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FDA: Guardian Or Rubber Stamp?

- *Seven Drugs Pulled From The Market After FDA Approved Them*
- *Some Argue The FDA Doesn't Do Enough Testing For New Drugs*
- *Sill Others Say The FDA Is Getting Too Close To Drug Companies*

WASHINGTON, July 12, 2001



CBS

(CBS) Dr. Robert Misbin is a sort of scientific detective at the FDA, hunting for early warning signs in the newest drugs seeking FDA approval.

As reported in a **CBS News** investigation last year, Misbin wanted the diabetes drug Rezulin taken off the market for safety reasons. But he locked horns with his FDA superiors and even publicly accused his own agency of putting the drug maker's interests ahead of the public.

"It was a painful experience really for everybody, but it's over now," said Misbin.

Misbin eventually got his way, reports **CBS News Correspondent Sharyl Attkisson**. Rezulin was taken out of pharmacies and off the market. But by then it was linked to 63 deaths from liver failure.

It was the same with fen-phen, according to another FDA scientist, Dr. Leo Lutwak. The FDA approved the popular diet drug over his objections. Now it's off the market, too, linked to hundreds of deaths.

"I felt from the very beginning that these drugs were dangerous. I felt that there were multiple hazards associated with them," explained Lutwak in an April 7, 2000 interview.

Seven widely-prescribed drugs — Rezulin, Redux/fen-phen, Propulsid, Lotronex, Duract, Posicor, Raxar — have been pulled for safety reasons in the last few years after the FDA had judged them to be

The Complete Investigation

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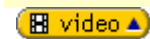
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safe and effective.

"The FDA just rolls over and either lets the drugs out too early without enough testing, or lets them out without a serious warning label even when their own FDA scientists want stronger warnings on these drugs," said Alicia Mundy, an author of a new book about the FDA's struggles.

She says the trouble began in the early 90's when Congress urged the FDA to speed up drug approvals. Now, she says, the FDA is too close to the \$100 billion drug industry.

"You see in some of their own internal news letters, they refer to the pharmaceutical industry as their clients," Mundy said.

FDA scientists are also worried about pharmaceutical influence.

In an e-mail, one FDA medical officer criticizes his superior for "cutting the red tape" for a drug company, and says the public wouldn't have gotten the same "speedy service."

In fact, when the public or media wants information on drug safety, the FDA makes them file formal Freedom of Information requests, and then wait weeks or months for answers.

Health and Human Services oversees the FDA, but Secretary Tommy Thompson wouldn't talk to **CBS News** on camera.

Neither would the FDA. "You can do these types of stories," an FDA spokesman told **CBS News**, "but we don't have to help you."

When we pressed the issue, the FDA only gave a written statement saying: "The FDA continues to uphold its traditional high standards... The rate of drug withdrawals for safety in the U.S. has remained steady...2.7 percent...for the past 30 years. All drugs have risks, and to imply otherwise is to mislead patients."

Still, Misbin remains hopeful his agency will learn from its mistakes.

"I think the FDA clearly suffered a lot of criticism for being too close to industry, too willing to go along and

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ingratiate itself to industry's demands," he said.

The FDA's official mandate is approving safe drugs and keeping dangerous ones off the market. But with increasing criticism over how well the agency is doing that job, the unofficial task has become proving it's putting the public's interests first.

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