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Charles G. Brown: FDA, mercury not affected by Obama's 'change'

CHARLESTON, W.Va. -- A target of consumer wrath for kowtowing to industry for the past eight years, the Food and Drug Administration was supposed to be different in the Obama era. But so far, the agency remains impervious to Obama's promised "change." Indeed, missteps of the new president's two FDA appointees - Commissioner Margaret Hamburg and Principal Deputy Commissioner Joshua Sharfstein - deviate so far from the president's vision that they threaten his health reform overhaul. After all, if the administration can't reform an existing agency, should it be handed a plethora of new responsibilities?

President Obama came into office promising to improve U.S. health care. Having fought throughout his career to protect children worldwide from mercury exposure, as a candidate he promised to reduce mercury's health risks. Obama explained that "exposure to mercury leads to serious developmental problems in children. The EPA estimates that every year, more than one in six children could be at risk for developmental disorders." Acknowledging that government coziness with industry could inhibit such goals, the president promised to halt the revolving door that permits officials to oscillate between regulatee and regulator.

Curiously, FDA's new commissioner, Margaret Hamburg, slipped into office through that revolving door. Wise to the world of Washington, dental products distributor Henry Schein Inc. and CEO Stanley Bergman had brought in Hamburg, a rising star from the party out of power, and paid her lavishly (a quarter million dollars per year) for the light work of sitting on the firm's board of directors. When Democrats returned to power, Hamburg ascended to FDA commissioner - the regulator of virtually every product Schein sells.

Hamburg continued to hold Schein stock options after becoming commissioner. Consistent with Obama ethical requirements, she signed a contract limiting her participation in actions affecting Schein while she retained this financial interest. Then came her first test: a rule to determine warnings for amalgam fillings, products that contain 50 percent mercury but are deceptively marketed to the public as "silver fillings." While this pre-Civil War material increasingly is being abandoned by modern dentists who favor resin, patients in institutional settings, including our military's pregnant soldiers and sailors, are still subjected to them. America's no. 1 seller of mercury amalgam is - Henry Schein Inc.

Skirting the contract she signed, Hamburg worked on the amalgam rule. After her participation, she admitted that she had to recuse herself from the amalgam issue "based on the requirements of federal ethics laws and the standard of ethical conduct" - but by then the rule was a fait accompli.

And what a rule it was - for her benefactor, Henry Schein Inc. The rule allows amalgam to be sold without disclosing to consumers that it contains mercury. FDA even pulled from its consumer Web site a warning that amalgam could cause neurological harm to children and fetuses, burying it on a Web page entitled "Guidance for Industry and FDA Staff" - a place no parent will look.

After the rule was announced, Schein stock jumped \$1.50 per share. Immediately, Commissioner Hamburg assured Schein's general counsel that her "friendships" at Schein

"will outlast the period of my recusal!" In response, Schein's general counsel thanked the commissioner for her work at FDA: "We are indebted to you for your service to our country."

Just when the public was starting to wonder why a corporation would be indebted to its regulator, Schein CEO Stanley Bergman filled us in: During an earnings call to pitch his stock to analysts on the day the amalgam rule was published - and months after Hamburg left the Schein board - CEO Bergman thanked the commissioner for the "insight" she gave the company "throughout the years."

Grassroots protests against this "Henry Schein amalgam rule" exploded. "No final rule in FDA's modern history, or perhaps ever, has attracted this kind of organized opposition," according to the trade publication FDA Webview. Many Americans contacted FDA Principal Deputy Commissioner Sharfstein - ostensibly in charge of the rule now that Hamburg is recused - to recount mercury toxicity suffered by them or their children, to demand their right to proper consumer labeling, and to point out the rule's scientific flaws.

Showing contempt for free speech rights of the First Amendment, FDA's press chief proposed that the agency develop an "end game" to silence its critics. If this end game against consumers succeeds, how much further will corporate control at FDA extend? Does Hamburg, for example, plan to retract mercury warnings on fish too, as a sop to the tuna industry?

While Obama's FDA under Hamburg and Sharfstein defend a 19th-century mercury product, the rest of the world took another step forward this week in Geneva. The World Health Organization committed to a worldwide "phase down" of amalgam. So now we have the specter of an internationalist president pledging to reduce all mercury, the world's leading health body supporting the reduction of amalgam in particular - and the FDA granting carte blanche to Schein and other mercury sellers to market amalgam to American families without even disclosing that it's mainly mercury, not mainly silver.

President Obama needs appointees who adhere to his high ethical standards and work to fulfill his campaign promises, including protecting the public from unnecessary mercury exposure. If the administration feels it is too busy pushing for universal health-care coverage to keep its own house in order, it may fail at both.

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