



Office of the Chief Counsel
Food and Drug Administration
5800 Fishers Lane, GCF-1
Rockville, MD 20857

July 24, 2009

SENT VIA FAX AND
REGULAR MAIL

Charles G. Brown
National Counsel
Consumer for Dental Choice
316 F Street, N.E., Suite 210
Washington, D.C. 20002

Dear Mr. Brown:

We have received your July 9 letter concerning my July 8 letter to you. In the short period since her appointment as Commissioner of Food and Drugs, Margaret A. Hamburg, M.D., has not personally and substantially participated, within the meaning of the Standards of Ethical Conduct for Employees of the Executive Branch (the "Standards"), in the dental amalgam rulemaking.

FDA sent a draft of the final rule to the Department of Health and Human Services (HHS) after Dr. Hamburg became Commissioner, but she did not take any action with respect to it; Dr. Hamburg did not take any action with respect to the draft before it went from HHS to the Office of Management and Budget (OMB); Dr. Hamburg has not taken any action with respect to the draft since it has been at OMB; and Dr. Hamburg will not personally and substantially participate, within the meaning of the Standards, in the dental amalgam rulemaking. In short, Dr. Hamburg has recused herself from the rulemaking. Under the circumstances, we do not believe that the additional questions you posed in your June 9, July 1, and July 9 letters are material. Joshua M. Sharfstein, M.D., Principal Deputy Commissioner, is overseeing the dental amalgam rulemaking, and any inquiries concerning it should be directed to him.

We have also received your July 21, 2009, request for a meeting with Dr. Sharfstein and myself or Deputy Chief Counsel Senger this week. We appreciate your willingness to avoid litigation by meeting with us to discuss the rule, but the time period for receiving comments has closed, and we do not think it is advisable to meet with you at this time.

Sincerely,

Michael M. Landa
Acting Chief Counsel
Food and Drug Administration

cc: Joshua M. Sharfstein, M.D.
Jeffrey M. Senger



Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

July 8, 2009

SENT VIA FAX AND
REGULAR MAIL

Charles G. Brown
National Counsel
Consumers for Dental Choice
316 F Street, N.E., Suite 210
Washington, D.C. 20002

Dear Mr. Brown:

Commissioner of Food and Drugs Margaret A. Hamburg, M.D. has asked me to respond to your letters dated June 9 and July 1, 2009, concerning the dental amalgam rulemaking. She has decided not to participate in this rulemaking. Any inquiries concerning this rulemaking should be referred to Joshua M. Sharfstein, M.D., Principal Deputy Commissioner.

Sincerely,

Michael M. Landa
Acting Chief Counsel
Food and Drug Administration

cc: Dr. Hamburg
Dr. Sharfstein
Mr. Senger



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THE WALL STREET JOURNAL.

WSJ.com

MAY 26, 2009, 9:27 AM ET

FDA's Hamburg, Husband Have Health-Related Wealth

Margaret Hamburg will be making about \$150,000 a year as the FDA's new top dog. That may seem like small change compared with her income of at least \$10 million last year, most of it from her husband's role as a hedge-fund executive, WSJ reports from financial-disclosure forms.

The couple's income last year came from stocks, money-market accounts, trusts and funds, including several affiliated with hedge-fund sponsor Renaissance Technologies, where Hamburg's husband, Peter Fitzhugh Brown, works. The couple controls assets valued at between \$21 million and \$40 million, the disclosure forms say.

They have to divest themselves of several hedge-fund holdings. Plus, Brown has already sold his stock in Abbott Laboratories as well as shares in Johnson & Johnson, Merck and pharmacy-benefits manager Medco Health Solutions, which he inherited from his father.

Hamburg is also forfeiting stock and options from Henry Schein, a company that distributes medical and dental supplies, including vaccines, and on whose board Hamburg sat for five years. She will forfeit \$100,000 to \$250,000 in restricted stock and more than 11,000 unvested stock options, all of which have a strike price above the market value of Schein's shares. She will also have to sell vested stock, valued between \$250,000 and \$500,000.

She's not the first health-care official in the Obama administration who has to break some ties with industry. Nancy-Ann DeParle, who heads Obama's new health-reform office, had to step down from the boards of health-IT company Cerner, medical-device maker Boston Scientific and Medco.

Photo: Associated Press



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