Safety can't wait

by the St. Louis Post-Dispatch

Politicians long ago moved from talking about downsizing the federal government to doing something about it. We're starting to see the awful consequences.

A federal watchdog agency said this week that the U.S. Food and Drug Administration is so poor and short-staffed that it is unable to conduct the safety inspections of all the domestic and foreign plants over which it has responsibility. The agency regulates drugs, medical devices, some food products and finished ingredients used to manufacture drugs in this country.

The Government Accountability Office reported that at its current staffing levels, the FDA would need 13 years to inspect every foreign drug plant that sends products into this country; 27 years to inspect all foreign medical device makers; and 1,900 years to check every foreign food processor.

The American people depend on the FDA to protect them from unsafe drugs and impure food. But that protection has become increasingly elusive. Since 1994, the year that former House Speaker Newt Gingrich led the so-called Republican Revolution, the FDA has lost 1,311 employees. Adjusted for inflation, its budget is down by nearly $300 million over those 14 years.

As that was happening, imports of food, medicine and medical devices from overseas soared, dramatically increasing the need for this essential government service. Yet today's FDA computer databases are so dysfunctional that the agency cannot even say with certainty how many foreign plants now send such products into the United States, the GAO reported. And its inspection record is poor even with the plants it knows about.

American consumers cannot count on backup safety regulation taking place overseas. China, for example, has been at the center of a series of massive international recalls and alerts in recent years involving unsafe or adulterated drugs. Its regulatory system is so inadequate that last year, the head of China's drug safety office was executed for corruption. Yet during the five years between 2002 and 2007, the FDA conducted just 88 inspections at the 714 Chinese drug-manufacturing plants approved to ship products to the United States.

The FDA conducts no unannounced overseas inspections. Nor can it rely on independent translators for its inspectors; the inspectors depend, instead, on English-speaking employees of the very plants they're inspecting.

Although site visits to Chinese drug plants have been rare, the FDA has inspected plants regularly in more heavily regulated European countries such as Germany, Switzerland, Ireland and the United Kingdom. And

last week, the agency announced plans to station inspectors at U.S. embassies and consulates in developing countries to increase the number of inspections performed there.

But the GAO report found that the FDA is so short-handed and desperate for funds that it can't even inspect U.S. medical device makers as often as required by law. Meanwhile, Congress has added inspection responsibilities to the FDA's mandate - without providing it with the money required to fulfill its new duties.

The spate of defective and dangerous products dominating the news last year prompted President George W. Bush to form an import safety working group. But the panel has been told that any reforms would have to be made within existing budgets levels.

Americans rightly expect protection from dangerous and adulterated products. It takes money to deliver that public service, and it is money that most of us would regard as well spent. It cannot be done with shrunken agency staffs and starved agency budgets.

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