



## Deadly Drugs and the FDA

Article Review



By Wm H. Peniston, MD

**Dangerous Medicine: So what if the speedup at the FDA is putting poisons on pharmacy shelves? Congress doesn't want to know.** *The American Prospect*, vol. 13, issue 17, Sept. 23, 2002, by Daniel W. Seligman.

HOW CONFIDENT ARE YOU of the safety of the drugs you prescribe? How familiar with the potential side effects?

Are you aware the FDA depends on you "to take into account the risks, to read the label....That's why drugs are prescription drugs."

But what if the risks are not known, are minimized, or just not printed on the label? How much time do you have to gather all the information needed before prescribing? An FDA administrator has been quoted as saying that as medical practice has changed, it's more difficult for doctors to manage the expanded drug supply. "They rely upon us much more to make sure the drugs are safe." Unfortunately, it would appear that such reliance might be placing some of your patients at unacceptable risks.

This article by Mr. Seligman is a summary of a frightening indictment of our Congress, the FDA, and the drug industry; a series of articles in the *Los Angeles Times* that won the Pulitzer Prize for investigative reporting in 2001.

The FDA had its beginning in the Food and Drug Act of 1906, following Upton Sinclair's description of the filthy conditions in meat packing plants. More than 100 deaths from a poisonous "elixir" resulted in 1938 legislation requiring that drugs be proven safe before they could be marketed.

The thalidomide tragedy led to legislation in 1962 requiring the FDA to ensure that drugs are effective as well as safe. From then through much of the 1980s, Congress was active in evaluating dubious drugs, uncovering FDA weaknesses and ordering corrections.

But since that time Congressional interest seems to have shifted more toward protecting investments than lives.

Although Congressional oversight began to wane in the late 1980s, it was in 1992 that a drastic decline started after "user fees" were first authorized by Congress. These are fees paid by the drug industry to provide revenue for the FDA. In exchange for the fees, the FDA was made to hasten new drug approvals to meet increasingly stringent deadlines.

In 1994, lawmakers began targeting the FDA as their prime example of regulatory excess. The agency was called "the leading job-killer in America" and Dr. Kessler a "thug" and a "bully."

In 1997, user fees were reauthorized as part of a "modernization" package, reducing the standard for new drug reviews from two clinical trials to just one, and allowing

manufacturers to promote drugs for "off label" uses never approved by the FDA. The new law did not enhance the safety of the drug-review process. For the first time in 91 years the FDA's public health protections were rolled back.

These laws have resulted in the time for review of "priority" drugs (those with significant therapeutic advances) being reduced to a record low in 1995. In 1996, 53 new drugs were approved, almost twice the previous largest number.

This push for speed has created a "sweatshop environment causing high staffing turnover." And Congressional oversight of FDA drug regulation has declined to four hearings in five years, all called to ensure that drug approvals were being expedited. Currently the House is investigating whether ImClone Systems Inc. misled investors about FDA approval prospects for its anticancer drug Erbitux. They have yet to investigate a drug-safety issue.

Readers interested in this subject can find the complete report by David Willman at [www.pulitzer.org/year/2001/investigative-reporting/works/](http://www.pulitzer.org/year/2001/investigative-reporting/works/).

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