Latest Report Blasts FDA Bungling Drug Safety Tracking--Waste & 4-year Delay

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A front page report in The Wall Street Journal states:
"The Food and Drug Administration has bungled its effort to build a new system for detecting the side effects of medicines after they go on the market, delaying its implementation by at least four years, according to a report commissioned by the agency itself."

The report (dated November, 2006) delivers the ultimate insult to FDA administrators whose incompetence or perhaps a deliberate effort to stall drug tracking for hazardous effects, poses a serious danger to public health. The report notes that safety officers were deprived of "the basic tools they need to perform their jobs, e.g. a computing system that meets their requirements." They continue to rely on FDA's existing "dysfunctional" computing system hampering their ability to detect safety hazards.

The report notes that the FDA has been fiddling since 2003 on upgrading its AERS (adverse event reporting system). Agency administrators at the
Office of Information Technology rejected a recommendation in 2004 that the agency buy an off-the shelf software program that would have entailed a one-time cost of $4.5 million and would have been operative by 2005.

Instead, FDA administrators "mishandled the initiative through bureaucratic infighting, flawed planning and duplicative work performed by outside contractors." The report estimates that agency administrators wasted $25 million on a computer system that won't be functional before 2009.
"Echoing other recent outside examinations of the FDA, the Breckenridge analysis says the 'root cause' of the problems can be found in the culture of the agency's drug regulators." The report blames a "lack of effective leadership and management."

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THE WALL STREET JOURNAL
Report Blasts FDA's System To Track Drugs
Consultant Says Mission
Is Hobbled by Missteps;
Agency Disputes Claims
By ANNA WILDE MATHEWS
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The Food and Drug Administration has bungled its effort to build a new system for detecting the side effects of medicines after they go on the market, delaying its implementation by at least four years, according to a report commissioned by the agency itself.
As a result, the agency must continue to rely on its existing "dysfunctional" computer system as a primary tool for tracking the safety of medications sold in the U.S., according to the November 2006 report, which hasn't been made public.
The situation is "frustrating and undermining...the post-marketing drug safety work" of its staff "because they lack some of the basic tools they need to perform their jobs, e.g. a computing system that meets their requirements," says the report. It was prepared by the Breckenridge Institute, a research and consulting firm in Breckenridge, Colo.

The FDA's drug-tracking system, called the Adverse Event Reporting System, consists of a database and other software and hardware that amass and help sift reports of potential side effects that have been filed by drug makers, doctors and others. The data are the FDA's main way to detect drug-related hazards, and can lead to changes in label warnings or even withdrawals of drugs from the market.
But, the report says, FDA safety experts waste time -- an average of 45 minutes per day -- dealing with the inefficiencies and snags caused by the current software. The Adverse Event Reporting System is overwhelmed by the growing volume of adverse-event reports, which exceeds 400,000 a year, the report says.

The FDA track record on drug safety has faced harsh scrutiny in the wake of major problems, including the 2004 withdrawal of the painkiller Vioxx after it was linked to cardiovascular problems. Such incidents underscore the importance of monitoring drugs after they go on the market, where some end up being prescribed to millions of patients. In clinical trials conducted before FDA approval, drugs typically are tested on thousands of people at most -- not enough to turn up every potential danger.

The FDA has sought to upgrade the technology used in its safety-tracking program for years. But efforts that date back at least to 2003 haven't produced the planned successor to the Adverse Event Reporting System, dubbed AERS II. Instead, the Breckenridge report says a new system isn't likely to be up and running until 2009 at the earliest, and that the FDA has wasted an estimated $25 million on its efforts. The report argues that the FDA could have had a new Adverse Event Reporting System working in 2005 if it had simply relied on off-the-shelf software.

A document prepared by FDA officials in response to the report, which is marked as a draft, said it is "riddled with editorial conclusions based on misleading or incorrect facts." Douglas Throckmorton, deputy director of the agency's drug center, said the current Adverse Event Reporting System "is a system that is working" despite "exploding" amounts of data. "Is it the best it can be? Of course not," he said. The FDA wants to develop a replacement "as quickly as anyone else does, but we want it to be done right."

Echoing other recent outside examinations of the FDA, the Breckenridge analysts say the "root cause" of the problems can be found in the culture of the agency's drug regulators. More specifically, the report largely blames a "lack of effective leadership and management" by the center's Office of Information Technology, which it says mishandled the initiative through bureaucratic infighting, flawed planning and duplicative work performed by outside contractors.

Mark Bodnarczuk, executive director of the Breckenridge Institute, said he stands by the contents of the document. After it was completed, the FDA asked him to delete much of it, he said: "What they asked me to do was gut the report, and I refused to do it." The FDA's Dr. Throckmorton said he believes Breckenridge was asked by FDA to extend its work, at no cost, which would have "given us an opportunity to talk about those misunderstandings, those inaccuracies."

FDA contracting practices, as well as the agency's handling of drug safety, are already the focus of congressional investigations. Senate Finance Committee Chairman Max Baucus, a Montana Democrat, and ranking Republican Charles Grassley of Iowa have sent a letter to the FDA about the computer-system issue. Mr. Baucus said the report raises "troubling questions," and Mr. Grassley said the report is evidence of a "broken-down process" at the agency. In the House Energy and Commerce Committee, Democrats John Dingell and Bart Stupak, both of Michigan, are also examining FDA contracting.

According to the Breckenridge report, the agency by June 2004 was considering moving forward with a package of off-the-shelf software. That potentially could have allowed AERS II to be up and running in 2005, at a one-time cost that had been projected at about $4.5 million, according to the report.

But, the report says, an official in the drug center's information-technology office in June 2004 advocated a different approach: a system that could track adverse events from all products regulated by the agency, such as medical devices, rather than just drugs. Later, the report says, the information-technology office commissioned further analysis, including assessments of what a new adverse-event tracking system would need, with some work done by contractors.

The need for the new analysis was questioned by officials who worked in drug safety at the FDA, who argued they "could not wait two more years...to repeat the process they had just completed," according to the report. That analysis was nonetheless carried out. The Breckenridge report contends it "did not add any value" and helped delay a new system.

The FDA's Dr. Throckmorton said the agency is already moving to address issues related to its safety culture. Yesterday, the agency formally unveiled its plan to publicize emerging safety issues on its Web site.

As for the delay of AERS II, Dr. Throckmorton said, "based on what I know, those timelines were caused by the complexity of it, the need to get it right, and the need to consider integration into a larger system," rather than by strategic or management errors. He added that the integrated approach was endorsed at high levels of the FDA. Generally, analyzing goals is "absolutely essential" in developing a good system, he said, adding that the FDA "considered" the earlier off-the-shelf software package and "rejected it."

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