



CAN THE FDA BE TRUSTED TO PROTECT PUBLIC SAFETY?

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CAN THE FDA BE TRUSTED TO PROTECT PUBLIC SAFETY?

Increasing evidence says no.

Waxman Congressional Report

A report titled "Prescription for Harm," released by California Democratic Congressman Henry Waxman in June 2006 concludes:

- FDA enforcement actions have declined under the Bush Administration. The number of warning letters issued by the agency for violations of federal requirements has fallen by over 50%, from 1,154 in 2000 to 535 in 2005, a 15-year low.
- FDA headquarters officials have routinely rejected the enforcement recommendations of career field staff. Internal agency documents show that in at least 138 cases over the last five years involving drugs and biological products, FDA failed to take enforcement actions despite receiving recommendations from agency field inspectors to do so.
- FDA's recordkeeping and case tracking practices are inadequate. Although the Federal Records Act and internal agency procedures require FDA to keep records that document agency enforcement decisions, FDA does not appear to comply with these requirements.

Former FDA director pleads guilty

Lester Crawford, a former head of the FDA who resigned last year, will plead guilty to charges that he made false statements and violated conflict of interest laws with respect to his ownership of shares in companies that the FDA regulates.

On October 16, 2006, Crawford's lawyer said that under a plea agreement, Crawford faces a \$50,000 fine plus probation, house arrest, or up to six months in prison.

President Bush nominated Crawford to become FDA commissioner in Feb. 2005.



Senator Grassley

In May 2006, as part of an investigation into the FDA's handling of the antibiotic Ketek, Iowa Republican Senator Charles Grassley said,

“The allegations of misconduct in this case are as bad as I’ve heard yet. It looks like the FDA caught the drug company red handed and let them get away with it. On top of that, the FDA failed to set the record straight and, in fact, continues to cite a discredited safety study as a principal reason to feel okay about using this drug.”

Marcia Angell, M.D. *Senior Lecturer, Harvard Medical School*

- Annual cost of running the FDA, \$300 million to \$400 million, is about equal to the cost of one day in Iraq.
- The FDA behaves as if it serves the pharmaceutical industry, not the public.
- FDA often approves brand-name drugs contingent on companies conducting further safety studies after the drugs are on the market. But the companies usually don't honor that commitment. Of the roughly 1,200 such studies outstanding -- some for years -- over 70 percent haven't been started.
- The FDA refuses to release unfavorable research results in its possession without the sponsoring company's permission.
- The agency's coziness with industry is underscored by the composition of its 18 advisory committees — outside experts who help evaluate drugs.
 - Many of these advisers work as consultants for drug companies.
 - Supposed to recuse themselves if there is a direct conflict of interest, the FDA regularly grants exemptions.
 - Of the six members of the advisory committee that recommended approving Vioxx in 1999, four had waivers from the conflict-of-interest rule.



Fooled again

On September 21, 2006, an FDA advisory committee met to evaluate the safety of Trasyolol, a prescription drug manufactured by Bayer. After the meeting, the advisory committee affirmed that Trasyolol is safe and effective for patients undergoing coronary artery bypass graft surgery.

A week later, the results of a Bayer study, which had been withheld from the advisory committee, were released. This study of 67,000 patients confirmed an earlier study linking Trasyolol to an increased risk of kidney failure, heart attacks and strokes.

One member of the FDA advisory committee, Steven Findlay, a healthcare analyst, said he doubts that knowledge of the study's completion was limited to a few Bayer employees. "It just strains credulity that only they would know," he said.

Institute of Medicine Criticisms

The Institute of Medicine, a nonprofit, nonpartisan component of the National Academy of Sciences, reached the following conclusions in a September 22, 2006, report:

- The FDA is handicapped by a serious lack of money and people.
- The FDA's enforcement arm is functionally impaired.
- The FDA's policies, particularly its enforcement policies, are unclear and inadequate.
- The FDA has failed to consistently, promptly, and effectively communicate safety information to the public.



Government Accountability Office

Drug companies do not need FDA approval before running ads. The agency can demand a company pull a misleading ad after it runs. But the Government Accountability Office found the agency has only enough people to examine a “small portion” of ads.

In 2002, the FDA began having its attorneys review the agency’s warning letters about misleading or deceptive ads.

It used to take two weeks to draft a warning letter. In 2004 and 2005, it took an average of eight months, and in half the cases, drug companies had discontinued the ads by the time the letters were finally sent.

“FDA enforcement actions are a shadow of what they used to be,” said Dr. Sidney Wolfe of Public Citizen’s Health Research Group. “It’s a mess.”

January 2007

Dr. Jerry Avorn

“...the federal drug safety research effort piddles along in perpetual drought. FDA has to rely on contributions from pharmaceutical companies to support its drug evaluation activities, and has a trivially small budget to track the safety of thousands of prescription drugs that Americans take daily.

Boston Globe, Feb 18, 2007

Professor of medicine at Harvard Medical School and Brigham and Women’s Hospital and author of “Powerful Medicines: the Benefits, Risks, and Costs of Prescription Drugs.”

Dr. David Graham

In a congressional hearing looking into the Vioxx debacle in 2005, FDA scientist and physician David Graham testified,

“The FDA as currently configured is incapable of protecting America.”

