

# Obama's New Safety Cops

*After years of lax standards, the Food and Drug Administration is getting tough.*

By **Lester Feder** | Newsweek

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On July 31, 12 federal agents raided a facility in the suburbs of Salt Lake City, seizing \$2.7 million dollars worth of finished product and numerous 55-gallon barrels of raw materials. These were not narcotics officers taking down a meth lab, however. The raid was led by the Food and Drug Administration, and they were after skin-care products.

Actually, it was hand sanitizer manufactured by Clarcon Biological Chemical Laboratory Inc., including the brands CitruShield Barrier Lotion and Mom Nature Vastly Superior Sanitizer for Hands. In June, Clarcon voluntarily recalled several of its brands when the FDA discovered that they included "extremely high" levels of bacteria that could cause serious infections that might require "medical or surgical attention." But Clarcon refused to destroy the products after the recall, so the FDA sent in U.S. Marshals to ensure that the recalled sanitizer didn't find its way back onto the market. (Clarcon did not return messages seeking comment.)

Then, on Aug. 7, the FDA sent U.S. Marshals out yet again, this time to seize tuna-salad sandwiches manufactured by Southern Belle Sandwich Co. of Baton Rouge, La., whose Web site describes the company as a family-owned business that supplies convenience stores along the Gulf Coast. (Southern Belle also did not respond to a request for comment.) According to the agency's press release, "Recent FDA inspections found evidence of widespread and active rodent and insect infestation, filthy conditions, and poor employee practices, such as allowing food-processing utensils to lie on the floor near live insects."

The FDA only made eight such raids in all of fiscal year 2008, so executing two within one week is something of an enforcement bonanza. Under the previous administration, FDA enforcement actions of all kinds declined by roughly 50 percent, even though the number of problems identified by field inspectors remained steady, according to [a report by the Democratic staff of the House Government Reform Committee](#). To underscore just how serious the FDA is about cracking down on offenders, President Obama's new FDA commissioner, Dr. Margaret Hamburg, [made a speech](#) last week putting manufacturers on notice.

"That ... is a stronger speech on the need for enforcement than I've ever heard from an FDA commissioner," says Dr. Sidney Wolfe, acting president of the consumer watchdog group Public Citizen. Michael Druckman, who spent seven years in the FDA's Office of Chief Counsel under President George W. Bush, similarly remarked he could not recall a commissioner ever devoting an entire speech to enforcement.

It may be more alarming than reassuring to learn that Hamburg's speech was so remarkable to veteran FDA observers. Though she laid out some procedural changes to streamline enforcement, the core message of her speech was that, "a strong FDA enforces the law" by regularly inspecting food and drug manufacturers and taking swift and visible action when violators endanger the public health. One would like to think this has always been the standard operating procedure for the country's top consumer safety agency, not a radical new idea from a commissioner just confirmed in May.

But, Hamburg's pronouncement is "a radical notion," compared to past FDA actions, says Rep. Rosa DeLauro, Democrat of Connecticut and chair of the House Agriculture-FDA Appropriations Subcommittee, "In the past eight years ... regulation and oversight over industry was not a mission that [the FDA leadership] wanted to carry out. Quite frankly, with the prior [Republican] majority in the House, the Congress abdicated responsibility of its oversight function." Instead of reining in corporate malfeasance, she says the FDA was essentially "handmaidens of the industry—whatever industry wanted to do, they facilitated."

That may partly explain big safety lapses in the past. Public confidence in the FDA was shaken in the last years of the Bush administration by several high-profile incidents: dangerous side effects of Vioxx discovered after it had become a blockbuster drug, contaminated Heparin imported from China that killed more than 80 people, and bacterial outbreaks in foods ranging from spinach to peanut butter. Constantly changing leadership also took a toll—the longest-serving of President George W. Bush's three commissioners served for just over two years, and the agency was in the hands of temporary acting commissioners for most of the Bush administration.

Dr. Mark McClellan, who served as Bush's first FDA commissioner, agrees that the agency has not fulfilled its mandate, though he points to some victories during his tenure, 2002-04, including getting the supplement ephedra off the market. And McClellan himself wasn't appointed until two years into Bush's term. But McClellan says insufficient funding, not inadequate leadership, has been the agency's chief problem, and the FDA has been underfunded since the Clinton administration. "The agency did not have the resources to do enforcement as well as other things," he says. "The agency's personnel support has held steady over 20 years despite having far more products to regulate."

More than an estimated 25 percent of consumer spending in the United States goes to products regulated by the agency, yet it received appropriations for 2009 of only \$2.04 billion—less than the operating budget of a single school district in the Washington suburbs. (The agency is also partly funded by fees paid by medical companies applying for approval of new drugs, which added an additional \$600 million to its budget that year.) With this limited funding, the agency is tasked with approving medical devices and drugs for both people and animals, monitoring the food supply, and regulating cosmetics. This summer, Congress gave the agency new responsibility to regulate tobacco products—a task that will be financed with fees paid by manufacturers. And there is a bill making its way through Congress to enhance FDA's oversight of food safety, which the

Congressional Budget Office has estimated will cost the agency an additional \$2.2 billion over five years. While the FDA's mandate has expanded and the market has become infinitely more complex, the number of inspections has fallen to under 10,000 per year from a high of 35,000 in 1978, according to the Alliance for a Stronger FDA.

DeLauro says that a leadership that budgeted poorly, disregarded science, and got too cozy with the industries it regulates meant that increasing the FDA's budget would have been "throwing good money after bad" when the Republicans were in control of Washington. But since gaining oversight power as chair of the subcommittee in 2007, she has helped increase the agency's budget almost 40 percent, and President Obama's 2010 budget requests an additional 19 percent budget increase over last year, to \$3.2 billion. The agency is in the midst of a three-year plan to raise the number of inspectors from 1,200 to 1,700 by 2010.

But even with such increased resources, Commissioner Hamburg says, finding a way to regulate globalized commerce requires more than increased inspection: "We have a huge challenge in terms of the number of producers of food products and medical products in this country and around the globe, and our ability to provide regular inspections and monitor the safety of the supply chain." Her road ahead requires not only rehabilitating a battered agency, but coming up with new strategies for protecting consumers in a world in which it is virtually impossible to send inspectors everywhere we might like them to be.