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Betreff: Write your Rep. re Hamburg conflict & FDA culture of corruption

(You may post, publish, or circulate, and/or send to your Representative.)

With Schein conflict of interest and mercury amalgam rule, Commissioner Hamburg continues culture of corruption at FDA

We ask that you write and call your Representative in Congress (how-to is below) and ask that he or she get answers from FDA re Commissioner Margaret Hamburg's stock deal with amalgam distributor Henry Schein, Inc. Here are some talking points.

1. Margaret Hamburg served on the Schein board from 2003-2009, and owned \$250,000 to \$500,000 of Schein stock at the time she became Commissioner, according to the *Wall Street Journal*, after which she participated in the amalgam rule-making.
2. The FDA's new amalgam rule has neither contraindications for children and pregnant women (as even Wall Street had predicted), nor the lesser requirement of warnings for children and pregnant women. This is in spite of the fact that FDA concedes that children and the unborn are more susceptible to mercury's neurotoxic effects and that no study indicates that mercury amalgam does not pose these known neurological risks to this subpopulation. Mercury is a substance so toxic it can cause permanent neurological damage to children and kill unborn children. However,
3. As pointed out in the Watson-Burton letter to FDA, signed by 19 Members of Congress, <http://www.toxiceeth.org/Mercury%20Letter%20to%20FDA-5-2009.pdf>, most consumers and parents still don't know that amalgam is mainly mercury, due to its marketing under the deceptive term "silver fillings." FDA wants to keep the mercury unknown, and has gone so far as to justify marketing amalgam as "silver fillings" because of the color. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm> To its extreme discredit, FDA under Commissioner Hamburg actually **pulled off the website a warning** that was prudently posted by Commissioner Von Eschenbach: "*Dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses.*"
4. The only beneficiary of this secretiveness is the amalgam industry, which raises even more concerns – from 2003-2009, Commissioner Margaret Hamburg served on the board of Henry Schein Inc., the largest distributor of dental products (including amalgam). Owning the large amount of stock in a company she would regulate, she was given 90 days to sell it, but the amalgam rule had to be finished within her first 75 days (by July 28). Clearly Commissioner Hamburg had a conflict of interest that should have prevented her from participating in the amalgam rule. Instead, she indicated her intention to work with staff on the rule in response to Senator Enzi's question about amalgam during the confirmation process last May.
6. Certainly Dr. Hamburg was aware that in 2005 Commissioner Lester Crawford was fired, then pleaded guilty to a federal crime, for issues regarding his stock holdings. However, she proceeded to promise the Senate she would clean up FDA while telling Senator Enzi she would also work on a rule where she held a quarter million dollar of stock in the largest seller of that product.
7. After she became Commissioner, Dr. Hamburg failed to recuse herself immediately despite the obvious conflict. Concerned that the Schein connection would prevent a fair rule, Consumers for Dental Choice wrote Dr. Hamburg about her conflict in early June. That first letter was ignored, but after two more letters the FDA Chief Counsel told us that her participation was not "personal and substantial." FDA's culture of corruption is maintained by such loopholes – participating in rule-making to protect your stock value is OK if you participate just a little. Not until July 24,

just four days before the rule issued, did he finally advise the counsel for Consumers for Dental Choice, at this midnight hour, that Dr. Hamburg had finally recused herself due to ethical issues. (The letters to FDA are at http://toxicteeth.org/FDA_letters_JunJul2009.pdf; the Chief Counsel's letters and the *Wall St Journal* article about the Commissioner's stock ownership are at http://toxicteeth.org/FDA_letters2_Jul2009.pdf)

8. Commissioner Hamburg's failure to remove herself from this rule from the start is particularly reprehensible in light of the well-publicized corruption at the Center for Devices and Radiological Health (which was charged with the amalgam rulemaking). Yesterday, Center for Devices Director Dan Schultz (part of the group that has given *carte blanche* to amalgam sales with no disclosure) resigned "by mutual agreement" with Dr. Hamburg, amidst complaints that he pressured staff to approve devices that they did not think were safe in order to benefit industry. FDA staff believe amalgam to be one of these devices; an employee commented thusly off the record to a reporter on 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." (*A 'Shocking' Decision – Bias Seen in Dental Amalgams Rule*, FDA WEBVIEW, 31 July 2009).

9. Considering this situation, Commissioner Hamburg's defense that she "took no action" while overseeing the rule is meaningless. Dan Schultz, was approving devices precipitously, putting unsafe devices on the market. Hamburg said in June she planned to make major changes at that dysfunctional Center. But she conveniently waited until Schultz and his Center for Devices prepared the pro-industry, anti-disclosure amalgam rule before moving Schultz out. So when Hamburg says she took "no action," she had arranged the cards in the deck so she did not need to. Near the end of the process, she could drop the case the lap of Principal Deputy Commissioner Joshua Sharfstein, confident that it was too late for him to overhaul Dan Schultz's pro-amalgam work product.

10. This rule is so pro-Henry Schein and anti-patient that in the fine print it even expresses FDA's concern about a possible decline in mercury exposure if it did not act to protect amalgam: "The daily potential exposure to mercury vapor originating from dental amalgam is expected to decrease gradually in the absence of the final rule." This concern may come as a shock to President Obama, who is negotiating a treaty to phase out all anthropogenic mercury, and who realizes that mercury is so dangerous that he wrote a law, signed by President Bush in 2008, that bans mercury exports.

11. The children of America will be mercury toxic for another generation because FDA Commissioner Hamburg put her corporate benefactor and her stock ahead of them. (Henry Schein, whose stock rose the week the rule issued, was still thanking Dr. Hamburg at a meeting pitching company stock the morning after the rule was published – months after she supposedly cut her ties with it.) The children have no voice.

Folks, please ask your Congressman or Congresswoman to look into this underhanded dealing. To find out who is your Representative and to contact him or her, go to <https://writerep.house.gov/writerep/welcome.shtml>. Phone him or her too: the House of Representative switchboard is 202.224-3121 or 202.225-3121 or look up his or her phone number online at http://clerk.house.gov/member_info/mcapdir.html. (Folks from outside the United States who want FDA to do the right thing, which will certainly accelerate change in your country, could write two champions of the anti-amalgam cause, Representative Diane Watson, Democrat-California, via <http://www.house.gov/watson/zipauth.shtmland>, and Representative Dan Burton, Republican-Indiana, via <http://www.indianadan.com/contact>).

Ask your Representative to write FDA Commissioner Hamburg to get answers to these questions:

(1) When Senator Enzi asked Dr. Hamburg a written question about the amalgam rule, why did

she not then disclose the stock and say she would be disqualified from participating?

(2) Why, when taking office as Commissioner and holding at least \$250,000 of stock (says the *Wall Street Journal*), did she not recuse herself from participating in the rule-making right away?

(3) On what date did Margaret Hamburg recuse herself?

(4) On what date did Margaret Hamburg sell her stock in Henry Schein?

(5) Since Commissioner Lester Crawford was forced out of office in 2005 for insider stock deals, why does Commissioner Hamburg believe this situation is different, and why does she believe she should remain in office?

(6) Why is the amalgam rule so incredibly favorable to Henry Schein, giving it the right to untrammled amalgam sales without even a requirement that patients be told of the mercury in amalgam?

Charlie Brown

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