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Senate Approves Tighter Policing of Drug Makers

By ROBERT PEAR

WASHINGTON, May 9 — By a vote of 93 to 1, the Senate passed a bill on Wednesday that would give the Food and Drug Administration new power to police drug safety, order changes in drug labels, regulate advertising and restrict the use and distribution of medicines found to pose serious risks to consumers.

The bill calls for a fundamental change in the philosophy and operations of the drug agency, requiring it to focus on the entire life cycle of a drug — not just the years before its approval — as well as the experience of patients who later take it.

Under the bill, the government would establish a surveillance system to track the adverse effects of prescription drugs. Scientists would analyze data on tens of millions of patients, looking for signals that particular drugs pose serious risks.

In passing the measure, the Senate sent a clear signal that it wanted stronger action by the agency to protect public health. Senators said the bill responded to a widespread loss of confidence in the ability of the agency to protect consumers against the dangers of drugs like Vioxx, a popular painkiller withdrawn from the market in 2004.

Major provisions of the bill, which would carry out recommendations from the National Academy of Sciences, appear broadly acceptable to the House and are likely to become law.

The Bush administration has not actively opposed the measure, although it says the agency already has all the regulatory authority it needs. Within the agency, officials have been divided about whether they have the enough power.

The bill is widely seen as “must pass” legislation because it renews authority for the government to collect fees from drug companies to speed reviews of their products. Without action by Congress, the authority expires on Sept. 30.

Billy Tauzin, president of the Pharmaceutical Research and Manufacturers of America, the main trade group for manufacturers of brand name drugs, applauded the passage, of the bill, saying it “will preserve

and even strengthen the F.D.A.'s ability to do its job."

Drug company executives succeeded in their efforts to block a proposal to legalize imports of lower-priced medicines from Canada. And many were happy that the final Senate version sidestepped a multibillion-dollar question, how to give consumers access to lower-cost copies of biotechnology drugs that cost tens or hundreds of thousands of dollars a year.

Lawmakers from both parties said they intended to create a procedure for approval of such copycat drugs, sometimes called generic biologics.

Dr. Sidney M. Wolfe, director of Public Citizen's Health Research Group, a consumer organization, said: "The bill's improvements in F.D.A. authority are important but inadequate. The bill would increase collaboration between the agency and the drug industry by increasing the agency's reliance on user fees to finance drug reviews."

Work on the bill began long before Democrats won control of Congress. At a time bills often pass or fail on party-line votes, the Senate drug bill was a product of bipartisan cooperation. Republicans were full partners in drafting it.

"This legislation will make a major difference for families in America, ensuring the safety of our prescription drug system," said the chief sponsor of the bill, Senator Edward M. Kennedy, Democrat of Massachusetts.

Senator Michael B. Enzi, Republican of Wyoming, said the bill was the "most comprehensive drug safety overhaul in more than a decade."

The no vote was cast by Senator Bernard Sanders, independent of Vermont, an outspoken critic of the pharmaceutical industry who said he was "extremely disappointed" that the bill did not legalize imports.

Just minutes before the bill passed, the Senate voted, 64 to 30, to double the maximum civil fine that could be imposed on a drug company for violating a drug safety plan approved by the F.D.A. The maximum fine would be $2 million.

"If fines are nothing more than the cost of doing business, you cannot deter bad behavior," said Senator Charles E. Grassley, Republican of Iowa, who proposed the increase.

Under current law, the government and drug companies sometimes haggle for months over changes in drug labeling, and the drug agency can request but not compel manufacturers to perform studies after a drug has been approved.

Under the Senate bill, the government could order changes in a label and require the manufacturer to

conduct more studies and clinical trials of a drug already on the market.

“For Vioxx, it took 14 months to change the drug’s label to warn doctors and patients of the danger,” Mr. Kennedy said. “Companies routinely promise to conduct studies that are never even started, much less completed.”

The bill would also require the government to establish a public database of clinical trials and their results. Lawmakers said this would make it difficult for drug companies to hide evidence of safety problems, as, they said, some companies had done.

The database would also make it easier for patients to learn of clinical trials testing drugs that could save their lives.

Mr. Enzi said the bill could speed the approval of new drugs, by giving the agency more tools to protect patients after treatments had been approved. The agency would no longer have to rely on “the nuclear option, which is pulling a drug completely off the market,” an extreme step that may disrupt patients’ care, Mr. Enzi said.

The agency could instead require a manufacturer to adopt a “risk evaluation and mitigation strategy” for a drug that posed serious risks.

As part of a risk-management plan, the agency could require that any television or radio advertisements for a drug describe its risks “in a clear and conspicuous neutral manner,” with fines for false or misleading commercials.

To make that sure patients could have access to drugs with extraordinary risks like thalidomide, for a type of cancer, and Tysabri, for multiple sclerosis, the drug agency could require additional precautions like special training for doctors and close monitoring of patients.

Senator Judd Gregg, Republican of New Hampshire, said any restrictions on using or marketing a drug would have to be based on “sound science.”

The bill would give financial incentives to drug companies to study the effects of their products in children. The reward would be scaled back for drugs that already had sales of more than $1 billion a year in the United States.

Experts estimate that two-thirds of the drugs prescribed for children have not been studied or labeled for pediatric use.

Representative John D. Dingell, Democrat of Michigan and chairman of the House Committee on Energy and Commerce, said Wednesday that he shared the goals of the Senate bill.

“Incidents like the recall of the arthritis drug Vioxx have created a crisis of confidence in the Food and Drug Administration,” Mr. Dingell said.

Representative Frank Pallone Jr., Democrat of New Jersey who is the chairman of the health subcommittee, said the House would hold hearings this month and probably write its bill next month, with a vote by the full House likely in July.

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