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HEADLINE: Ex-FDA chief: Pharma goal at odds with safety

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BODY:

The Food and Drug Administration's diminished credibility on drug safety is due in part to the pharmaceutical industry's tactic of mass marketing medicines, a former agency commissioner said yesterday.

"The notion that you can come up with a new drug and have millions and millions of people take it safely - the blockbuster - that is what got us in trouble," said David Kessler, who led the FDA from 1990 to 1997.

Kessler, one of four former FDA commissioners participating in a panel discussion at the George Washington University School of Public Health, said large-scale promotion of prescription drugs through direct-to-consumer advertising has been a mistake.

The former FDA leader said the agency looks at statistical evidence from relatively small numbers of patients in clinical trials to determine safety and effectiveness of drugs, and then seeks to balance risks and benefits. But he said the goal of the pharmaceutical companies has been to create "a mass market and sell as many drugs as they can."

Kessler said it was inevitable that there would be an increase in serious side effects from many heavily promoted drugs because the question of whether it is "the right drug, the right person, the right disease and the right dose" often hasn't been asked.

He said he doesn't believe this model is sustainable, and suggested "limits should be placed" on marketing medicines as "just another commodity." Kessler opposed direct-to-consumer advertising when he was commissioner.

Joining Kessler during the panel discussion were former commissioners Donald Kennedy (1977 to 1979), Frank Young (1984 to 1989) and Jane Henney (1999 to 2001).

All four expressed unhappiness that the agency's integrity and credibility has been under attack in the last few years. They attributed the problems to a lack of consistent and sustained leadership, a paucity of resources and insufficient power to deal with safety issues.

The FDA in the last three years has been assailed for being lax on drug and medical device safety, and being too cozy with those industries. It also has been accused of stifling scientific dissent and for letting political considerations guide decision-making.

A May 2006 public opinion poll showed the majority of Americans don't think the FDA is doing a good job.

Many of the FDA's problems came to public attention in the wake of its mishandling of Merck's blockbuster Vioxx pain medication, which was taken off the market after being linked to heart attacks and strokes. A number of FDA reform proposals are pending in Congress to strengthen drug-safety laws.

At a separate conference held yesterday by the Center for Medicine and the Public Interest, Andrew von Eschenbach, the current FDA commissioner, said he thinks trust in the agency can be regained through "honesty, openness, transparency and a recognition of vulnerabilities." He said "science" will be the foundation for all decisions.

Von Eschenbach also defended direct-to-consumer advertising as a First Amendment right as long as the ads remain truthful.

He said he is committed to insuring all different points of view within the agency are heard and part of the deliberative process. But he added he won't tolerate whistleblowers who go outside the agency just because they disagree with a final outcome.

"The people have to understand to go outside that process is not constructive. It is actually destructive," von Eschenbach said. (Emphasis Added)

At the GW panel discussion, Young said the "FDA needs to be a high priority for the administration and the Congress, and the administration must avoid political meddling."

He said the FDA has been consistently underfunded, and needs more money and added powers including greater ability to monitor drugs after they are on the market. Henney said the FDA needs the authority to order rather than negotiate labeling changes and recalls.

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