Food and drug agency to study greater openness

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(AP) -- The government's food and drug regulators want to open their files to the public.

Well, maybe not all of their files. And not right away.

Food and Drug Administration Commissioner Margaret Hamburg announced Tuesday she has created a task force to make recommendations on how the agency can release more information in such areas as drug evaluation and enforcement matters. She wants a report in six months.

The FDA has long operated under strict confidentiality rules. Its scientists routinely handle reams of private information from drug companies, medical device manufacturers, even laboratories working on genetically engineered animals. The clinical data is critical for government experts to make decisions about the safety and effectiveness of products that could be sold to the public. But improper disclosure - for example, to a competitor - can severely damage a company laboring to bring a new product to market.

Hamburg said she believes the need for secrecy may have been taken too far, and is harming the FDA's credibility within the medical community and among consumers.

"The agency has been referred to as a 'black box,' " she said.

A central question for the task force is what do about unpublished clinical trial data it receives from drug manufacturers. Early signs of problems sometimes emerge from these scientific studies, but they are not routinely released. The meaning of the data is often hotly debated.

In the past few years, the FDA has been criticized for taking too long to disclose safety concerns about antidepressants, a painkiller and a diabetes drug. Antidepressants now carry strong warnings about suicide risks for youths. Vioxx, a painkiller, and Rezulin, a diabetes drug, were withdrawn from the market. Critics say lives could have been saved if the agency had opened up.

Hamburg said the task force will seek the views of a broad range of interested parties, including industry, medical researchers and consumer groups. She expects the FDA will be able to act quickly on many of the recommendations. In some cases, however, the agency may have to rewrite regulations, or even ask Congress to change laws that restrict release of information.

Consumer groups applauded the FDA's search for a new direction. Information on safety and effectiveness should be released routinely so it can be analyzed by independent scientists, said Dr. Sidney Wolfe, director of Public Citizen's health research group. "There is still an enormous amount of information that's considered trade secrets," said Wolfe. "Are doctors and patients fully aware of the risks and benefits of a drug? Certainly not if the data is kept secret."

The drug industry said while it's not opposed to disclosure, the pendulum could swing too far, undermining competition to develop new medicines.

The task force, chaired by Deputy Commissioner Joshua Sharfstein, will represent all of the FDA's major divisions, as well as its law enforcement branch. It will hold two public meetings, the first on June 24. Public

comment will be accepted until Aug. 7.

On the Net:

The Food and Drug Administration: http://www.fda.gov