Consumers for Dental Choice
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Working for Mercury-Free Dentistry

The Honorable Margaret Hamburg, M.D., Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857 (*and via fax 301.443-3100*)

Re: Concerns about mercury amalgam regulation and your Henry Schein board membership

Dear Commissioner Hamburg:

Henry Schein, Inc. – a company on whose board you served for the past five years – is America's #1 distributor of dental products. One of those products is mercury amalgam, a device you are charged with classifying by July 28. FDA says on its website: "Dental amalgam contains mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses."

The Henry Schein company and its chief executive have extremely close ties with mercury amalgam's chief advocate: the American Dental Association. Schein contributes significantly to ADA-controlled organizations, and in return the ADA recently named Schein CEO Stanley M. Bergman an honorary member of the trade group. The ADA's interest in keeping amalgam is financial; it grants amalgam its Seal of Acceptance based on a pay-to-play system and even owns patents on amalgam (now expired). While the patents were in effect, ADA adopted (and still retains) a rule of conduct in its code of ethics directing dentists to stand silent rather than disclose the mercury in amalgam. The ADA campaign to hide the mercury from the American people (which went so far as to distribute brochures that on their cover promote amalgam as "silver fillings") has been tragically successful; a 2006 Zogby poll revealed that 78% of Americans could not identify the amalgam's major component.

Your participation on Henry Schein's Strategic Advisory Committee raises particular concerns. In no endeavor has the dental products industry been as strategically successful as it has been in concealing amalgam's mercury content. The Center for Devices followed suit, failing to even classify amalgam despite the fact that it classified all other filling materials during the *Reagan* administration. In order to camouflage amalgam's toxic component, **mercury**, the Center audaciously proposed a rule in 2002 directing dentists to disclose instead the nutrient **zinc**. In September 2006, however, two FDA Scientific Advisory Committees decisively voted to repudiate the Center's claim that amalgam is safe – and separately voted to condemn the Center's methodology.

To your great credit, you were an activist New York City Health Commissioner. You were visibly condemnatory of mercury, calling any form of mercury exposure "highly poisonous to the brain and kidneys" (news release, June 18, 1991). Your views accord with all science on the subject – and with the regulations and policies adopted by all FDA Centers (except the Center for Devices), which (1) ban mercury in farm animals

and pets, (2) warn against its consumption in fish, and (3) prohibit its use in topical applications and drugs for humans. Considering your knowledge of mercury and the probable obstacles involved in distributing a product widely known as the largest source of mercury exposure in humans (according to both WHO and Health Canada), Henry Schein may well have enlisted your strategic advice on how to sell amalgam.

Forbes magazine claims Henry Schein paid you $282,365 in 2007. We are concerned about this for two reasons. First, although amalgam is no longer needed in dentistry – 50% of dentists have stopped using it entirely, *http://www.thewealthydentist.com/blog/910/amalgam-controversy-is-thriving/* – Henry Schein is the main supplier to institutionalized settings (the military, prisons, and Indian reservations) and "drill, fill, and bill" dental practices. Second, Henry Schein could face massive legal exposure if the FDA's new amalgam rule protects children and pregnant women.

While we are aware that you took steps to divest your interests in Henry Schein and cannot possibly recuse yourself from all matters connected to the company's products, in the interest of ensuring a rule that protects vulnerable consumers from mercury exposure, we would appreciate your consideration of these questions:

1) Was Henry Schein your #1 source of earned income?

2) Were you in any way involved in the mercury amalgam issue at Henry Schein?

3) Did you ever contact FDA, the ADA, or a dental manufacturer about amalgam?

4) Were you involved in keeping amalgam unclassified by FDA or in keeping its mercury content away from consumer knowledge?

Thank you in advance for these assurances.

Sincerely,

Charles G. Brown
National Counsel
9 June 2009

cc -- Joshua Sharfstein, Deputy Commissioner
Michael M. Landa, Acting Chief Counsel
Jeffrey Senger, Associate Chief Counsel

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The Honorable Margaret Hamburg, M.D., Commissioner
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Rockville, MD 20857 *(and via fax 301.443-3100)*

Re: Requesting your response to our concerns about mercury amalgam regulation and your former Henry Schein board membership

Dear Commissioner Hamburg:

As we have received no reply to our letter of June 9, we feel obliged to raise this issue a second time before the July 28 deadline for the amalgam rule. As a consumer group, we have fought for over a decade against industry concealments of amalgam's mercury (for example, the term "silver fillings" is misleading; the material has twice as much mercury as silver), and against industry refusals to advise parents and young women of the mercury exposure from amalgam and the availability of composite resin, an interchangeable alternative. Hence, we are determined to ensure that FDA's amalgam regulation is free from any industry influence.

With your income from Henry Schein, Inc. at $282,000 in 2006 and $249,000 in 2007 (according to *Forbes*), it may well be that the company paid you over a million dollars over the course of your five year tenure on the board. Dental products distributor Henry Schein has, in effect, partnered with dental amalgam manufacturers and the American Dental Association in a long-term deception of the American people. Unfortunately, FDA aided and abetted this deception by
(1) refusing to classify mercury amalgam for 33 years and (2) issuing news releases with the rosy pro-amalgam rhetoric of its industry supporters.

We are concerned about possible conflicts of interest now because we have seen how this effort to extract profits from a primitive 19th-century device was buttressed by "independent" sources, sadly, with the collaboration of federal health regulators:

- First, NIH's dental arm handed Drs. DeRouen and Martin, two University of Washington dental school professors, a multi-million dollar contract to conduct an experiment that involved implanting mercury fillings in Portuguese orphans without providing disclosures of risks, as required under U.S. law. Trials on institutionalized children are forbidden in the U.S. due to the requirement that one person cannot grant consent for whole groups of children. So the experimenters chose Casa Pia, a scandal-plagued Portuguese orphanage and home for troubled and delinquent children. They failed to disclose the risks to either the children or their supervisor according to a ruling of the **Office of Human Research Protections** of HHS. Citing only partial data, DeRouen and Martin proclaimed mercury amalgam to be safe. But their own toxicologist then disclosed additional data revealing that a large percentage of the Casa Pia boys remain mercury toxic – and therefore subject to future health problems, which could also be passed on to their children. That DeRouen and Martin declared amalgam safe after the

experiment was no surprise, because they had already done so before examining the data – at a public hearing in King County in 2002! With the ethics issues swirling in 2006, both refused to testify and defend their work before the FDA Scientific Advisory Committee, the panel that voted 13 to 7 to reject the FDA staff position that amalgam is safe.

- Second, at a hearing in 2002, FDA's Director of the Center for Devices and Radiological Health promised Congress that FDA would table a proposed rule on amalgam while it did an "outside" and "independent" literature review. However, instead of performing a truly independent literature review, dental interests inside FDA's Center for Devices and NIH's dental arm, National Institute for Dental & Craniofacial Research (NIDCR), conducted secret negotiations with LSRO Inc., a Beltway consultant that has close ties to Big Tobacco, handing LSRO a blueprint of the desired result, namely that amalgam is safe. Belatedly realizing that by law they could not simply appoint this consultant with no competitive bidding, FDA and NIDCR appointed as contractor BETAH Associates, a "meetings planning company" that originally had been hired to arrange conferences (get phones, get vans, get rooms, etc.). BETAH, patently unqualified to do a scientific report, appointed LSRO (per agreement with the federal officials) as "subcontractor" to do the work. This subterranean deal was so outrageous that NIH Director Elias Zerhouni, to his credit, appointed the national CPA firm Clifton Gunderson to conduct a full investigation. Clifton Gunderson's report is concluded, but we have been denied access to it despite two FOIA requests.

- Third, the report on amalgam that LSRO finally issued is a landmark in intellectual dishonesty. In order to reach the result outlined in the NIDCR-FDA blueprint, LSRO flipped the contractual research question, which asked for evidence of harm, to proof that amalgam was unsafe. Of course, proof that a product is unsafe contradicts FDA's mission to allow on the market only products proved safe.

In light of these earlier experiences, respectfully, we must again ask you the questions we posed in our previous letter:

1) Was Henry Schein your #1 source of earned income?

2) Were you in any way involved in the mercury amalgam issue at Henry Schein?

3) Did you ever contact FDA, the ADA, or a dental manufacturer about amalgam?

4) Were you involved in keeping amalgam unclassified by FDA or in keeping its mercury content away from consumer knowledge?

Thank you.

Sincerely,

Charles G. Brown
National Counsel
1 July 2009

cc -- Joshua Sharfstein, Deputy Commissioner

Michael M. Landa, Acting Chief Counsel
Jeffrey Senger, Associate Chief Counsel

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Rockville, MD 20857 -- *via fax, 301-827-3054, and regular mail*

Dear Chief Counsel Landa:

Your letter to me dated July 8 takes a step forward, but raises more questions than it answers.

Regarding this "dental amalgam rulemaking," you state that Commissioner Hamburg "has decided not to participate in this rulemaking."

1. "Not participating": By "not participating," do you mean that Dr. Hamburg has recused herself? Or is she still in any way involved in the rulemaking?

2. Time frame: When did Dr. Hamburg decide not to participate? At the time of her written answer to Senator Enzi on this issue, during the confirmation hearings, it was clear that she intended to participate.

3. Actions taken before "not participating": What actions did Dr. Hamburg take on this rule before she decided not to participate? For example, did she sign onto a draft before it went to OMB? Did she suggest changes in the rule?

4. Personnel: Did she approve of the assignment of personnel to this rule? Did she meet with, or exchange e-mails with, staff members who were working on the rule; if so, whom? The importance of the personnel questions cannot be understated; see below.

5. Pending questions from Consumers for Dental Choice: Why won't Dr. Hamburg answer the four questions we posed in our letters of June 9 and July 1? Certainly the public deserves to know that whether she has ever participated in amalgam marketing, in blocking amalgam regulation, or in the failure to disclose amalgam's mercury content.

6. Dr. Sharfstein's role: You state that "[a]ny inquiries concerning this rulemaking should be referred to" Principal Deputy Commissioner Sharfstein. Is Dr.

Sharfstein in charge of this rule-making now? Does the chain of command for purposes of this rule go from Dr. Sharfstein directly to Secretary Sebelius?

As noted above, your vague reply has raised concerns about Dr. Hamburg's influence on the staff involved in this rulemaking. We have been verbally informed that the drafting of the rule has been delegated to two agency principals who for years spearheaded the effort to conceal the mercury, rejected the determination of FDA scientists, and refused to classify amalgam.

One principal, dentist Susan Runner, played a pivotal role in sabotaging FDA's promise to do an "independent review" of the amalgam literature. Runner worked with the chief assistant to the Director of NIDCR to appoint a meetings planning company, patently unqualified to do a scientific report, which in turn subcontracted the review to beltway consultant LSRO, best known for its attempts to protect Big Tobacco's additives. LSRO, handed a blueprint in advance by the Runner team and given an unbid contract through the back door, had to alter the questions called for in the contract in order to exonerate amalgam, just as it exonerates tobacco additives.

The other principal, we are informed, is veterinary scientist Norris Alderson, who privately advised anti-amalgam scientists that he was furious that his grandchildren got mercury fillings while he publicly is a stalwart defender implanting them in low-income Americans. Alderson was the FDA staffer who orchestrated the effort to persuade two FDA Scientific Advisory Committees in September 2006 to vote that amalgam is "safe," but the scientists voted against Alderson, 13 to 7. Undeterred, the next year, Alderson testified before Congress that, in effect, the scientists are wrong and he is right. While endorsing mercury implanted an inch from a child's brain, Dr. Alderson takes the puzzling position of opposition to mercury use in animals: the standard at the Center for Veterinary Medicine is no mercury in any products given to farm animals or pets.

We urge the Commissioner to put her answers to the above questions on the public record. As a public official who held a quite high-paying position with the nation's #1 amalgam distributor, Henry Schein, Dr. Hamburg needs to explain the role she may have played in the amalgam issue, her role in the amalgam rule before deciding not to participate, and what role she plays currently in light of the indefiniteness of the term "not participating."

Should these issues not be addressed now, and the FDA rule is appealed, a failure to put these issues on the public record could result in a Court of Appeals returning the issue to FDA for such fact-finding.

Sincerely,

Charles G. Brown
National Counsel
9 July 2009

cc--Commissioner Hamburg, Deputy Commissioner Sharfstein, Deputy Chief Counsel Senger