US Senate passes FDA

Revitalization Act

Legislation aimed at strengthening the US Food and Drug Administration's ability to scrutinize new and existing drugs passed the Senate last month, but it may not be the elixir needed to quell growing concern over prescription drug safety in the United States. Critics say the bill is too weak to make any significant improvements and that it maintains a "cozy relationship" between Congress and pharmaceutical companies.

Sponsored by Senators Edward Kennedy (Democrat, Massachusetts) and Mike Enzi (Republican, Wyoming), the Food and Drug Administration (FDA) Revitalization Act was passed by a 93:1 margin. It now heads to the House, where it is expected to be strengthened.

Drug safety reforms have been on the Congressional docket since the popular pain drug Vioxx led a parade of drugs that were withdrawn from the market for safety reasons. Vioxx was yanked in 2004 after it was shown to increase the risk of heart attack and stroke. The diabetes drug, Rezulin, and a heavily-advertised pill for digestive ailments, Zelnorm, have since followed suit. Reports of suicides among youths taking antidepressants have also fueled demands for an overhaul of the agency. "The FDA should be the gold standard for safety. But its luster has been tarnished in recent years," said Kennedy.

The legislation obligates the government to establish a post-market surveillance system to track the adverse effects of drugs and to create a public database of clinical trial results.

It also renews FDA authority to collect fees from drug companies to speed reviews and increases the amount of money the drug industry will pay for such user fees, from US\$300 million this year to a projected US\$539 million in 2008. The funds will be used to double the size of the FDA drug safety office.

As well, drug companies can be fined if they give misleading or false information on direct-to-consumer advertisements, or if they fail to do required follow-up safety studies.

Consumers would also see stronger warnings on medications already on the market and be privy to more information about how drugs are developed and eventually get a government stamp of approval, as internal FDA memos about scientific debates surrounding the risks and benefits of drugs would be made publicly available.

But the legislation did not lift limitations on the import of cheaper drugs from Canada and other nations as pharmaceutical industry lobbyists successfully fought off proposals to legalize such imports. Had it done so, though, US President George Bush had vowed he'd step in and veto the bill.

Nor did the legislation establish procedures or processes for the approval for lower-cost copies of biotechnology drugs (so-called generic biologics), or provide the authority that would enable the FDA to ban prescription drug advertising for the first 2 years a drug is on the market, or require that FDA scientists who conduct post-market surveillance differ from those who initially approved the drug. The latter measures were among dozens recommended by the Institute of Medicine, a division of the National Academy of Sciences, after it was asked to examine drug safety in the wake of the Vioxx scandal and a host of controversies which had resulted in widespread public perception that FDA drug regulation had largely become a vehicle for satisfying the needs of the pharmaceutical industry and that the agency's scientific advisory system was untrustworthy (*CMAJ* 2007;176[11]:1571-72).

Kennedy's original bill did contain stronger measures to oversee direct-to-consumer drug advertisements, but that provision was removed before the final vote.

The powerful pharmaceutical industry called the reforms workable.

"There has been a loss of confidence in the FDA and we can't afford to have that," Dr. Joseph M. Feczko, Pfizer's chief medical officer, told the *New York Times*. "When our medicines come out, we want people to understand they have gone through a rigorous review process."

Billy Tauzin, president of the Pharmaceutical Research and Manufacturers

The US Senate has proposed an overhaul of the troubled FDA, increasingly seen as the rubber stamp of the drug industry rather than the ensurer of drug safety.

of America and a former Louisiana Congressman who once chaired the House committee that oversees the FDA, said in a statement that the legislation "will preserve — and even strengthen — the FDA's ability to do its job."

Consumer groups were less convinced.

Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, warned that the user fee program, which allows drug makers to pay millions of dollars to the FDA in exchange for faster drug review times, continues the cozy relationship between Capitol Hill and Pill Hill.

"Lives have been lost," added Bill Vaughan, senior policy advisor for Consumers Union, publisher of *Consumer Reports*, in an interview. "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."

Vaughan said stronger reforms will be sought from the House, particularly with regard to drug advertising. The First Amendment doesn't guarantee drug companies "can push medications with health risks on the public." — Patricia Guthrie, Seattle, Washington

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