg was recused.

Third, Dr. Hamburg's legal defense appears to concede that she participated. FDA's Chief Counsel asserted on July 28 that Dr. Hamburg's participation was not “personal and substantial,” whatever that means.

Fourth, during an earnings call the morning after the rule was published, Schein CEO and honorary American Dental Association member Stanley Bergman publicly thanked Dr. Hamburg for “insights” she provided the board “throughout the years.”⁵ Since Commissioner Hamburg had resigned from the corporate board months earlier, it is hard to imagine what “insights” he was referring to and why he was bragging about them to analysts unless Dr. Hamburg had done something recently to benefit the company such as ensure an amalgam rule favorable to industry. Obviously corporations believe that Dr. Hamburg is looking out for their interests.

Dr. Hamburg's inappropriate involvement in the rule necessitates a reconsideration that takes consumer interests into account.

#3: Hamburg's evasiveness about her role in the amalgam rule indicates that the rule is tainted

Dr. Hamburg continually refuses to release information regarding her ethical problem and the amalgam rulemaking. Then in response to intense media criticism of her Schein relationship and the amalgam rule, the FDA press office issued an inaccurate and non-responsive statement on August 18.⁶ Three times the statement denied that Dr. Hamburg owned any Henry Schein stock at the time she took office, which is untrue, but the Commissioner never corrected it. In keeping with her pattern of deception, the statement specifically explained the Schein stock options that she was still holding until the day before the rule issued, but deliberately avoided the more critical question – her role in the rulemaking.

Commissioner Hamburg maintains that she is recused from the rulemaking currently, but remains evasive when we ask for specific information about her recusal. She won't say when exactly she recused herself from the amalgam rulemaking (the first time recusal was mentioned so far as the public knows was two weeks before the rule was announced). She won't provide written proof of her earlier recusal. She won't advise the public of the status of the rule when she recused herself – for example, whether it was already in its final form when she recused herself. She will not tell anyone when Principal Deputy Commissioner Sharfstein took charge of the rule.

Dr. Hamburg says she did not participate in the decision-making, but she will not tell us, for instance, whether she approved the decision-making, whether she determined which staff members continued to work on it, whether she clarified to staff which agency leader was overseeing this rule, and how she is defining participation that is not “personal and substantial.”

This stonewalling of legitimate questions from the public and her outright deceit about not owning Schein stock when she took office leads us to believe that Commissioner Hamburg knows that her conflict tainted the rule, a situation that calls for reconsideration.

#4: Commissioner Hamburg recused herself so late in the rulemaking that Dr. Sharfstein did not have the time to adequately consider the rule

Not only did Commissioner Hamburg fail to provide adequate leadership due to her own ethical issue, but she refused to recuse herself and turn the rule over to Principal Deputy Commissioner Sharfstein soon enough to allow him enough time to intervene effectively before the amalgam rule issued. Having first indicated her recusal to the press on July 14,⁷ and with no indication that she recused herself any earlier, Dr. Sharfstein would have had less than two weeks to consider the rule in addition to his other duties. Consideration of a product as complicated and controversial as mercury amalgam would have required more time than Dr. Sharfstein was permitted. The result of the delayed passage of control was a rule riddled with non sequiturs, inconsistencies, and ambiguities.

#5: Commissioner Hamburg's belated and ambiguous recusal resulted in Dr. Sharfstein's inability to effectively take charge of the rule

Due to Hamburg's belated and ambiguous recusal, Dr. Sharfstein did not have the opportunity to effectively take charge of the amalgam rule. By "decid[ing] not to participate,"⁸ but apparently not recusing herself, Hamburg appears to have also decided that no one in the Commissioner's Office should be in charge. Instead, she seems to have given free reign to the Center for Devices, even though she acknowledges that the Center "obviously" had "some problems."⁹ As a result of this confusion, Dr. Sharfstein's staff continually refers callers who ask about the rule to the Center for Devices, apparently unaware that on July 8, Commissioner Hamburg (through FDA counsel) instructed that "[a]ny inquiries concerning this rulemaking should be referred to Joshua M. Sharfstein, M.D., Principal Deputy Commissioner."¹⁰ With Commissioner Hamburg's vague passage of control, it was unclear even to his immediate staff that Dr. Sharfstein was in charge of the rulemaking.

By not unambiguously recusing herself, not only did Commissioner Hamburg make it unclear who was responsible for this rule, but she left Dr. Sharfstein in an indefinite position of authority. This would have had an impact on his ability both to interact with the staff working on the rule and to intervene to ensure the rule's fairness and accuracy. As a result of these limitations, Dr. Sharfstein was not able to effectively take charge of this rule.

#6: The rule itself suggests that Dr. Sharfstein did not have the opportunity to adequately consider it

The rule itself reveals no indication that Dr. Sharfstein had an opportunity to adequately consider its implications for children and the unborn. It contains no trace of the concern for children that characterized Dr. Sharfstein's work before he came to FDA. Previously, he helped to bring a citizen's petition before FDA asking that the agency tell parents that over-the-counter cold and cough medicines were never found to be safe for children. Likewise, mercury amalgam has not been found safe for children under six and the unborn and FDA even acknowledges that these populations are particularly at risk because they are more susceptible to the effects of mercury exposure. However, FDA inexplicably has decided that this information is irrelevant for parents who are trying to make the best health decisions for their children. That Dr. Sharfstein would choose to not at least inform parents of these risks is not consistent with his prior actions as a child advocate and indicate that he did not have the opportunity to thoroughly consider this rule.

Similarly, Dr. Sharfstein is well aware of the effects of toxic exposure in children and has even led efforts to eliminate lead from children's jewelry. The rule not only fails to demonstrate any of his commitment to protecting children from toxins, it even states that it will stop the trend of decreasing exposure to mercury from amalgam.¹¹ A child advocate concerned about toxic exposure would not have permitted a rule that increases children's risk of being exposed to mercury.

#7: The rule was written under Center Director Schultz who is alleged to have pressured staff into approving unsafe devices and at least one employee has suggested that amalgam was one of these devices

FDA scientists and FDA critics were troubled by former Center of Devices and Radiological Health Director Daniel Schultz's reputation for pressuring his staff to approve unsafe devices, apparently in response to industry influence. The media widely reported that the Center for Devices and Radiological Health's review process was "corrupted and distorted by current FDA managers, thereby placing the American people at risk."¹²

FDA leadership is well aware of the Center's dysfunction under Dr. Schultz,¹³ and some staff have suggested that amalgam was among the products that were approved under Dr. Schultz's leadership despite reservations about safety. One FDA employee, speaking with a reporter off the record, commented, "Why continue to use and recommend mercury amalgam when there is safer composite alternative?...I really question FDA's motivation here. It seems to be more responsive to industry than human health."¹⁴ Even FDA employees do not believe that the public's interest was adequately considered in this rule.

#8: Dr. Runner's involvement tainted the rulemaking process

Dr. Susan Runner, a dentist with no background in toxicology, was the bureaucrat charged with the amalgam rule despite all of the evidence indicating that she could not examine this subject objectively. The one constant marking Susan Runner's career is her dedication to concealing the mercury in amalgam from the American people.

Time and again Runner's views are repudiated by scientists, including FDA's own scientists, but time and again she emerges in control of the agenda. This rule – no warnings, no disclosures, even support for the deceptive term "silver fillings" – is a reflection of Dr. Runner's own biases and need to protect her own interests, which were not consistent with the interests of children and consumers.

For years, Dr. Runner failed to take any serious steps to classify mercury amalgam. Her 2001 proposal was a sham – it required the disclosure only of zinc and not mercury, amalgam's main ingredient. Her maneuvering to hire LSRO (a tobacco consultant who was informed of the desired result in advance and who skirted competitive bidding rules to land the contract) led NIH Director Elias Zerhouni to appoint an independent CPA firm to investigate and write a report (see #11). While NIH condemned the LSRO charade, Dr. Runner still praises it. Then in 2006, two scientific advisory committees condemned Dr. Runner's "white paper," rejecting its conclusion that amalgam is safe and finding the methodology unacceptable (see #10). Visibly shaken and embarrassed after the vote repudiated her work, Dr. Runner's new rule appears to be trying to rewrite history by not even acknowledging the vote or heeding its conclusion (see attached minutes from the administrative record).

It was clearly in Dr. Runner's interests to determine that mercury amalgam was safe – she does not have to admit that she might have harmed her own patients with mercury amalgam, she does not have admit that she was wrong not to classify the device sooner, she does not have

to admit that the LSRO report was biased, and she does not have to admit that her white paper was flawed. To allow a staff member with so much interest in protecting her own reputation to write a rule and with so little supervision (see #1-7) is an abomination of the regulatory process. This situation requires a reconsideration of the mercury amalgam rule without the involvement of Dr. Runner.

FDA'S RULE IS NOT BASED ON SCIENCE

#9: The rule not only has no basis in science, but it was contrary to science

FDA concedes that children and the unborn are more susceptible to mercury's neurotoxic effects: "The developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor."¹⁵ FDA also knows that EPA estimates that more than one in six children could be at risk for developmental disorders because of mercury exposure in the mother's womb even before they get their own mercury fillings. FDA could find no study indicating that mercury amalgam does not pose these known risks to these populations. As a result, the only definitive scientific information that FDA has regarding the effects of mercury amalgam on children and the unborn is the known fact that mercury puts children and the unborn at risk for serious and permanent health problems.

However, FDA did not act to protect children under age six, nursing infants, and unborn babies from this known risk by providing contraindications or even warnings for parents, nursing mothers, and pregnant women. Inexplicably, the agency chose to ignore this critical information and decided against the weight of scientific evidence to permit dentists to continue endangering children.

In addition to this decision with no basis in science, FDA makes exaggerated claims of safety to defend its decision not to provide contraindications or warnings for breastfed infants. FDA asserts in its special controls document that "the existing data support a finding that infants are not at risk for adverse health effects from the breast milk of women exposed to mercury vapors from dental amalgam."¹⁶ However, in the same document FDA concedes that "very limited to no clinical information is available" regarding mercury amalgam's effects on breastfed babies.¹⁷ Since the "existing data" that FDA cites to support its conclusion is "very limited" to nonexistent, its conclusion that breastfed infants are not at risk is little better than a guess.

#10: The rule does not reflect the votes of the scientific advisory committee

FDA's rule fails to reflect the views of its own scientific advisory committee. In March 2006, FDA agreed to hold a hearing before the scientific advisory committee to address the mercury amalgam issue. That September, the independent scientists convened. FDA asked them to answer two questions: (1) Do you agree with our methodology? and (2) Do you agree with our conclusion that mercury amalgam is generally safe? After an intense two-day hearing, the scientists voted no to each question – both by recorded votes of 13 to 7. Since the majority of scientists on its own committee do not believe that mercury amalgam is generally safe, it is difficult to understand how FDA bypassed their determination to conclude that the toxin is so

safe that it does not require contraindications, warnings for patients, or even disclosure of mercury content to consumers.

#11: The rule reflects the biased LSRO report

FDA relies heavily on the LSRO report to defend its ruling. The agency claims that “[I]n conducting its review, LSRO engaged an independent panel of academic experts,”¹⁸ but this is hard to believe since LSRO itself was not legitimately retained to prepare an independent report.

Instead of getting an independent literature review, dental interests inside FDA and NIH’s dental arm, the National Institute for Dental & Craniofacial Research (NIDCR) conducted secret negotiations, essentially preparing a blueprint of the desired result, with LSRO Inc., a Beltway consultant that has close ties to Big Tobacco. Belatedly realizing that they cannot simply appoint this consultant with no competitive bidding, FDA and NIDCR altered the contract terms of an previously engaged contractor who had been hired to arrange conferences (get phones, get vans, get rooms, etc.), and directed the latter to choose LSRO. The deal was so outrageous that NIH Director Zerhouni appointed a national CPA firm to conduct an investigation. The CPA’s report is complete but has been withheld from the public. Meanwhile, LSRO issued its “independent” conclusion that mercury fillings are safe.

The report itself not only whitewashes the hazards of amalgam – the very result requested in e-mail exchanges involving the leadership of NIH’s dental arm and LSRO CEO Michael Falk – but violates the contract terms. The contract required information about evidence of amalgam’s harms, but CEO Falk and the author of the report (for whom absolutely no biographical information is provided) flipped the question to examine proof that amalgam is unsafe.

As a result of LSRO’s bias, no report prepared by it should be considered a legitimate source of scientific information and the report’s conclusions – such as the proclamation that “mercury absorption through breast milk is not a significant source of mercury exposure to infants”¹⁹ – should be considered as biased as its creator. A letter addressing the chicanery involved in the LSRO deal is on the record, under comment tracking number 8069de5b, and needs to be considered by the agency.

#12: The rule disregards studies that demonstrate the hazards of mercury amalgam

While FDA gave undue weight to the biased LSRO report, it gives no indication that it took into consideration the extensive comments debunking the “science” that concluded that mercury is safe. One such comment was submitted by the International Academy of Oral Medicine and Toxicology, whose scientific advisory panel evaluated reams of studies and data including the studies reviewed by LSRO (see #11), explained the deficiencies of studies that LSRO relied upon, and reached the opposite conclusion – dental amalgam is a hazard to human health. FDA’s dismissive treatment of such authorities in favor of the partial LSRO team whose conclusion defies common sense clearly necessitates a reconsideration of this rule.

#13: The rule fails to provide contraindications or warnings for “persons who may have a health condition that makes them more sensitive to mercury”

FDA’s pre-rule website recognized “persons who may have a health condition that makes them more sensitive to mercury” as a distinct subpopulation that of people who need to take precautions before allowing a dentist to implant mercury. FDA does not name any scientific studies that have demonstrated that people with other health conditions are not more susceptible to mercury amalgam’s toxic effects. Without any explanation for the oversight of this group, the final rule fails to provide any warnings or contraindications against using mercury amalgam in patients who are already suffering from other health conditions that might increase the risks of mercury exposure. By failing to mention this population, the agency indicates that it did not consider them when it wrote its rule.

#14: The rule fails to demonstrate any consideration of amalgam’s contribution to total mercury bioburden and mercury’s bioaccumulative nature

The final rule states that that “dental amalgam exposes adults to amounts of elemental mercury vapor below or approximately equivalent to the protective levels of exposure identified by ATSDR and EPA,”²⁰ however it gives no indication that FDA considered dental amalgam’s contribution to a person’s total mercury bioburden or mercury’s bioaccumulative effect. People are exposed not only to dental mercury, but to multiple sources of mercury, such as fish and coal-fired power plants.²¹ FDA’s pre-rule website recognized that “individuals with existing high levels of mercury bioburden” compose one of the populations with “a health condition that makes them more sensitive to mercury exposure.” FDA did not reference any scientific studies that have shown that those with a high mercury bioburden are not more sensitive to mercury exposure, a fact that it acknowledged just last year. Without any explanation for the omission, the final rule fails to provide any warnings or contraindications against using mercury amalgam in patients who already suffer a high mercury bioburden. By neglecting to even raise the matter, the agency indicates that it did not consider it at all.

Mercury fillings themselves are a source of an individual’s total mercury bioburden due to a concept that seems to be overlooked in the FDA rule. The rule refers repeatedly to “daily doses” of mercury,²² but does not ever address the fact that these “daily doses” can be trapped in the human body, especially in the brain and kidneys, for months due to mercury’s bioaccumulative nature.²³ It is unclear that FDA even considered this issue when it decided that mercury amalgam did not require warnings or contraindications for children, pregnant women, nursing mothers, and individuals with a high mercury bioburden.

#15: The rule places consumers at risk by failing to clarify the concept of mercury allergy

While it contraindicates amalgam for people with a “known mercury allergy,” FDA’s amalgam rule fails to adequately address this concept. FDA makes no attempt to clarify how anyone can distinguish between reactions that are caused by an allergy and reactions that are caused by exposure to a toxin. FDA needs to clarify what it means to be allergic to a substance that is toxic under the best of circumstances.

Likewise, FDA failed to explain how anybody would know that they had a mercury allergy before having mercury fillings implanted. FDA has made no attempt to determine how many people suffer from mercury “allergies,” but studies suggest that it is an underreported phenomenon because most people are not aware of mercury as the source of their problem. Additionally, since most consumers are unaware of amalgam’s mercury content and FDA will not require them to be informed of it, no patient will be conscious of any need to inform dentists of sensitivities to other mercury-containing products, such as tuna, that they might know of. Beyond expensive mercury allergy testing, the only way most dentists are going to “know” about a patient’s mercury allergy is to “experiment” on each individual patient – that is, implant mercury amalgam fillings before they know if they are safe for that individual in order to determine whether the patient is allergic. If it turns out the patient is allergic, the dentist once again places the patient in harm’s way by exposing him or her to even more mercury during the removal process. Clearly, FDA’s rule needs to counter people’s lack of knowledge of their mercury allergies with at least mandatory disclosure of amalgam’s mercury content so that patients have the opportunity to tell their dentists about their sensitivities to other mercury-containing products.

#16: The rule endangers consumers by failing to clarify what it means when it says “do not place the device in direct contact with other types of metals”

The amalgam rule’s vague precaution “do not place the device in direct contact with other types of metals”²⁴ belies what is really a complicated issue. Of course, amalgam varies in its metal content depending on the manufacturer and when it was made, for instance some amalgam fillings contain zinc and others do not. If FDA means that one type of amalgam cannot be placed next to another amalgam with a differing metallic composition, the rule needs to clarify this point.

#17: The rule fails to address the effects of zinc in amalgam when it recommends that amalgam be used in high moisture environments

Without stating any basis other than FDA’s belief that “the effects of zinc on the expansion of dental amalgam are well understood,”²⁵ the agency eliminates a proposed warning about zinc. However, dentists who “typically” use amalgam “[w]hen moisture control is problematic” and FDA which endorses amalgam’s utility for this purpose²⁶ apparently do not understand zinc’s properties very well themselves. Amalgam that contains zinc may, in fact, show excessive expansion if moisture is introduced during mixing or compacting. This would render the material unsuitable for the high moisture environment in which FDA recommends that it be used. Even if zinc’s effects were well understood before this rule, FDA needs to clear up the confusion generated by its misleading attempt to justify the continued use of amalgam on the basis of its dubious utility in cases of difficult moisture control.

FDA’S REASONS FOR REJECTING ALTERNATIVES THAT
WOULD PROVIDE INFORMATION DIRECTLY TO
CONSUMERS ARE INCOMPREHENSIBLE, FLAWED, AND
UNSUPPORTED BY THE ADMINISTRATIVE RECORD

#18: An “error” in a key part of the final rule obscures its meaning and indicates that no one at FDA scanned this section, much less actually considered it

In its discussion of alternatives to the final rule, FDA further demonstrates that it failed to adequately consider options that would protect consumers. FDA rejects proposals to provide patients with direct information, including disclosure of amalgam’s mercury content, declaring that “[t]he costs of this alternative would include the opportunity costs both dentists and patients of discussing treatment options...”²⁷ As if the faulty logic was not enough of an affront to consumers (see #19), with this sentence FDA fails to even do the American people the courtesy of rejecting their proposal in accordance with the laws of the English language. By presumably omitting the word “to” from the phrase “opportunity costs both dentists and patients of discussing treatment options,” it appears that at best, no one at FDA so much as scanned this section of the rule, much less actually considered the proposal to disclose information to patients. At worst, it appears that FDA is rather transparently attempting to obscure its flawed reasoning.

Before the rule becomes effective, FDA must verify the meaning of this section in the Federal Register so that the public has the opportunity to exercise its right to evaluate and challenge FDA’s final rule.

#19: The rule contradicts itself by stating that providing information directly to consumers would discourage patient-dentist discussion while acknowledging that such discussion could not be avoided by patients in any situation because filling materials can only be obtained by prescription

As described in #18, it is difficult from a grammatical standpoint to decipher the reasoning behind FDA’s decision not to require that consumers receive direct information about dental amalgam, including its mercury content. This reasoning is so poorly written, that it is hard to determine FDA’s meaning and therefore difficult to challenge (presumably this was the purpose of writing it this way). Despite FDA’s apparent inability to communicate effectively, we will endeavor to challenge the most readily accessible meaning of the phrase “[t]he costs of this alternative would include the opportunity costs both dentists and patients of discussing treatment options...,”²⁸ which is to say that providing information directly to patients will deprive dentists and patients of the chance to talk about different filling materials.

Assuming this to be the correct interpretation, it appears that FDA has reached the Orwellian conclusion that giving patients nothing to talk about will encourage discussion with dentists. If dentists broach the subject at all, it would have to take the form of a lecture and not a give-and-take discussion considering FDA’s promotion of public ignorance. However, the odds of such a topic ever being raised in a dental office or clinic in the first place are severely diminished by FDA because its rule relies solely on the dentist to raise the topic with the patient.

If patients had direct information that informed them about filling materials, they too would be in a position to bring up a discussion, thereby doubling the chances that someone – either patient or dentist – will start talking about treatment options. As it is, patients do not realize that there is anything to discuss because they do not know of amalgam’s mercury content (76% of Americans cannot identify the main component of amalgam²⁹), they do not know the risks of mercury exposure, they do not know that there are alternative filling materials, and FDA policy is to make sure that they do not find out.

Any counterargument asserting that providing patients with direct information would prevent dentist-patient discussion is flawed because as FDA’s rule concedes, filling materials are only available by prescription and “patients cannot receive the device without the involvement of a learned intermediary, the dental professional.”³⁰ Therefore, patients cannot possibly obtain a filling material without dentists having the opportunity to talk about the decision regardless of whether consumers are provided with direct information about mercury amalgam. By contrast, by not providing patients with direct information, FDA’s policy is encouraging dentists to bypass the very discussion that it claims to be protecting.

With this doublespeak, FDA dismisses alternatives that would ensure that consumers are informed and proves that its reasoning is just as flawed as its writing. As a result, all of FDA’s cost calculations for this alternative are erroneous. This bungled attempt to explain the advantages of ignorance over knowledge necessitates a reconsideration of FDA’s refusal to require that consumers receive information, including amalgam’s mercury content and the risks associated with it, before their fillings are installed.

#20: FDA’s rule increases patient anxiety, resulting in delayed and deferred treatments

One reason FDA lists for dismissing alternatives that involve giving consumers information directly is “potentially delayed or deferred treatments.”³¹ However, FDA also concedes that providing such information would result in a “potential reduction in anxiety for patients.” The rule makes no attempt to quantify the number of patients who delay and defer treatments due to anxiety that can be allayed by direct information. It fails to recognize that its policy of non-disclosure will increase the number of patients who delay or defer treatments due to anxiety produced by the FDA-sanctioned atmosphere of secretiveness and distrust in dental offices and clinics. Clearly, FDA failed to fully consider that its rule would result in the delayed and deferred dental treatments that it claims to want to prevent (see also #33).

#21: The rule miscalculates the costs to manufacturers

The rule cites the costs of manufacturer testing to eliminate the possibility of providing consumers with direct information regarding mercury amalgam.³² While it is unclear what such “testing” would involve, any costs of providing information directly to consumers would be easily recouped by the manufacturers. 77% of people who were made aware of amalgam’s mercury content have stated that they would be willing to pay more for an alternative filling material.³³ FDA appears to have overlooked the fact that amalgam manufacturers also produce the alternative filling materials. Since knowledge of amalgam’s mercury content resulting from direct consumer labeling will ultimately increase the sale of alternative filling materials even if

they cost more, it is difficult to understand how FDA concluded that the costs of such labeling for consumers were detrimental to manufacturers in the long run.

#22: The administrative record does not support FDA’s reliance on dentists to convey information to consumers

The administrative record not only fails to support FDA’s reliance upon dentists to convey information about mercury amalgam to their patients, but it powerfully demonstrates that most dentists will not talk with their patients about this issue. Most dentists have not ever conveyed this information before as indicated by the fact that 76% of Americans cannot identify mercury as amalgam’s main component.³⁴ Knowing that dentists have already failed to educate consumers, FDA has no reason to believe that they will do so in the future, but has every reason to believe that they will continue their current deceptive practices. This inexplicable reliance on a profession that has already proved itself unreliable requires a reconsideration of this rule.

THE RULE IS CONTRARY TO FDA’S MISSION, NATIONAL POLICY, AND AMERICAN VALUES

#23: The rule is contrary to FDA’s stated mission of providing the public with accurate, science-based information because it ineffectively delegates its duty to ensure consumers’ ability to obtain this information

Contrary to the mission statement on FDA’s website that proclaims “[t]he FDA is also responsible for advancing the public health by... helping the public get the accurate, science-based information they need to use medicines and foods to improve their health,”³⁵ FDA’s amalgam rule obstructs the consumer’s ability to obtain accurate information and shrugs off the agency’s responsibility for providing it. Not only does FDA use its consumer website to perpetuate the deceptive term “silver fillings” and exaggerate the safety of amalgam to the point that it is not even consistent with the rule (see #26 & #36), but the agency has decided it has no duty to ensure that consumers receive accurate information. Instead, the agency has determined that dentists should carry out FDA’s duty to provide consumers with information despite all of the evidence indicating that the profession is incapable of this task (see #22). If FDA intends to be consistent with its own mission statement, it will need to reconsider this rule.

#24: FDA’s rule fails to ensure that patients and parents will be provided neutral information about mercury amalgam contrary to FDA’s mission

By not requiring that patients and parents receive direct information about mercury amalgam, FDA has left them with no source of neutral information about the subject. As evidenced in the administrative record, there is a sharp divide within the dental profession over amalgam. About 50% of dentists use it and about 50% do not, many citing its negative effects on health. Patients and parents will no doubt be confused when one dentist adamantly tells them that mercury amalgam is perfectly safe while a second opinion persuasively indicates that it is not.

Considering the virulence of this controversy, dentists are unlikely to provide patients and parents with unbiased opinions. As evidenced by threats of liability for implanting amalgam, far from being neutral sources of information, some pro-amalgam dentists actually have a vested legal interest in providing distorted information to patients and parents (or no information at all) so as to discourage litigation for consumer injuries. Far from providing consumers with accurate information, dentists simply use their patients as pawns to further their own interests in this ongoing debate.

With professional opinions so divided and a high potential for biased opinions, it is FDA's responsibility to ensure that patients receive neutral information regarding mercury amalgam. FDA cannot shrug its responsibility off to a profession that is so internally divided and conflicted.

#25: The rule fails to disclose amalgam's mercury content to consumers, a measure which protects amalgam sales at the expense of consumers contrary to FDA's mission

The FDA rule fails to require that patients be informed of amalgam's mercury content before it is implanted, despite the obvious relevance of this information to patients' decisions about their dental care. The majority of consumers (over 77%) say that they would rather pay more for an alternative filling material than have mercury-containing fillings.³⁶ If FDA had chosen to require disclosure, clearly amalgam sales would have dropped precipitously. This effort to keep patients and parents ignorant clearly benefits corporations' short term interests. The rule ensures continued amalgam sales, allows them to avoid any expense associated with informing patients, permits them to evade responsibility for the harm their product is wrecking on public health, and saves them the costs of transitioning to alternative filling materials. Consumers and children are left to pay the costs of these overwhelming corporate benefits, and they pay with their health and the denial of their right to control their own bodies.

#26: Contrary to its stated mission of ensuring that the public receives accurate, science-based information the agency is encouraging industry and dentists to deceptively market amalgams as "silver fillings" and discouraging them from correcting widespread public misconception

Perhaps because the President's executive order disfavors rules that preempt private remedies, the amalgam rule inserts sentences that appear specifically designed to help corporations defend themselves before judges and juries, such as the statement that the term "silver fillings" merely refers to the color.³⁷ Usually, the term "silver" refers to the material (the first definition of "silver" in the dictionary refers to the material; the color, by contrast, is typically listed fourth or lower). More importantly, according to surveys, the vast majority of consumers understand "silver" to refer to the filling material and not the color.³⁸ It is a reasonable assumption on the part of consumers since other filling materials are identified by their main components (for instance, gold fillings are primarily gold and resin fillings are made of resin). FDA has a duty to correct deceptions by industry – not to give industry a blueprint for maintaining industry-instigated consumer misconceptions. By endorsing this deceptive marketing practice, FDA not only enables amalgam sellers to push their product onto patients

who would reject it if they knew its true contents,³⁹ but this statement could be used by amalgam sellers to defend their deception in lawsuits brought by consumers who are injured by the product. FDA's protection of the term "silver fillings" serves no purpose other than to benefit industry at the expense of consumers, and as such it is a clear example of how FDA is ignoring its mission in order to permit industry to exploit consumer ignorance.

#27: The rule discourages a decrease in mercury exposure contrary to FDA's general mercury policy

Consistently, the other Food and Drug Administration centers already prohibit, restrict, or warn about the use of mercury. i) The Center for Veterinary Medicine bans mercury in veterinary medicines.⁴⁰ ii) The Center for Drug Evaluation and Research bans the disinfectant Mercurochrome solely because of its mercury content. iii) The Center for Biologics Evaluation and Research took action to eliminate mercury from childhood vaccines based on the Precautionary Principle.⁴¹ iv) The Center for Food Safety and Applied Nutrition issued warnings to pregnant women and parents of young children about mercury in fish⁴² and severely restricts the use of mercury compounds in cosmetics.⁴³ By contrast, the Center for Devices and Radiological Health has defied all logic to determine that the other centers are wrong – mercury is so safe that it does not require contraindications, warnings, or even disclosure. Indeed, the rule states that FDA is aware that it will create a rise in mercury exposure, but it takes no action (such as providing disclosure, warnings, or contraindications) that might counter this expected increase.⁴⁴

#28: The rule discourages a decrease in mercury exposure contrary to our national mercury policy

FDA's rule states "the daily potential exposure to mercury vapor originating from dental amalgam is expected to decrease gradually in the *absence* of the final rule,"⁴⁵ but fails to explain how the agency justifies this result in light of our national policy against increasing the public's exposure to mercury. This out-of-date mercury amalgam rule clearly conflicts with federal mercury policy. Last year, the Mercury Export Ban Act, which was sponsored by then-Senator Obama, prohibited the export of mercury from the United States.⁴⁶ President Obama's Plan for a Healthy America has listed reducing mercury as one of its goals, citing the same information that was available to FDA in the administrative record: "More than five million women of childbearing age have high levels of toxic mercury in their blood, and approximately 630,000 newborns are born at risk every year. The EPA estimates that every year, more than one in six children could be at risk for developmental disorders because of mercury exposure in the mother's womb."

FDA made no attempt to minimize the expected increase in the public's exposure to mercury that it caused with this rule. Measures such as disclosing amalgam's mercury content to consumers, providing warnings for patients, or contraindications for children, pregnant women, and those already suffering a high mercury bioburden would have ensured that the public's exposure to mercury was kept to a minimum, but FDA has apparently determined that it knows better than the President and the rest of the federal government.

#29: The rule promotes dental apartheid contrary to our national policy

FDA's rule is promoting the "choice for the rich, mercury for the poor" that Emmitt Carlton, former president of the Virginia State NAACP, has spoke out against in his testimony before Congress. The elite do not have toxins implanted in their bodies because amalgams are not worth the risk of mercury exposure when alternatives are available. However, by authorizing dentists to continue their use of amalgam, especially when they have determined that "a patient's commitment to oral hygiene is poor"⁴⁷ (in other words, when the patient cannot afford better care), FDA is sanctioning the infliction of the cheapest but riskiest material on the poor, the middle class, minorities, Native Americans, the military, prisoners, and people with disabilities for no better reason than their socio-economic status. FDA has even provided dentists with a ready – albeit flimsy – explanation for why they are discriminating against those with limited funds for to oral hygiene "commitment."

Furthermore, the rule seemingly authorizes dentists to make decisions for these non-elite sub-populations based on the whims of prejudice, deciding without any input from patients that mercury is acceptable for some, but not for others (see #30). FDA's rule affords no protections from such discrimination, such as requiring that that even the non-elite be informed that mercury is being installed in their mouths. These groups are thereby denied any opportunity to protest that they deserve the same treatment as the elite. With its rule, FDA has condoned and furthered a system of dental apartheid that requires a reconsideration that will protect the interests of consumers whose dentists do not deem worthy of non-mercury filling materials.

THE RULE'S FAILURE TO CLARIFY WHO DECIDES WHICH FILLING MATERIAL TO USE IS MISLEADING DENTISTS AND HARMING CONSUMERS

#30: The rule contradicts itself as to the role of the dentist in the filling material decision

FDA's mercury amalgam rule is so ill-considered that it constantly contradicts itself with regard to the key issue of who should make the decision as to which filling material is used – the dentist or the dentist and patient together. Sometimes the final rule says only dentists make this decision, for instance references such as "[a] *dentist's* decision concerning the use of a particular restorative material"⁴⁸ and dentists "mak[ing] treatment decisions *for* their patients"⁴⁹. Then a few pages later, FDA vacillates and starts referring to dentists "mak[ing] appropriate treatment decisions *with* their patients"⁵⁰ and "dental professionals plan[ning] appropriate treatment *recommendations* for their patients,"⁵¹ implying that the patient should make the ultimate decision.

By failing to clarify the decision-maker, FDA is sending contradictory messages to dentists, one of which appears to exhort dentists to avoid making such decisions in conjunction with their patients. This will certainly discourage the dentist-patient discussions that FDA claims it wants to promote with its policy of non-disclosure to patients.⁵² Already, some dentists who believe they are the ultimate decision makers refuse to treat patients who reject amalgam against

the dentists' preference, resulting in delayed and deferred treatments (see #33). Furthermore, these contradictions indicate that no one at FDA thoroughly considered the ramifications of this ruling.

#31: The rule contradicts itself by describing the decision as to filling materials as too “complex” for consumers while also stating that there is very little to no clinical information regarding children under age six and the unborn available on which to base the decision

FDA concedes that “[v]ery limited to no clinical information is available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed,”⁵³ however it knows that “[t]he developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor.”⁵⁴ With such a dearth of scientific information regarding the safety of amalgam and such a devastating known risk of mercury exposure, it's hard to see how the decision as to whether to use amalgam on children and pregnant women is "a complex matter that requires the expertise of the dental professional."⁵⁵

The legitimate factors to be weighed are not complex. A professional degree is not required to understand that mercury fillings release a toxic vapor that can cause neurological damage to children and the unborn (if it was required, most dentists would not qualify since few of them have their doctorates in toxicology or neurology). A parent can determine that the petty alleged conveniences of mercury amalgam (such as it's quicker and easier for the dentist to implant) and its inapplicable supposed advantages (it's durability and longevity are not terribly relevant for baby teeth) are outweighed by the risks of mercury exposure. Since complicated scientific data on which dentists could base decisions is not available in the case of children under age six and the unborn, dentists and parents are left with an equal or superior ability to understand the remaining “complexities” – such as income and race – that are weighed when determining whether mercury amalgam is an appropriate filling material for their children. FDA's attempt to discredit the intelligence of American parents is unconvincing.

#32: The rule fails to respect patients' right to make their own decisions about their bodies and their health

FDA's decision to grant dentists the authority to make decisions about their patients' bodies and to permit them to sneak toxins into people's bodies without informed consent is contrary to our national policy and values. American citizens are fiercely protective of their right to control their own bodies as indicated by the abortion debate, our right to refuse medical treatments, and the fact that 92% of people want to give informed consent before dentists implant mercury into them.⁵⁶ 77% of people who were made aware of amalgam's mercury content have stated that they do not want mercury fillings in their mouths and would be willing to pay more for an alternative.⁵⁷ Clearly, Americans do not want dentistry's controversy in their mouths. In a country where citizens have right to know and control the ingredients of the food they consume, how does FDA justify a decision that permits dentists to surreptitiously slip into an unsuspecting victim's mouth a toxin that continually emits poisonous vapor? This is clearly not a decision for the dentist to make.

#33: FDA's rule emboldens dentists to refuse to treat patients who object to mercury, resulting in delayed and deferred treatments

The rule itself has emboldened dentists to refuse to treat patients, which is causing delayed and deferred treatments. With 77% of people who are aware of non-mercury filling materials saying they do not want mercury,⁵⁸ with FDA failing to provide contraindications for children despite acknowledging their higher risk from mercury exposure, and with the rule seeming to authorize the roughly 50% of dentists who persist in using amalgam to make the decision as to filling material alone (see #30), FDA should have foreseen that its rule was going to lead to undesirable consequences.

The rule has already resulted in autistic children being refused treatment by dentists because parents refuse to subject their children to any additional source of mercury. The parents' concerns are justified considering that even FDA concedes that children might be more susceptible to mercury's harmful neurological effects and numerous studies have linked autism to mercury exposure. These parents now face the daunting task of locating another dentist capable of treating autistic children (who sometimes require a general anesthetic) and acclimating their children to this new dentist and a different office setting.

Clearly, dentists who use this easily-misconstrued rule to refuse treatment to patients who reject a substance that places their children at higher risks for neurological problems will cause more delayed and deferred treatments unless FDA clarifies that patients have the right to make ultimate decisions about their own bodies and must be given the information that they need to make these decisions.

FDA IS USING ITS CONSUMER WEBSITE TO DECEIVE THE PUBLIC

#34: The consumer website fails to mention mercury on the introductory page even though it does discuss acrylic

FDA's commitment to keeping the public ignorant about amalgam's mercury content is further demonstrated by its post-rule consumer website. The introductory page manages to describe dental amalgam without mentioning mercury.⁵⁹ This appears to be yet another attempt to deceive consumers because even in this brief introductory page, FDA does explain the components of other filling materials, noting that, "[o]ther materials, based on acrylics, are also used for dental fillings."⁶⁰ Why the agency chooses to mention acrylics but not mercury on a page entitled "Dental Amalgam" is inexplicable unless FDA is deliberately trying to mislead the public by covering up the mercury just as industry and the dental profession have done for so many decades. FDA needs to reconsider its use of such deceptive tactics on the opening page of its website. To counteract the misleading information that FDA itself is now disseminating, the agency needs to require that consumers be informed of amalgam's mercury content before it is placed.

#35: FDA goes so far to hide information from consumers that it removed an accurate advisory from its consumer website and then buried it in a section entitled “Guidance for Industry and FDA Staff”

FDA goes so far in its efforts to protect industry with its amalgam rule that it removed accurate information that might discourage amalgam use from its consumer website. To settle a lawsuit with Consumers for Dental Choice, Moms Against Mercury, Connecticut Coalition for Environmental Justice, and Oregonians for Life among others,⁶¹ FDA Commissioner Andrew Von Eschenbach agreed to maintain this advisory on FDA’s consumer website: “*Dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses.*”⁶² FDA removed this advisory from the consumer website at the time of the rule’s announcement, not even waiting until the date the rule was published. The current consumer website fails to even mention the higher risk that dental mercury poses to children and the unborn.

The agency concedes the truth of the pre-rule advisory, including the dangers to children and fetuses (“The developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor”⁶³), but now buries it deep in the Special Controls document in language intended for dental professionals only.⁶⁴ Consumers are not likely to even look through the long website page containing the Special Controls document for information because while it is technically available to them by way of a link that is obtainable from a related resources listing that can be reached from the consumer website, not only is getting to it a convoluted process, but the Special Controls are clearly labeled in bold at the top “Guidance for Industry and FDA Staff.”⁶⁵ FDA’s apparent attempt to conceal information about the particular risks to children and the unborn is clearly contrary to its mission of providing accurate information for consumers, but does achieve the dubious objective of protecting the amalgam industry.

#36: FDA’s post-rule consumer website’s description of the clinical information is inconsistent with the rule’s description of the same information

FDA informs consumers on its post-rule consumer website that “There is limited clinical information about the potential effects of dental amalgam fillings on pregnant women and their developing fetuses, and on children under the age of 6, including breastfed infants,”⁶⁶ a gross understatement compared to the rule’s description of the clinical information. In the final rule, FDA states that “*Very limited to no* clinical information is available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed.”⁶⁷ There is a substantial difference between limited information and very limited information and between limited information and no information. Since FDA admits in its rule that it has no clinical information regarding the safety for some of these groups (FDA’s rule does not specify which ones it has no information regarding) the agency is blatantly lying about the safety of this product on its website. Instead of using its website to inform consumers, FDA is using it to push propaganda onto the unsuspecting public.

#37: The website fails to inform consumers that mercury is bioaccumulative and implies that it is not

FDA's consumer website fails to accurately describe the risks of amalgam because it does not acknowledge that amalgam is only one source of mercury and mercury is bioaccumulative. Consumers need to be able to evaluate their risks from amalgam based on all of the sources of mercury they encounter, but the website presents amalgam mercury in a vacuum.

Additionally, consumers need to be informed that mercury is bioaccumulative, meaning that even if amalgam only accounts for a small amount of mercury exposure each day, that toxin not only combines with mercury from other sources, but it also accumulates in the body, especially in the kidneys and brain, over time. In light of the absence of information about mercury's bioaccumulative nature on FDA's consumer website, the references to "daily doses" of mercury are particularly misleading because they imply that mercury "wears off" every day like a daily dose of medicine.

FDA's website needs to clarify that even if "mercury exposure due to dental amalgams has been found to be far below the lowest levels associated with harm," this does not mean that this level of exposure is safe for everyone because everyone is subject to different sources of mercury and has different levels of pre-existing mercury bioburden.

#38: The serious potential risks of mercury exposure were not originally posted on the consumer website that was posted following the rule's announcement

When FDA pulled its pre-rule consumer website just prior to the rule's announcement on July 28, it was replaced by a hastily-written substitute that reflects the ill-considered rule itself. Most blaringly, a section entitled "Potential Risks" originally failed to explain any potential serious risks, such as the effects of mercury. Instead, the entire section was dedicated to defending FDA's rule and reiterating the agency's unfounded belief that amalgam is safe for young children based on the existing data (even though FDA admits there is no data or almost no data). The omission was so noticeable that the agency has already had to go back to make a correction, adding the statement that "High levels of mercury vapor exposure are associated with adverse effects in the brain and the kidneys" on August 11.⁶⁸ The rule and website associated with it are riddled with similar errors that necessitate reconsideration.

CONCLUSION

For these reasons, the petitioners named below respectfully ask for a reconsideration of the Final Rule for Dental Amalgam.

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ENDNOTES

¹ Jim Dickinson, *Hamburg Recuses Herself From Dental Mercury Rulemaking*, FDA WEBVIEW, 14 July 2009.

² Alicia Mundy, *New FDA Chief Must Divest Several Stock, Fund Holdings*, WALL STREET JOURNAL, 26 May 2009.

³ <http://toxiceeth.org/settlement%20agreement.PDF>

⁴ “Dental amalgam:

[Senator Enzi:] Q: FDA has a court-ordered deadline to issue a regulation placing dental amalgam in one of three device classes. That deadline is fast approaching. FDA's current proposal is to classify encapsulated amalgam and its components as class II devices with special controls (materials and labeling.) Is this regulation on schedule to be issued this July? Will you make a commitment that if the regulation will not be issued by the deadline that you will tell me why not, and when you do expect to issue the regulation?

[Dr. Hamburg] Answer: It is my understanding that the regulation is on schedule to be issued in July. Although I do not expect the regulation to be delayed, in the event that an unforeseen delay does occur, I will be happy to let you know the reasons for the delay and update you on the timeframe for its issuance. I will also be happy to keep you informed of its progress.

Q: FDA's website states that “[d]ental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses.” Furthermore, the agency raises concerns about the safety of dental amalgam for many other vulnerable demographics, including pregnant women, the hypersensitive, “individuals with existing high levels of mercury bioburden,” children under age 6, lactating women, immunocompromised individuals, dental patients generally, and dental professionals. Will the forthcoming classification take into account FDA's professed concerns about the impact of mercury amalgam on these vulnerable groups?

Answer: I have not been briefed on all the substantive details of this matter. If confirmed, I will undertake a review of this and all other pending regulatory matters, and work with agency staff to be as responsive to your concerns as possible.”

⁵ "So as a closing comment, I would like to extend on behalf of the company, our Board and our shareholders our sincere thanks to Dr. Margaret Hamburg, who has served as the Director of Henry Schein Company's Board since 2003. As has been known in public announcements, Dr. Hamburg left our Board following her confirmation as Commissioner of the U.S. Food and Drug Administration. We would like to thank Dr. Hamburg for the insight she shared with the Henry Schein Board throughout the years and wish her continued success." Stanley Bergman, CEO, Q2 2009 Earnings Call; 4 August 2009, <http://seekingalpha.com/article/153742-henry-schein-inc-q2-2009-earnings-call-transcript?page=-1>

⁶ Jim Dickinson, *FDA: Lawyer's Charges Against Hamburg 'Incorrect,'* FDA WEBVIEW, 18 August 2009

Associate Commissioner George Strait's statement to FDA WEBVIEW (reprinted in full):

The claims you have published regarding the FDA's recent rule on dental amalgams and Dr. Hamburg's connection to it are incorrect.

First, as we have told you before, Dr. Hamburg was not involved in the decision making for the dental amalgam rule and is recused from it.

Second, allegations that Dr. Hamburg had a vested interest in the dental amalgam decision because she would profit from the Schein stock that she held are false. By May 20th (six days before she took office as FDA Commissioner), Dr. Hamburg had divested all her Schein stock and all Schein options which had any market value, and by July 27th she had no interest whatsoever in Schein. In fact, Dr. Hamburg lost hundreds of thousands of dollars on the sale of Schein stock and options.

These are the details. Dr. Hamburg was confirmed by the Senate on May 18th, but did not take office until May 26th. In the days following her confirmation and BEFORE she took office, Dr. Hamburg resigned her position as a Board Director at Schein, sold all of her Schein stock, exercised all the Schein options she owned that had monetary value (so called in the money), and immediately, that same day, sold all of that resultant stock.

At that time, Dr. Hamburg also forfeited unvested restricted Schein stock worth \$262,000. By the close of the markets on May 20th, she did not own any Schein stock. The only Schein interests she had left were non-transferable out-of-the-money Schein options, which according to her statement from Fidelity had zero value.

During July, the market went up and some of those options gained value (came into the money). On July 16th, in order to continue to immediately divest herself of any Schein interests as rapidly as possible, she exercised all of the options that had value and sold the resultant stock for a profit of \$2,593.73. The profit on the sale was less than one percent of what it cost Dr. Hamburg to forfeit the unvested Schein stock when she resigned from the board on May 20th. During that same period she contacted Schein to see if there was some way to get rid of the remaining non-transferable options before they were due to expire in August. On July 27th, Schein canceled the remaining options.

To reiterate, by May 20th Dr. Hamburg had divested all Schein stock and all Schein options which had any market value, and by July 27th, she had no interest whatsoever in Schein. In addition these stock forfeitures and stock option sales and cancellations resulted in a loss to Dr. Hamburg of over \$200,000.

⁷ Jim Dickinson, *Hamburg Recuses Herself From Dental Mercury Rulemaking*, FDA WEBVIEW, 14 July 2009.

⁸ Letter available at http://toxicteeth.org/FDA_letters2_Jul2009.pdf

⁹ Alicia Mundy, *FDA Chief Eyes Device Group*, WALL STREET JOURNAL, 17 June 2009.

¹⁰ Letter available at http://toxicateeth.org/FDA_letters2_Jul2009.pdf

¹¹ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.89).

¹² Alicia Mundy & Jared A. Favole, *FDA Scientists Ask Obama to Restructure Drug Agency*, WALL STREET JOURNAL, 8 January 2009.

¹³ Alicia Mundy, *FDA Chief Eyes Device Group*, WALL STREET JOURNAL, 17 June 2009
(Regarding the Center, Commissioner Hamburg is quoted as saying, “There obviously have been some problems.”)

¹⁴ Jim Dickinson, *A ‘Shocking’ Decision – Bias Seen in Dental Amalgams Rule*, FDA WEBVIEW, 31 July 2009.

¹⁵ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.32).

¹⁶ Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy – Guidance for Industry and FDA Staff,
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073311.htm>

¹⁷ Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy – Guidance for Industry and FDA Staff,
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073311.htm>

¹⁸ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.11, 45).

¹⁹ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.25).

²⁰ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.33).

²¹ Agency for Toxic Substances and Disease Registry (ATSDR), *Toxicology profile for mercury*, <http://www.atsdr.cdc.gov/ToxProfiles/phs46.html> (“Other sources of mercury [besides dental amalgam] may increase your overall exposure, such as the amount of fish consumed per week, especially if caught in local waters contaminated with mercury or of certain species known to be higher in mercury content (shark and swordfish), or an exposure to mercury from a nearby hazardous waste site or incinerator.”).

²² Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy – Guidance for Industry and FDA Staff, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073311.htm>

²³ Agency for Toxic Substances and Disease Registry (ATSDR), *Toxicology profile for mercury*, <http://www.atsdr.cdc.gov/ToxProfiles/phs46.html> (“Once in your body, metallic mercury can stay for weeks or months. When metallic mercury enters the brain, it is readily converted to an inorganic form and is ‘trapped’ in the brain for a long time. Metallic mercury in the blood of a pregnant woman can enter her developing child. Most of the metallic mercury will accumulate in your kidneys, but some metallic mercury can also accumulate in the brain. Most of the metallic mercury absorbed into the body eventually leaves in the urine and feces, while smaller amounts leave the body in the exhaled breath.”).

²⁴ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (pp.37-38).

²⁵ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.51).

²⁶ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.7-8).

²⁷ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.95).

²⁸ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.95).

²⁹ Zogby poll, <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>

³⁰ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.68).

³¹ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.95).

³² Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.95).

³³ Zogby poll, <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>

³⁴ Zogby poll, <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>

³⁵ <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm>

³⁶ <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>

³⁷ <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm> (“Dental amalgam fillings are also known as “silver fillings” because of their silver-like appearance.”)

³⁸ A Zogby poll indicates that 76% of Americans cannot identify the main component of amalgam. <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>

³⁹ <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>

⁴⁰ FDA, *Enforcement Story 2002*, http://www.fda.gov/ora/about/enf_story/archive/2002/ch5/cvm1.htm. The Center for Veterinary Medicine even recalled Miracle Leg Paint II, a lotion that went on horses’ legs, after discovering it had mercury, noting that such products had caused poisoning and death in humans. FDA, *Nationwide Recall of Miracle Leg Paint Veterinary Drug Because of Potential Health Risk to Animals and Humans*, www.fda.gov/oc/po/firmrecalls/equine05_02.html.

⁴¹ See FDA, *Thimerosal in Vaccines: Frequently Asked Questions*, <http://www.fda.gov/cber/vaccine/thimfaq.htm> (noting that the Institute of Medicine’s Immunization Safety Review Committee “believed that the effort to remove [the mercury preservative] thimerosal from vaccines was ‘a prudent measure in support of the public health goal to reduce mercury exposure of infants and children as much as possible’” and “urged that ‘full consideration be given to removing thimerosal from any biological product to which infants, children, and pregnant women are exposed’”).

⁴² *What You Need to Know About Mercury in Fish and Shellfish*,
<http://www.cfsan.fda.gov/~dms/admeHg3.html>

⁴³ *FDA, Ingredients Prohibited and Restricted by FDA Regulations*,
<http://vm.cfsan.fda.gov/~DMS/cos-210.html>.

⁴⁴ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.89).

⁴⁵ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.89) (emphasis added).

⁴⁶ P.L. 110-414.

⁴⁷ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.7).

⁴⁸ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.7).

⁴⁹ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.93).

⁵⁰ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.68).

⁵¹ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.34).

⁵² Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.95).

⁵³ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.32).

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- ⁵⁴ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.32).
- ⁵⁵ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.67).
- ⁵⁶ Zogby poll, <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>
- ⁵⁷ Zogby poll, <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>
- ⁵⁸ Zogby poll, <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>
- ⁵⁹ <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/default.htm>
- ⁶⁰ <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/default.htm>
- ⁶¹ *Moms Against Mercury et al. v. Von Eschenbach, et al.*
- ⁶² The settlement agreement is located at <http://toxicteeth.org/settlement%20agreement.PDF>
- ⁶³ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.32).
- ⁶⁴ Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy – Guidance for Industry and FDA Staff, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073311.htm> (“The developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor. Very limited to no clinical information is available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed.”)
- ⁶⁵ Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy – Guidance for Industry and FDA Staff, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073311.htm>
- ⁶⁶ <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm>

⁶⁷ Final Rule for Dental Amalgam,
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.32) (emphasis added).

⁶⁸<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm>