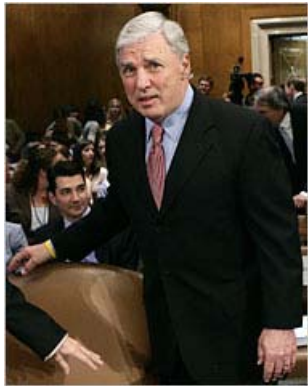




F.D.A. Widens Safety Reviews on New Drugs

By GARDINER HARRIS
Published: January 31, 2007

The [Food and Drug Administration](#) announced changes yesterday that were intended to ensure that marketed drugs are as safe as advertised, including the first effort to do a comprehensive assessment of the safety of drugs 18 months after introduction.



Doug Mills/The New York Times

Dr. Andrew C. von Eschenbach, commissioner of the Food and Drug Administration, in August.

The agency also announced the creation of an advisory panel to improve the way it announces safety worries and a collaboration with the Veterans Health Administration to track how real patients fare after taking drugs.

The F.D.A. plan is the latest effort to fix the agency after a series of missteps. In September 2004, Merck withdrew its arthritis drug, Vioxx, after a study showed that it doubled the risks of heart attack. About the same time, the agency announced that antidepressants cause some teenagers to think more about suicide.

In both cases, the agency took years to acknowledge risks to millions of patients that had been apparent to some researchers.

“We don’t see this as the only answer,” said Dr. Andrew C. von Eschenbach, the F.D.A. commissioner, at a news conference in Washington announcing the initiatives. “It’s merely a step as we continue a process of improvement that will be ongoing.”

Senator [Christopher J. Dodd](#), Democrat of Connecticut, said in a written statement that far greater changes were needed at the agency. Mr. Dodd promised to introduce two bills today that would reorganize the F.D.A. and require drug makers to disclose the results of all clinical trials involving humans. The bills’ co-author, Senator [Charles E. Grassley](#), Republican of Iowa, has called the agency far too “cozy” with drug makers.

In many cases, the date that the agency will begin the efforts announced yesterday is uncertain. For instance, Dr. Steven Galson, director of the agency’s drug center, said at the news conference that the pilot program to assess systematically a drug’s safety 18 months after its introduction would probably take about a year to put into place — with the assessment due 18 months after that.

“We’re just organizing that process to get started,” Dr. Galson said.

In a scathing assessment released in September, the [Institute of Medicine](#) concluded that the F.D.A. was rife with internal squabbles and hobbled by underfinancing, poor management and outdated regulations. The institute, the most important medical advisory organization in the country, suggested that the agency undergo 25 major changes, many of which would require Congressional authorization.

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Alta Charo, a professor of law and bioethics at the [University of Wisconsin](#) and one of the authors of the Institute of Medicine's report, described the F.D.A. announcement yesterday as "a good set of first steps towards improving the safety of the drug supply in the United States."

Professor Charo said she was "disappointed" that the agency had failed to adopt some of the institute's bolder recommendations, including one suggesting that the agency give greater authority to officials who assess the safety of drugs after they go on the market.

"We viewed that as critical," she said.

Alan Goldhammer, deputy vice president for regulatory affairs for the Pharmaceutical and Research Manufacturers of America, praised the F.D.A.'s announcement as a "very thoughtful and comprehensive response" to the Institute of Medicine's report.

"The agency has made substantive and significant progress in improving and enhancing the drug safety system in the U.S." said Mr. Goldhammer, whose organization represents drug makers.

Still, the plan does little to address a problem that nearly all agree underlies many of its woes: a chronic shortage of government money. As Dr. von Eschenbach noted at the news conference, the agency has regulatory authority over about a quarter of the American economy. After the Sept. 11 attacks, the agency was asked to increase its efforts to prevent bioterrorism. Despite having greater responsibilities, its budget has remained relatively flat for years.

There are now thousands of drugs in routine use. Figuring out which of these medicines may have undiscovered side effects will take a lot of money. The agency gets about \$400 million of its \$1.9 billion budget from fees assessed on drug makers. Under a formula negotiated with the drug industry, this money comes with strings attached. One restriction was that the F.D.A. could use little of the money to track the safety of approved drugs.

That deal between the F.D.A. and drug makers expires this year, and the drug companies have agreed to allow more of their money to be used for postmarket safety assessments. Whether those fees are enough, whether there should be any strings attached to them and whether that money should be coming from drug makers at all has become the subject of fierce debate.

"Drug makers clearly get their money's worth with all this money," said Dr. Sidney Wolfe, director of [Public Citizen](#)'s health research group. Dr. Wolfe and other consumer advocates say that the F.D.A.'s dependence on drug industry fees has softened its oversight.

Dr. Scott Gottlieb, who last week left his job as the F.D.A. deputy commissioner to return to the American Enterprise Institute, a free-market research group, said the real debate unfolding around the agency is between those who believe that it needs more money and tools to assess drug risks, and those who believe that the agency should begin regulating the practice of medicine.

"I think we need to give the agency the resources it needs to get information about drug risks quickly," Dr. Gottlieb said. "But we don't need the government telling doctors and patients what to do."

The F.D.A. plan promises to return the agency to its scientific roots. It once had robust laboratories that conducted original studies to assess drug risks on its own. Those laboratories were largely eliminated in the past decade to apply more money to the drug-approval process and the support of a bare-bones computer program to track side effects of drugs.

But in the past two years, the agency has begun an effort to improve the science of drug safety, making itself an active participant in scientific endeavors once left exclusively to

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drug makers and basic scientists.

The efforts announced yesterday included the creation of a database of genetic codes associated with bad drug outcomes, the development of a computer model to identify patients who are most likely to suffer liver injury, and the design of screening tests that would identify patients most at risk of general drug problems.

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