New FDA Drug Safety Initiatives: Does the Agency Have Enough Money and Authority?

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There is an enormous amount of hubbub in Washington over drug safety. The Food and Drug Administration (FDA) announced two sets of initiatives in January, and congressional reform bills are flying. But if you are on a P&T committee or working in a hospital pharmacy and you want more accurate information about potential drug interactions and side effects now—or at least some time soon—don’t hold your breath. Many of these initiatives and the Democratic bills for improving FDA surveillance are studded with “ifs, ands, and buts.”

There are going to be changes at the FDA, that is a certainty. Congress must reauthorize the Prescription Drug Users Fee Act (PDUFA), which expires on June 30, 2007. PDUFA has been reauthorized three times already. According to this law, enacted in 1992, drug companies must pay user fees in exchange for the faster approval of new drugs. PDUFA IV will become a magnet for all sorts of amendments, ostensibly strengthening the FDA’s pre-marketing and post-marketing safety reviews.

The FDA itself announced its PDUFA IV reform agenda in January. The agency wants drug companies to increase their annual user fees by $87 million, to a total of $392.8 million. The largest chunk of that extra money, $29.2 million, would be used for the hiring of 82 extra staffers in the area of post-marketing surveillance, which has been perhaps the biggest problem area for the agency.

Any extra PDUFA funds—of course, the industry would have to agree to these—will be used for extra personnel, not new programs. But on January 30, the FDA, in a separate announcement, stated that it would undertake some vague drug safety initiatives with $11 million in additional drug safety funds that it hopes Congress will approve. Certainly, $11 million isn’t much, when measured against the FDA’s $2.1 billion budget. That might be why the FDA explains these initiatives by saying that they would “strengthen,” “improve,” and “upgrade” existing programs.

There appear to be only two new initiatives: a pilot project to review the safety profile of new molecular entities on a scheduled basis, and a publication of a Web-based newsletter with summaries of post-marketing drug reviews. Of course, drug companies are completing only a few of their assigned post-marketing studies; one therefore wonders whether this newsletter will be longer than a few paragraphs.

Democrats in Congress have grander ideas. The Enhancing Drug Safety and Innovation Act, sponsored by Senator Ted Kennedy (D-Mass.), relies on risk evaluation and mitigation strategies for all new drugs; however, a second bill, called the Food and Drug Administration Safety Act, includes more systemic changes. Senator Chris Dodd (D-Conn.) and Representative John Tierney (D-Mass.) are pushing that bill.

A new, independent center within the FDA, called the Center for Postmarket Evaluation and Research for Drugs and Biologics, would be responsible for monitoring the safety of drugs and biologics after they are on the market. For example, the center’s director could require manufacturers to conduct post-marketing clinical or observational studies if there are questions about the safety or efficacy of a drug or a biologic agent after it is already on the market. This center could require studies (which the FDA cannot do now), post extensive information about them on the Internet, and drop a civil penalty of $250,000 on any company that missed its deadline by one month. The penalty would be doubled for each successive month.

The only problem with the Dodd/Tierney bill is that it requires funding for the new center at a level of $50 million in 2008; this figure would rise $150 million in 2012. There is absolutely no chance that Congress will fork over that new money. It is doubtful that Congress would make even $11 million available to the FDA in 2008 for its purported “initiatives.”

It would be more sensible to give the FDA the authority in the Dodd/Tierney bill (i.e., the ability to require studies and assess large fines) without requiring the creation of a new FDA center. After all, there will be new PDUFA drug safety money earmarked for the hiring of new employees. Why not put them to work on new Dodd/Tierney programs?

The drug companies object to making post-marketing studies public, as Dodd/Tierney would require. Rather than creating such a roadblock, it might be better for the FDA to set up an outside advisory committee that would be evenly balanced with consumer and drug company representatives to decide how much of each study to make public.

The primary goal is to collect much more pre-marketing and post-marketing data. The sooner that can happen, the sooner pharmacists and P&T committee members will have the information that they need.