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Senate OKs drug-safety bill

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The Associated Press

Prescription drugs would be monitored more closely for side effects under legislation the Senate approved Wednesday aimed at staving off future high-profile drug withdrawals.

Federal health officials were criticized for not reacting sooner when serious problems were linked to the painkiller Vioxx. The drug was withdrawn voluntarily in 2004 after research showed that it doubled the risk of heart attacks and strokes.

The Senate legislation, approved 93-1, would require the Food and Drug Administration to actively monitor the safety of drugs on the market and require pharmaceutical companies to develop plans to manage any serious risks associated with new medications.

A companion bill has yet to be considered in the House.

The legislation's underlying purpose was to renew, through 2012, a program that has the drug industry pay fees to the agency to defray the cost of reviewing new medicines.

But in the wake of the Vioxx withdrawal, lawmakers seized on the bill to overhaul how the FDA handles the safety of the drugs it regulates.

"Right now, the FDA has its hands tied behind its back when it tries to manage the risks of drugs already on the market. This bill will clarify and strengthen the FDA's authority and give it new tools to take measured and appropriate steps to protect the health and safety of Americans," said Sen. Mike Enzi, R-Wyo., who wrote the main piece of legislation with Sen. Ted Kennedy, D-Mass.

A provision that would have placed a freeze on consumer advertising of newly approved drugs was stripped from the legislation.

Kennedy called the measure "constitutionally sound" after lawmakers objected, on free speech grounds, to any advertising freeze.

The Senate also voided an effort to allow consumers to buy prescription drugs from abroad at a significant savings.

The bill would require stricter production and labeling standards for cat and dog food so people have more information about what they are feeding their pets.

"Too many lives have been lost because the FDA has been too slow to act or didn't have the power to change a warning label or require a follow-up safety study," said Bill Vaughan, senior policy adviser for Consumers Union.

Drug bill at a glance

Drug companies would be required to do follow-up studies on certain drugs or risk fines.

The bill would require stricter production and labeling standards for cat and dog food. An active database surveillance program would replace the passive way the FDA now learns of potential problems with drugs on the market.

Fines can be assessed for ads that are false or misleading.