

Obama expected to bolster FDA oversight of imports



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WASHINGTON – The Food and Drug Administration, bedeviled by a salmonella outbreak and tainted medicine from China, is likely to monitor imports and fresh produce more closely under an Obama administration.

With President Bush no longer a roadblock, health officials also can expect new powers to control tobacco, from cigarettes to the recently introduced smokeless products called snus.

President-elect Obama, a former smoker struggling to avoid relapse, is a sponsor of legislation giving the FDA authority to control, but not ban, tobacco and nicotine.

Long seen as the government's premier consumer protection agency, the FDA stumbled under Bush. Recurring drug and food safety lapses came against a backdrop of shrinking budgets and long periods without a permanent leader. In Congress, a senior Republican complained the FDA had gotten too cozy with industry.

Obama is being urged to move quickly to appoint an FDA commissioner. Already more than a half-dozen names are in circulation: outside critics such as Cleveland Clinic cardiologist Dr. Steven Nissen; insiders such as Susan Wood, a former director of the FDA's women's health office; and public health advocates such as Dr. Joshua Sharfstein, Baltimore's health chief.

Food safety will be a priority for Obama's FDA. "He thinks this is a fundamental role of government to ensure that people's food is safe and he has been concerned that we are not in a position to ensure that," said Neera Tanden, a senior campaign adviser.

Obama will be working with a Democratic-led Congress, including lawmakers who have written legislation to bolster import inspections.

Only a fraction of imported food is inspected now. Foreign drug manufacturing plants can go years without an FDA visit. Democrats had considered fees on industry to pay for more FDA inspectors, but could not persuade the Bush administration to go along. They expect Obama to be receptive.

Tanden said Obama is open to the idea of requiring a tracing system for fresh produce. That became an issue during this summer's salmonella outbreak, after the FDA spent weeks hunting for tainted tomatoes only to find the culprit might have been hot peppers.

"An Obama administration would swing the pendulum back more to protection of public health," said William Hubbard, a retired FDA official who held top posts. "This bodes well for greater regulation in the food safety area, on imports, and on drug safety."

Under the tobacco proposal, the agency would be able to order changes in tobacco products to make them less toxic and addictive, but could not ban tobacco or nicotine. The bill passed the House and Senate with bipartisan support, but a veto threat from Bush kept it from getting out of Congress.

Aides to Sen. Edward M. Kennedy, D-Mass., co-author of the tobacco bill, say there is strong interest in getting the legislation passed soon after the new Congress convenes in January. Obama is a co-sponsor.

The FDA could receive new powers from an Obama administration in the field of biologic drugs. These medications are not made from chemicals but from living cells, and represent the cutting edge of medical treatment for many intractable diseases.

Industry officials expect the Obama administration to work with Congress to create a legal framework for the FDA to review and approve generic versions of biologic drugs. Brand name biologics are very expensive, easily costing \$1,000 a month or more.

On the Net:

Food and Drug Administration: <http://www.fda.gov/>