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Study Condemns F.D.A.'s Handling of Drug Safety

By [GARDINER HARRIS](#)

WASHINGTON, Sept. 22 — The nation's system for ensuring the safety of medicines needs major changes, advertising of new drugs should be restricted, and consumers should be wary of drugs that have only recently been approved, according to a long-anticipated study of drug safety.

The report by the [Institute of Medicine](#), part of the [National Academy of Sciences](#), is likely to intensify a debate about the safety of the nation's drug supply and the adequacy of the government's oversight. The debate heated up in September 2004 when Merck withdrew its popular [arthritis](#) drug Vioxx after studies showed that it doubled the risks of heart attacks.

Several senators have already proposed significant changes, some of which the report seems to endorse.

The report's conclusions are often damning. It describes the [Food and Drug Administration](#) as rife with internal squabbles and hobbled by underfinancing, poor management and outdated regulations.

"Every organization has its share of dysfunctions, unhappy staff members and internal disputes," the report said. But panel members said that they were deeply concerned about the agency's "organizational health" and its ability to ensure the safety of the nation's drug supply.

The report made these recommendations, most of which would require Congressional authorization:

¶ Newly approved drugs should display a black triangle on their labels for two years to warn consumers that their safety is more uncertain than that of older drugs.

¶ Drug advertisements should be restricted during this initial period.

¶ The F.D.A. should be given the authority to issue fines, injunctions and withdrawals when drug makers fail — as they often do — to complete required safety studies.

¶ The F.D.A. should thoroughly review the safety of drugs at least once every five years.

¶ The F.D.A. commissioner should be appointed to a six-year term.

¶Drug makers should be required to post publicly the results of nearly all human drug trials.

In a telephone conference with reporters on Friday, top F.D.A. officials struck an awkward balance between thanking the institute for its work and defending their own leadership. They said they needed to study the report before deciding which of its recommendations to endorse.

“While considerable work has been done over the past two years to improve our approach to drug safety, work still needs to be done,” said Dr. Andrew C. von Eschenbach, the acting commissioner of the agency and the nominee for commissioner.

An internal e-mail message sent Friday to agency staff members by Dr. Sandra L. Kweder, deputy director of the Office of New Drugs, was blunter, bemoaning the report’s criticism of what it described as the agency’s dysfunctional culture.

“It is a long, inflammatory section of the report that will certainly generate the most public attention and hit our people hard,” Dr. Kweder wrote, according to a copy provided to The New York Times.

Agency critics were elated.

“The new report validates what the watchdog community has been saying for the last two years,” said Senator [Charles E. Grassley](#), Republican of Iowa, who as chairman of the Senate Finance Committee has overseen investigations into drug safety problems. “Problems are systemic, and solutions must reflect a new mind-set by the agency leadership.”

The drug industry, through its trade organization, reacted warily. “Though there is always room for improvements, it would be a mistake to accept the notion that the F.D.A. drug safety system is seriously flawed,” said Caroline Loew, senior vice president of the Pharmaceutical Research and Manufacturers of America.

The Institute of Medicine is a nonprofit organization created by Congress to advise the federal government on health issues. The report was issued by the Committee on the Assessment of the United States Drug Safety System, led by Sheila P. Burke, deputy secretary and chief operating officer of the [Smithsonian Institution](#).

The report described fierce disagreements between those who approve drugs and those who study their effects after approval, disputes that repeated F.D.A. efforts have not resolved. Indeed, managers’ failure to address such disagreements competently “has played an important role in damaging the credibility” of the agency, it said.

Critics of the food and drug agency have long been divided into two warring camps. Some say the agency fails to approve life-saving medicines quickly enough, while others say that it is so intent on

rapid approvals that it fails to ensure the safety of the drugs.

The institute's report champions the latter view by calling for greater caution. It suggests that one of the agency's biggest problems is a deal struck in 1992 between Congress and the drug industry in which drug makers agreed to pay millions in fees to speed reviews. This deal has increased pressures on drug reviewers to act quickly, and it has limited "the ability of reviewers to examine safety signals as thoroughly as they might like," the report said.

"Some also have serious concerns that the regulator has been 'captured' by industry it regulates, that the agency is less willing to use the regulatory authority at its disposal," the report said, criticizing the agency's regulatory tools as "all-or-nothing."

"The agency needs a more nuanced set of tools to signal uncertainties, to reduce advertising that drives rapid uptake of new drugs, or to compel additional studies in the actual patient populations who take the drug after its approval," it said.

The pharmaceutical industry is likely to fight at least some of the proposals, said Charlie Cook, a Washington political analyst.

"One should never underestimate the influence of the drug industry," Mr. Cook said. "But I would think that at least the outlines of many of these recommendations would have a decent chance of getting through Congress."

Senators Michael B. Enzi, Republican of Wyoming and chairman of the Health, Education, Labor and Pensions Committee, and [Edward M. Kennedy](#) of Massachusetts, the ranking Democrat on the committee, have jointly proposed a bill that would undertake at least some of the changes advocated by the report.

Another bill, sponsored by Senator Grassley and Senator [Christopher J. Dodd](#), Democrat of Connecticut, offers similar proposals.

There is little chance that Congress will act on any of these proposals before next year, when it must reauthorize the 1992 financing deal with the drug industry. Negotiations between the drug industry and agency about the parameters of that deal are already under way.

Despite its fierce criticisms, the report may bolster the confirmation prospects of Dr. von Eschenbach. A Senate committee approved his nomination on Wednesday, but two Republican senators have vowed to block it.

Over the past 10 years, no commissioner has served more than two years, though the term is open-ended. The report deplored this "lack of stable leadership."

“Without stable leadership strongly and visibly committed to drug safety, all other efforts to improve the effectiveness of the agency or position it effectively for the future will be seriously, if not fatally, compromised,” the report states.

It recommends that the commissioner be nominated for a six-year term, but such a change may not solve the problem of early exits. President Bush has nominated two past commissioners. The first left for another job within the administration; the second left amid accusations of financial improprieties.

The report recommends that [Michael O. Leavitt](#), the secretary of health and human services, appoint an independent board to advise the commissioner “to implement and sustain the changes necessary to transform” the agency’s culture.

It rejects suggestions by Mr. Grassley and others that the F.D.A. create a center for drug safety to monitor drugs after approval.

“Achieving a balanced approach to the assessment of risks and benefits would be greatly complicated, or even compromised, if two separate organizations were working in isolation from one another,” the report concludes.

The F.D.A. asked the Institute of Medicine to review its drug safety system shortly after the Vioxx withdrawal in 2004, and the agency has agreed to pay \$3 million for the study.

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