FDA Reform Legislation to Move Forward Soon: Bills Emphasize Better FDA Evaluation and Surveillance

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C ongressional pressure to improve the U.S. Food and Drug Administration’s (FDA’s) surveillance of drugs, especially after they go on the market, has been building. So far, however, there has been a lot of smoke and not much fire.

The latest evidence of this was a study released at the end of May by Representative Edward Markey (D-Mass.). Apparently, the FDA has not done what it promised: conduct postmarketing studies on drugs for life-threatening illnesses—drugs that have been approved under its expedited approval process.

Aside from Congressional studies, there have also been hearings, and one bill has been introduced by Senator Charles Grassley (R-Iowa). As Chairman of the Senate Finance Committee, he is someone to be taken seriously. Despite all the criticism of the FDA for its handling of rofecoxib (Vioxx®, Merck), antidepressants, and other agents, no votes have yet been taken in any committee on either side of Capitol Hill.

Part of the reason that Congress has been slow to act is that Mike Leavitt, the new secretary of the Department of Health and Human Services (DHHS), has been pressed to approve a drug or biological product.

The FDA is not enthusiastic about the reorganization proposed by the Grassley/Hinchey bill. Steven Galson, MD, MPH, Acting Director of CDER, explained that keeping the Office of Drug Safety and the Office of New Drugs within CDER has significant benefits.

“Having both independent offices in FDA’s CDER ensures efficient decision-making, expeditious resolution of disputes, and the rapid dissemination of critical drug safety information to the public and health care providers,” he said.

In addition to creating a new CPDER, the Grassley/Dodd bill would authorize the Center’s Director to require manufacturers to conduct postmarketing clinical or observational studies if questions arise about the safety or efficacy of a drug or biological product.

“There have been disturbing reports that suggest that the FDA does not place enough emphasis on drug safety and that concerns raised by those in the Office of Drug Safety are sometimes ignored and even suppressed,” explained Senator Dodd.

He added: “An internal study conducted by the [DHHS] Office of the Inspector General in 2002 revealed that approximately one fifth of drug reviewers had been pressured to approve a drug despite concerns about safety, efficacy, or quality. In addition, more than one third said they were ‘not at all’ or only ‘somewhat’ confident that final decisions of CDER adequately assessed safety.”

Senator Enzi will probably bring his bill up for a committee vote soon because he already held two days of hearings earlier this year. He is likely to have the support of the committee’s top Democrat, Senator Edward (“Ted”) Kennedy (D-Mass.), just as Senator Grassley has support from Democrat Dodd. As a result, upgrading the FDA’s safety surveillance is not likely to engender the partisan rancor that has prevented congressional action on other issues.