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Complaint to the Inspector General, Department of Health and Human Services

To the Honorable Daniel Levinson:

FDA's amalgam rule – unabashedly against disclosure of amalgam's mercury content to parents and dental patients – is manifestly tainted by (1) Commissioner Margaret Hamburg's surreptitious involvement while intertwined with the nation's top amalgam seller (whose stock jumped after the rule was unveiled and whose CEO thereafter announced appreciation to Dr. Hamburg for her "insights") and (2) well-publicized charges that Director Daniel Schultz was pressuring for the approval of unsafe devices under industry influence.

Background: FDA's Amalgam Rule

On August 4, FDA published a rule that allows amalgam sellers to conceal from consumers the fact that amalgam's major component is mercury. FDA won't even require disclosure of this highly relevant information to young women and parents – despite admitting that children and the unborn are more susceptible to mercury's neurotoxic effects and conceding that no study indicates that mercury amalgam does not pose these known neurological risks to these subpopulations.¹ Not only does FDA's new rule cover up the mercury in amalgam from American dental patients, but it withdraws an accurate FDA consumer website that advised parents and young women that dental mercury can cause neurological harm to children and unborn children.² Instead, FDA hands amalgam sellers *carte blanche* authority to market mercury amalgam under the deceptive term "silver fillings"³ (the phrase that has for so long confused dental patients, most of whom, according to surveys, would choose an alternative based solely on awareness that amalgam is mainly mercury).⁴ The rule is so callous toward children and so deferential toward amalgam sellers that it actually states an aspiration to reverse a decline in mercury exposure⁵ even though FDA acknowledges that mercury exposure can lead to neurological damage, kidney problems, and similarly-severe injuries.⁶

The rule was such an outlier in favor of amalgam industry giants like Henry Schein, Inc. that it shocked Wall Street, which had advised investors that contraindications were coming for pregnant women and children.⁷ It defied the expectations of a bipartisan group of Representatives, led by Congresswoman Diane Watson (D-CA) and Congressman Dan Burton (R-IN), who wrote the agency in May asking for a rule providing clear disclosures of the mercury to all, as well as additional protections so pregnant women and children would not be subjected to amalgam.⁸ The

more than 50% of American dentists who have already abandoned this pre-Civil War device in favor of modern alternative filling materials⁹ were no doubt stunned. Even FDA employees were surprised that the agency would go this far in favor of industry.¹⁰

Clear evidence exists that a bias toward industry led to this shockingly unbalanced rule. The following six factors demonstrate a troubling nexus between the egregious amalgam ruling, Commissioner Hamburg's unethical handling of the rule, and Dr. Schultz's involvement:

(1) Margaret 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."¹¹ She 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.,¹² a relationship that began in 2003, existed until the day before the rule was announced on July 27, 2009, and caused Schein's CEO to boast the morning after the rule was published on August 4.

While on the corporate side of the revolving door, 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,¹³ 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.

(2) Hamburg was involved in the rulemaking despite her ethical problem

Dr. Hamburg denies participating in the decision-making for the amalgam rule, but we have three reasons for believing she was nonetheless involved in spite of her ethical problem.

First, when Senator Enzi, as part of the confirmation process, asked Dr. Hamburg two written questions about the amalgam rulemaking, 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.¹⁴

Second, Dr. Hamburg failed publicly to 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. We kept writing. In response to our second letter, she said she "decided not to participate"; the legal meaning of such terminology is unclear. Two weeks after our third letter, FDA's Chief Counsel, just four days before the rule was due, notified us that she was recused.

Third, her 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." Apparently, we are supposed to accept Dr. Hamburg's view of the facts on faith.

In response to Dr. Hamburg's loophole defense – participated, but in her opinion not both personally and substantially – we express two concerns:

- The Inspector General, not Dr. Hamburg, should determine whether the sum of her actions – including ratifying what others in her employ were doing – constitutes "personal and substantial" participation.
- That Dr. Hamburg concedes the ethical issue and retreats to a legalistic defense is profoundly disappointing. It is against the spirit of ethical government that President Obama brought to Washington. For the American people hoping for change at FDA, it is an inauspicious start.

(3) Hamburg is evasive about her role and recusal

We thrice sought details about Dr. Hamburg's ethical problem and the amalgam rulemaking, and were thrice refused. Then in response to intense media criticism of her Schein relationship and the amalgam rule, Commissioner Hamburg, through the FDA press office, issued a non-responsive statement on August 18.¹⁵ While specifically explaining the Schein stock options that she was still holding until the day before the rule issued (we already knew she had an ethical problem), she appears to be avoiding the more important question – her role in the rulemaking.

Commissioner Hamburg maintains that she is recused from the rulemaking currently, but is likewise 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 we know was two weeks before the rule was announced). She won't provide written proof of her earlier recusal. She won't advise us of the status of the rule when she recused herself – for example, whether it was already in the final form when she recused herself. She will not tell us 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."

If Commissioner Hamburg has done nothing unethical, why does she continue to undermine public confidence in agency decisions by stonewalling legitimate questions about her public work?

(4) Hamburg left Center for Devices Director Daniel Schultz in charge of the amalgam rule without proper oversight despite awareness of corruption

FDA scientists and FDA critics, Margaret Hamburg among them, were troubled by Dr. 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."¹⁶ Having been briefed by a former FDA Commissioner who told her that the Center was "dysfunctional" and "in meltdown," Dr. Hamburg was aware of the trouble at the Center for Devices, telling a reporter back in June that "There obviously have been some problems."¹⁷

Despite this admission, Commissioner Hamburg allowed Dr. Schultz to remain at FDA until a week after the amalgam rule was published, arranging for the Director to end his tenure abruptly on August 11. FDA staff believes 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."¹⁸

Dr. Hamburg's defense that she "took no action" on the amalgam rule, apparently just rubber stamping it along as it proceeded to approval, is meaningless when she knew that under these egregious circumstances all she had to do to produce a rule favoring Henry Schein was "take no action" to stop the pro-industry Dr. Schultz. The amalgam rule needed a strong leader to counter the Center for Device's corruption. However, not only did Commissioner Hamburg fail to provide this leadership due to her own ethical issue, she refused to recuse herself and turn the rule over to Principal Deputy Commissioner Sharfstein soon enough to allow him to intervene effectively before the amalgam rule issued. As a result of Dr. Hamburg's bungled management of her ethical problem, the amalgam rule was written by a staff under pressure to find products safe for industry with insufficient oversight and support from unbiased FDA leaders.

(5) The rule resulted in benefits to the amalgam industry at the expense of consumers

The rule has resulted in at least three benefits to the amalgam industry. As these perks are actually harmful to consumers, they are inexplicable unless industry influence, such as Dr. Hamburg's connection to Henry Schein, is considered.

First, in an apparent effort to keep patients and parents ignorant and thereby boost amalgam sales, FDA refused 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. An overwhelming number of consumers surveyed (92%) believe that they should be informed of their alternatives before fillings are placed, and the majority of consumers (over 77%) say that they would rather pay more for an alternative filling material than have mercury-containing fillings.¹⁹ If FDA had chosen to require disclosure, clearly amalgam sales would have dropped precipitously.

Second, FDA goes so far in its efforts to protect amalgam sales 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,²⁰ 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.*"²¹ 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.²² The agency concedes the truth of the pre-rule advisory, but now buries it deep in the Special Controls in language intended for dental professionals only, making it almost impossible for consumers to find.²³

Third, 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 outrageous statement that the term "silver fillings" merely refers to the color.²⁴ 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.²⁵ 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,²⁶ 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 another example of how industry connections, such as Dr. Hamburg's stock options, tainted the amalgam rule.

These corporate benefits raise the question of partisan motivation. By refusing to disclose the mercury content to consumers, reversing the pro-consumer website of Republican Commissioner Von Eschenbach, and writing industry defenses to consumer lawsuits right into the ruling, the Democrats seem to be signaling to FDA regulatees that their pro-consumerism is mere campaign rhetoric and that they are even more willing than their predecessors to favor corporate interests over child protection and consumer disclosure.

(6) The FDA amalgam rule benefited Henry Schein

Henry Schein's stock value jumped \$2/share the week the amalgam rule was announced (July 28-31).²⁷ Then, the morning after the rule was published, Schein CEO Stanley Bergman boasted during an earnings call with analysts about the work Dr. Hamburg did for Schein as a director (this being months after she left the board) and thanked her for the "insights" she provided "throughout the years."²⁸ For Americans hearing the CEO issue a public thank-you to the Commissioner right after the publication

of a rule that so benefits the company, answers are needed about the relationship between Margaret Hamburg and Henry Schein Inc. if the rulemaking process is going to have even the appearance of integrity.

Conclusion

The consequences of the amalgam rule – children and unborn children willfully and needlessly exposed to the dangers of mercury – are tragic. That such an unbalanced rule could issue while the Commissioner (i) comes into office from the largest amalgam seller, (ii) still holds an interest in that company the month the rule is announced, (iii) refuses to divulge details of her role in the rulemaking, (iv) refuses to state the date of her recusal from the rulemaking, and (v) ratifies the continued participation of a Center for Devices Director whom she has reason to suspect is approving unsafe devices, significantly taints the rule and as such, cries out for investigation.

While Dr. Hamburg deems public ignorance – of both her ethical issues and the toxic content of amalgam – the best policy, we believe the public has a right to know. Since Commissioner Hamburg has repeatedly denied us information to which we have a right, we request that the Inspector General investigate (1) Commissioner Hamburg’s role in the amalgam rulemaking process and (2) the effect of inappropriate industry influence on the rule under the leadership of former Center Director Schultz.

Respectfully submitted,

Charles G. Brown, National Counsel
20 August 2009

¹Class 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.”)

² The pre-rule consumer website advised that “*Dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses.*”

³<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.”)

⁴ <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>

⁵ Final Rule for Dental Amalgam, <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.89) (“[T]he daily potential exposure to mercury vapor originating from dental amalgam is expected to decrease gradually in the absence of the final rule.”)

⁶<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm> (“High levels of mercury vapor exposure are associated with adverse effects in the brain and the kidneys.”)

⁷ The Bank of America and J.P. Morgan reports predicting warnings for women and children are available at http://www.toxicteeth.org/RB_565608.pdf and <http://www.toxicteeth.org/JPMorgam-2008.pdf>

⁸ <http://www.toxicteeth.org/Mercury%20Letter%20to%20FDA-5-2009.pdf>

⁹ http://www.thewealthydentist.com/SurveyResults/16_MercuryAmalgam_Results.htm

¹⁰ As one employee commented in response to the amalgam rule, “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.” Jim Dickinson, *A ‘Shocking’ Decision – Bias Seen in Dental Amalgams Rule*, FDA WEBVIEW, 31 July 2009.

¹¹ Jim Dickinson, *Hamburg Recuses Herself From Dental Mercury Rulemaking*, FDA WEBVIEW, 14 July 2009.

¹² Alicia Mundy, *New FDA Chief Must Divest Several Stock, Fund Holdings*, WALL STREET JOURNAL, 26 May 2009.

¹³ <http://toxicteeth.org/settlement%20agreement.PDF>

¹⁴ “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.”

¹⁵ 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 cancelations resulted in a loss to Dr. Hamburg of over \$200,000.

¹⁶ Alicia Mundy & Jared A. Favole, *FDA Scientists Ask Obama to Restructure Drug Agency*, WALL STREET JOURNAL, 8 January 2009.

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

¹⁸ Jim Dickinson, *A ‘Shocking’ Decision – Bias Seen in Dental Amalgams Rule*, FDA WEBVIEW, 31 July 2009.

¹⁹ <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>

²⁰ *Moms Against Mercury et al. v. Von Eschenbach, et al.*

²¹ The settlement agreement is located at <http://toxicteeth.org/settlement%20agreement.PDF>

²² Originally, FDA had excluded from its post-rule consumer website even universally accepted facts about the effects of mercury on the human body, which resulted in a “Potential Risks” section that did not actually explain any of the risks. After consumer outcry, FDA apparently recognized that this blatant omission went too far. It placed a new statement on its consumer website on August 11: “High levels of mercury vapor exposure are associated with adverse effects in the brain and the kidneys.” FDA's consumer website still contains no reference to the fact that any mercury exposure poses a higher risk to children and the unborn even though the agency acknowledges that the risk is higher because these subpopulations may be more susceptible to mercury's neurotoxic effects.

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

²³ 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.”)

²⁴ <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.”)

²⁵ A Zogby poll indicates that 76% of Americans cannot identify the main component of amalgam. <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>

²⁶ <http://www.toxicteeth.org/Zogby%20Poll--Results%202006.pdf>

²⁷ <http://apps.cnbc.com/view.asp?uid=stocks/charts&symbol=HSIC>

²⁸ Henry Schein CEO Henry Bergman stated during an earnings call with investment analysts:

"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."

Q2 2009 Earnings Call; August 4, 2009, <http://seekingalpha.com/article/153742-henry-schein-inc-q2-2009-earnings-call-transcript?page=-1>