

## New FDA chiefs stress science, better food safety

May 26 2009, By LAURAN NEERGAARD , AP Medical Writer

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(AP) -- The huge salmonella outbreak from peanut butter represented a failure of the Food and Drug Administration, that agency's new chiefs declared Tuesday - one they hope to fix.

Expect a "modern food-safety system focused on prevention of contamination," FDA Commissioner Margaret Hamburg and her deputy, Joshua Sharfstein, wrote in *The [New England Journal of Medicine](#)*.

Even its defenders acknowledge the FDA - the nation's chief consumer protection agency - is struggling, given increasing responsibilities overseeing ever-more-complex health industries, but not a budget sufficient to do the job. An independent review in 2007 concluded lives were at risk, and morale plummeted as the agency's own scientists charged their safety concerns were dismissed by leaders too cozy with industry.

Hamburg, who was just sworn in on Friday, and Sharfstein have pledged to restore the FDA's credibility. The two physicians introduced themselves to the country's doctors Tuesday in an article published online by the respected medical journal - and they didn't underestimate the work ahead.

One priority: Working with the Agriculture Department to improve food safety, following some high-profile crises including the [peanut butter](#) outbreak earlier this year that sickened nearly 700 people and is blamed for at least nine deaths. Peanut Corp. of America is under [criminal](#)

[investigation](#) for allegedly shipping peanut butter and another ingredient used in thousands of other products that it knew to be tainted.

That outbreak "represented far more than a [sanitation](#) problem at one troubled facility. It reflected a failure of the FDA and its regulatory partners to identify risk and to establish and enforce basic preventive controls," the duo wrote. "And it exposed the failures of scores of [food manufacturers](#) to adequately monitor the safety of ingredients purchased from this facility."

The FDA's success shouldn't be judged by how many factories it inspects or drugs it approves, but in its overall work to improve public health, the pair wrote. For example, FDA scientists are working behind the scenes to grow the new swine-flu virus and make the ingredients necessary to test if vaccines against it are potent enough, and eventually will oversee vaccine production quality.

"The agency's success will be determined by the nation's access to a safe and effective vaccine," the pair wrote.

And while "the FDA must make difficult decisions in the absence of ideal information," they acknowledged that recent controversies were "opening the door to legitimate questions from the media, the public and Congress about whether the public interest is being served."

To help get back on track, the new bosses promised "a culture that encourages scientific exchange" and to better explain the science behind their decisions to the public.

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