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Working for Mercury-Free Dentistry

Mr. Brian Downey
U.S. Senate Finance Committee
Washington, D.C. – *by hand delivery (with exhibits) and by e-mail (without exhibits)*

Re: **Request Senator Grassley investigate FDA's corrupt mercury amalgam rule**:

Dear Mr. Downey:

FDA's dental amalgam rule – unabashedly against disclosure of amalgam's mercury content to parents and dental patients – is manifestly tainted by Commissioner Margaret Hamburg's surreptitious involvement while she held a financial interest in the nation's top amalgam seller, an interest which she admits required her recusal from the issue. After participating, Commissioner Hamburg orchestrated her staff to deny this fact and cover up her involvement. She recused herself too late for the rule to be changed, then immediately initiated a scheme with Henry Schein, Inc., to undo her recusal – despite ethics rules prohibiting re-entry after recusal – so she could again start regulating (presumably regulating favorably) her million-dollar corporate benefactor. Hamburg then enlisted her hedge fund trader husband – while his fund was trading in Henry Schein stock – to participate in internal FDA deliberations and learn inside information about FDA decision-making.

Hamburg's deputy and alter ego Joshua Sharfstein rubber-stamped the rule, covering up the mercury a warning of neurological harm, and attempting to protect from lawsuits corporations marketing amalgam deceptively as "silver fillings." Hamburg and Sharfstein, both Presidential appointees, have violated the President's promises and directives in multiple ways – sanctioning rather than reducing mercury exposure, per the President's campaign promise; using agency rule-making to block consumer remedies (here, protecting malefactors who market amalgam as silver fillings deception) instead of allowing consumer remedies, per the President's executive order; and making permanent a system of two-tiered dentistry, what an NAACP witness before Congress called "choice for the rich and mercury for the poor."

Despite owning stock options in Schein, signing a contract not to participated, and receiving three written warnings, Commissioner Hamburg participates in rule-making

While on the corporate side of the revolving door, Dr. Margaret Hamburg served on the board of directors for top amalgam seller 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 (Mundy, *New FDA Chief Must Divest Several Stock, Fund Holdings*, WALL STREET JOURNAL, 5/26/09). Hence, she signed an ethics contract banning her from participating in actions affecting Schein while she still owned Schein stock or Schein stock options.
http://www.toxicteeth.org/ethics-agreement.doc

Senator Enzi posed two written questions during the confirmation hearings, one that apprised the nominee of the amalgam rule (the requirement it be completed by July 28) and one asking if the upcoming rule would heed FDA's stark warning to parents and young women (that the mercury could cause neurological harm to children and unborn babies), and posed two written questions. She responded, but oddly, did not mention the conflict of interest – even though she had signed the contract the month before. Exhibit A (attached).

Dr. Hamburg continued to hold onto Schein stock options after becoming Commissioner. Concerned about the million dollars she received from Schein over the years and not knowing whether she had ever lobbied FDA to protect amalgam use, I warned her of the conflict of interest in a letter dated June 1. Getting no answer, I wrote her again four weeks later. *http://toxicteeth.org/FDA_letters_JunJul2009.pdf* Yet (unbeknownst to me) she proceeded to schedule a policy meeting with staff; indeed, she insisted that such a meeting be held. *http://www.toxicteeth.org/scheduling%20briefing.pdf* That staff meeting finally and firmly was scheduled on July 1. The day before the meeting, she wrote her financial advisor to determine he status and worth of her Schein stock; Exh. B (lower half of page) -- suggesting a clear link between her scheduling the meeting to regulate the largest amalgam seller and the impact such rule would have on the stock. That same morning, June 30, the Commissioner received the answer she probably didn't want to hear: She must stay out of all matters where Schein affecting Schein; Exh. B (upper half of page).

Undeterred, the Commissioner proceeded to have the staff meeting, in plain violation of the contract she signed and of the ethics laws. The meeting was quite an important one; its purpose was "to secure feedback from the Office of the Commissioner" and to determine the rule's "next steps." Exh. C.

Hamburg allowed control of the rule to rest with a dentist with outspoken views favoring amalgam, with no neurological expertise, and whose views were decisively rejected, 13 to 7, by two FDA scientific advisory committees in 2006. In the rule, this dentist, Mary Susan Runner, dishonestly omitted the vote of the scientists, wrongly claiming in the rule that her pro-amalgam position was never rejected. At the July 1 policy meeting, Hamburg had the opportunity to learn that Runner's pro-amalgam advocacy dovetailed perfectly with the financial interests of Henry Schein Inc.; since she and her financial advisor discussed her Schein stock the day before the meeting, it is inconceivable she did not link the Schein stock value to the rule, especially since she had been warned not to have the meeting. And indeed, the amalgam rule was fantastic for Henry Schein Inc.; its stock jumped $1.50/share the day the rule's announcement was in the major newspapers.

All Hamburg needed to do to protect Schein's interests after July 1 would be to stay in charge of the rule long enough to make last-minute changes impossible, and to keep Runner instead of real scientists in charge – and that's what Hamburg did.

A week after hosting the policy meeting, Dr. Hamburg's counsel sent me an enigmatic letter that, rather than stating whether the Commissioner was recused, ambiguously claimed she decided to stop participating. The letter left open who was in charge, simply saying I could direct future questions to Dr. Sharfstein. *http://toxicteeth.org/FDA_letters2_Jul2009.pdf* I fired back a letter, asking if she really was recused and who was delegated the power to be in charge. *http://toxicteeth.org/FDA_letters_JunJul2009.pdf* I also went to the press, which got an answer just two weeks before the rule issued – Hamburg recused herself because it was required under the

rules of ethics. Dickinson**,** *Hamburg Recuses Herself From Dental Mercury Rulemaking*, FDA WEBVIEW, 14 July 2009. Hence Hamburg remained in charge of the rule for the first two months of her tenure, participating in the rule-making, then made a midnight exit – too late to scrutinize the work of the FDA staffer in charge, a person with zero expertise in neurology but with close ties to pro-amalgam interest groups.

It now appears that Hamburg never filed a written document recusing herself -- leaving the date and manner of delegation in a gauzy area between her and Sharfstein. And, as noted below, Hamburg never intended that her recusal be anything but temporary.

Commissioner Hamburg attempts to conceal her participation in rule-making

Throughout the summer, Dr. Hamburg's staff, in press statements, responses to the public, and public documents addressing dental amalgam has claimed that the Commissioner "did no work on this issue," "was not involved," "recused herself from this topic," and "has not personally and substantially participated." *http://www.toxicteeth.org/article-with-Strait-press-statement.doc*. In light of the documentation regarding Commissioner Hamburg's policy meeting about dental amalgam and her public proclamations that she is "involved in every aspect of FDA activity," all of those claims now have an utter lack of credibility.

After the cover-up of the July 1 policy meeting failed, Commissioner Hamburg had her staff claim the meeting was her "only exposure to the issue." *http://toxicteeth.org/FDA_letters2_Jul2009.pdf*. Since she and Senator Enzi had a written exchange about the issue in May, and since in that exchange she indicated she had consulted FDA staff on the issue, the claim is patently false.

Commissioner Hamburg works out a *quid quo pro* with Schein, enlisting her hedge-fund trader husband to consummate the bargain so she could again start "regulating" her million-dollar benefactor

As soon as she announced her recusal, Hamburg initiated a scheme with her corporate benefactor Henry Schein to get herself un-recused – even though the ethics rules are clear that once someone is recused, they stay recused. Her husband, Peter Fitzhugh Brown, Executive Vice President of Renaissance Technologies – a major hedge fund which bought and sold $6 million of Schein stock in the second quarter – had recommended that very course of action, before the amalgam rule was even issued. Exh. D.

On July 15, the day after the press announced she was recused, Hamburg secretly wrote the general counsel of Henry Schein Inc., Michael Ettinger, asking if she could dispose of her stock options. The purpose, she said, was to end "constraints on my activities." Exh. E. The only constraints on her activities of owning Schein stock, as the contract she signed in April makes clear, is regulating Schein. Hence her purpose was to regain the ability, immediately, to start regulating her million dollar corporate benefactor – this being two weeks before the amalgam rule was completed. To accomplish this task, she enlisted her husband, who had a conversation with Ettinger on or before July 16. Exh. F. The Schein-Hamburg secret stock agreement moved forward, but – and this is significant – with hedge fund trader Brown continuing as intermediary; Ettinger asked at one point: "You will let Peter know?" Exh. G.

On July 27, Ettinger sent the Commissioner a letter where, if she signed it, would return the stock to Schein. Exh. J (three pages). On the afternoon of July 28, Hamburg asked her husband – not FDA lawyers, not FDA ethics officers, but her hedge-fund trader husband – if she should sign it, Exh. K. He concurred. Exh. L. Thus, on the very afternoon that FDA was announcing its amalgam rule, Hamburg was consummating a deal with Schein, the rule's chief beneficiary. (Did she tip the company? Did she tip her husband?)

Dr. Hamburg, in writing Schein two days later, again made clear that the purpose of the stock deal was so she could more rapidly end her recusal from regulating Schein. Exh. M (middle of page).

Schein general counsel Ettinger's reply on July 30 was to thank Hamburg profusely: "we are indebted to you." Exh. M (top of page). Whether Ettinger meant the "indebtedness" was for a 100% pro-industry amalgam rule that Hamburg had orchestrated, or whether the "indebtedness" was for the promise by a Schein former board member to regain control over regulating Schein hardly matters. Schein is a winner. But so is the Brown-Hamburg couple. Mr. Brown now had quite useful knowledge about a stock that his hedge fund trades actively. And if Mr. Brown profits, well, so does his wife, the Commissioner of the United States Food and Drug Administration.

(Renaissance Technologies must disclose its third quarter stock actions by, I believe, November 15. As stated, the company was quite active in Schein stock in the second quarter.)

Plainly, a quid quo pro had occurred, an exchange between a powerful federal regulator and the one company that she was supposed to stay away from.

The Commissioner grants an interested hedge-fund trader access to, and participation in, FDA deliberations

Faced with the public outcry about her improper behavior, Dr. Hamburg inappropriately brought her hedge-fund trader husband into FDA's inner circle to help craft FDA's strategy to conceal her role in the amalgam rule. Peter Fitzhugh Brown was part of an e-mail round robin which included Principal Deputy Commissioner Sharfstein, the chief press aide, and FDA lawyers. Brown even advised Sharfstein and press official George Strait what to do, and in turn an FDA lawyer provided advice to the entire group, including Brown. Exh. I, Exh. N, Exh. O.

Publicly-held corporations had much at stake in this rule-making (transition costs, liability suits, etc.). It is hard to understate the impact an FDA Commissioner can have on the stock value of drug and device manufacturers and sellers (hence, the reason Schein's CEO was bragging about the Commissioner's ties to his corporation to analysts). Likewise, it is hard to understate the potential use a hedge fund trader can make of inside information about FDA decision-making, especially when, as in this case, he was participating in protecting a rule so beneficial to a company he trades in. Once that information is obtained, a hedge fund trader can disperse it in a way that may not be noticeable or traceable, which is why Commissioner Hamburg absolutely should never have brought him into FDA's inner realm.

The silence and acceptance of this wrongdoing by Principal Deputy Sharfstein, also a Presidential appointee, cries out for an explanation,. silence critics of the rule-making

Most baffling throughout this unfolding scandal has been the acquiescence, at every stage, of Principal Deputy Commissioner Joshua Sharfstein. Entering FDA as a child advocate and with Capitol Hill experience, he rubber-stamped the rule handed him by Hamburg and Runner, *sub silentio* making permanent a system of consumer deception and two-tiered dentistry; he facilitated the cover-up by failing to disclose the method and timing of the delegation of rule-making to him; and he allowed a hedge fund trader access to, and participation in, FDA decision-making on how to address the Schein and amalgam issues, giving Wall Street insiders a heads-up that the American people, and the American investor, were not obtaining.

FDA proposes "end game" to silence critics of the rule-making

As if the ethics concerns were not enough, FDA officials are now threatening constitutional rights in order to silence citizens who speak out against Commissioner Hamburg's actions. In an email sent to Principal Deputy Commissioner Sharfstein (and copied to Commissioner Hamburg and press specialist Mary Long) on August 14, Assistant Commissioner for Public Affairs George Strait suggests that they plan a "communications end game" to silence public criticism. *http://www.toxicteeth.org/endgame-email-from-Strait.doc*

Government employees who maneuver to silence legitimate public outcry over the behavior of government officials are threats to our Constitutional rights. We have attempted to determine if this "end game" remains in place; FDA will not comment.

Commissioner Hamburg's inappropriate behavior results in an abysmal 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. The rule is so callous toward children and so deferential toward amalgam sellers that it actually states that it will reverse a decline in mercury exposure even though FDA acknowledges that mercury exposure can lead to neurological damage, kidney problems, and similarly-severe injuries.

In a gift to the special interests and an act that the rule itself acknowledges will increase mercury exposure to children and unborn babies, Commissioner Hamburg and Deputy Commissioner Sharfstein rescinded this FDA website warning: *"Dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses."* The withdrawal of the warning from the consumer website is not only unconscionable, but it breaches the contract FDA signed with Consumers for Dental Choice, the Connecticut Coalition for Environmental Justice, Oregonians for Life, Moms Against Mercury, and several individuals, where FDA agreed to post this very language as part of the settlement of the lawsuit filed because FDA (in its ongoing cover-up of mercury led by in-house dentist Susan Runner) refused to classify mercury amalgam. On 2 October we put FDA on notice that Hamburg and Sharfstein

had breached this contract, for which we commend former Commissioner Andrew Von Eschenbach for approving.
http://toxicteeth.org/Offer%20FDA%20opportunity%20to%20cure%20breach%20of%20contract.pdf

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. Instead, FDA hands amalgam sellers *carte blanche* authority to market mercury amalgam under the deceptive term "silver fillings" (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).

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. *http://www.toxicteeth.org/JPMorgam-2008.pdf* . It defied the expectations of a bipartisan group of 19 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. The more than 50% of American dentists who have already abandoned this pre-Civil War device in favor of modern alternative filling materials were no doubt stunned.

Commissioner Hamburg's inappropriate behavior results in a rule that subverts the President's mercury policy

During his campaign, President Obama promised to reduce health risks and costs from mercury because "[m]ore than five million women of childbearing age have high levels of toxic mercury in their blood and approximately 630,000 newborns are born every year at risk" and "[t]he 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." This policy is not surprising considering President Obama's strong record of fighting mercury exposure; as a senator, he wrote a law banning the export of mercury products, inserting precatory language about its neurological, reproductive, and environmental harm. However, in its rule-making, FDA recognizes that its rule – by keeping consumers uninformed about the mercury – will increase human exposure to mercury. Hence the rule contradicts the President's policy and appears to willfully retract his promise to reduce mercury in order to advance public health.

This rule makes permanent what an NAACP witness (at a Congressional hearing chaired by Congressman Burton) called "two-tiered dentistry … choice for the rich, mercury for the poor." Over half of US dentists have switched totally to the resin alternative. Left behind, still getting mercury fillings, from a Congressional hearing), so amalgam is now administered mainly to soldiers and sailors (even pregnant ones), prisoners, Indian reservations, Appalachia, ghettos, and barrios. Certainly the President's health care agenda does not envision this kind of elitism in health care.

Investigation requested

Four years ago, upon discovering stock irregularities involving FDA Commissioner Lester Crawford and his wife, the Bush Administration fired, prosecuted, and convicted Dr. Crawford. Crawford's transgressions were infinitesimal compared to Hamburg. Crawford never did a stock exchange *quid quo pro* with a corporate benefactor. Crawford never brought a hedge fund trader into FDA inner circles of FDA decision-making. Crawford never enlisted his entire top staff to deny what is provably true. Crawford never plotted an end-game to those exposing wrongdoing.

We request that you investigate the corrupted amalgam rule and Commissioner Hamburg's and Principal Deputy Commissioner Sharfstein's egregious handling of it

Sincerely,

Charles G. Brown
National Counsel
23 October 2009