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Senate Takes Up Bill to Change Drug Agency Operations

By [GARDINER HARRIS](#)

WASHINGTON, April 30 — The Senate began debate on Monday on a bill that could fundamentally change the way the [Food and Drug Administration](#) operates by giving it more power and money to ensure that drugs are as safe as advertised.

The measure, which has bipartisan support, would renew and increase the fees paid by regulated drug companies. Such fees, which are to expire in September, are a significant part of the agency budget. If they are not renewed, it is likely that workers will be laid off.

The bill would provide more money to track the safety of drugs after they have reached consumers and more authority to force drug manufacturers to complete promised safety studies. It would also renew requirements and incentives for pharmaceutical companies to ensure that their products are safe for children.

“This is the most important legislation for F.D.A. in at least 10 years and, probably, forever on issues of drug safety,” said Dr. [Mark B. McClellan](#), a former food and drug commissioner appointed by Mr. Bush.

Dr. David A. Kessler, a commissioner in the Clinton administration, said, “This is a pivotal moment in F.D.A.’s history, as important as 1938 or 1962, when Congress gave the agency its fundamental responsibilities.”

Despite a widening scandal about the safety of imported food, the bill as written would do little to change the oversight of the safety of the food supply. Instead, the measure represents years of concern about the safety of drugs that began with studies showing that antidepressants seemed to cause suicidal tendencies in a small number of children and teen-agers. The agency suppressed an initial report on the problem, only to acknowledge later that it was real.

Concerns about the basic competence of the agency to protect public health grew in September 2004, when Merck withdrew a pain pill, Vioxx, after a study showed that it increased the risk of heart attacks.

Months later, a safety official from agency told a Senate panel that the agency was “virtually incapable” of protecting the public from unsafe drugs.

Senator [Edward M. Kennedy](#), the Democrat from Massachusetts who is chairman of the Senate Health, Education, Labor and Pensions Committee, is the principal sponsor of the bill.

It has the strong support of Senator Michael B. Enzi, the Wyoming Republican who is the ranking minority member on the panel.

The committee passed the bill, 15 to 6 vote, but details about what Mr. Kennedy and Mr. Enzi would introduce on the Senate floor were a subject of furious speculation throughout much of Monday as drug and biotechnology lobbyists circulated updates to executives of drug companies.

The speculation centered on whether the senators would include proposals to speed the approval of copycat versions of biologics, drugs like insulin and growth hormone that are made by cells in processes that are more difficult to control than the chemical mixing used to make most [pharmaceuticals](#).

In the end, the senators decided against including that provision. The biotechnology industry opposed it, and the makers of generic drugs supported it.

Generic biologics legislation is to be introduced separately.

Nonetheless, the Kennedy-Enzi bill is dizzyingly complex and includes an alphabet soup of provisions that finance and define many basic operations of the agency.

The most important of those allows faster consideration of applications for drug approvals in return for payments from manufacturers.

The previous action on the fees expires in September. If it is not renewed, the agency would lose \$320 million of its \$1.5 billion budget.

Mr. Kennedy and Mr. Enzi have proposed increasing the fees by more than \$80 million. The bill would direct the agency to spend much of the additional money on combing through millions of health records collected by insurers to measure what effects popular drugs have had after their approval.

The agency is now able only to track drug side effects through doctors and patients' voluntary reports, a system that even top officials agree is incapable of uncovering problems like those with Vioxx.

The bill also would give the agency for the first time the power to fine on drug makers that fail to carry out promised safety studies. Presently, the agency has no power to enforce these pledges, so only a fraction are completed.

"The F.D.A should be the gold standard for safety, but its luster has been tarnished in recent years by failure to protect the American people from unsafe drugs," Mr. Kennedy said on the Senate floor.

The House will most likely consider on its own many provisions in the Senate measure, rendering its prospects uncertain.

Senator [Charles E. Grassley](#), the Iowa Republican who is the ranking minority member of the Senate Finance Committee and who has conducted several investigations of the agency, said in an interview that something had to be done.

"We'll never get another bite at this apple," said Mr. Grassley, who intends to offer amendments to reorganize the agency and increase fines for noncompliance with its rules.

"But the drug companies are a powerful lobby in this town," he said, "and there's a big question mark about whether all my work of the last three or four years is going to shine through."