With Health Care Reform Out of the Way, Congress Can Now Confront Drug Safety

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Now that President Obama’s health care reform legislation (known as the Patient Protection and Affordable Care Act) is no longer blocking the movement of other significant health care-related bills through Congress, the floodgates are open for bills that have been eddying in the Capital’s backwaters. Two bills related to drug safety are now scheduled to be pushed forward through the formerly logjammed House Committee on Energy and Commerce (E&C), which was the lead committee for health insurance reform in the House of Representatives. The bills are designed to guarantee the safety of imported drug ingredients and to prevent counterfeit drugs from entering our nation’s distribution system.

Those two bills were the pre-eminent topics during hearings in the E&C health subcommittee on March 10. Members quizzed Joshua M. Sharfstein, MD, Principal Deputy Commissioner at the FDA, on how the agency was implementing the FDA Amendments Act (FDAAA), the major pharmaceutical safety bill passed into law in 2007. That law gave the agency new authority to order postmarketing studies, to require Risk Evaluation and Mitigation Strategies (REMSs) for individual drugs, and to crack down on potential conflicts of interest among academicians serving on FDA advisory committees.

Some revisions to FDAAA might be forthcoming. Its conflict-of-interest provisions have seemingly caused academicians to flee FDA advisory committees. Many of these committees now are missing anywhere from five to 10 members; for instance, there are 21 vacancies on the pharmaceutical science advisory committee. My March 2010 column in P&T addressed drug manufacturers’ unease with how the FDA has used its REMS authority.

At the hearing, Dr. Sharfstein admitted:

[The] FDA is committed to addressing the concerns we have heard from prescribers, pharmacists, distributors, and payers about their roles in implementing [REMSs] and from patient groups about the effects of [REMSs] on access to needed products, and [it is] planning to hold a public meeting to hear from these and other stakeholders.

If Congress does make some adjustments to the FDAAA, it would be in the context of a larger drug safety bill that, at a minimum, would include aspects of two separate bills that were introduced in 2008; however, these bills were shoved to the side of the congressional agenda as health insurance reform dominated Congress’ attention starting in early 2009. As previously mentioned, one bill deals with potentially substandard, or even dangerous imported drug ingredients; the other bill pertains to the drug-distribution chain in the U.S. and its vulnerability to counterfeiting. Dr. Sharfstein tied the two together in his statement to the E&C committee:

Where Americans once used drugs that were mostly manufactured domestically, now up to 40% of the drugs we take are imported, and up to 80% of the active pharmaceutical ingredients in the drugs we use are from foreign sources. . . . Simultaneously, the supply chain from raw material to consumer has become more and more complex, involving a web of repackagers and redistributors in a variety of locations. This makes oversight significantly more difficult and leaves weaknesses through which counterfeit, adulterated, and misbranded products might infiltrate the legitimate supply chain.

Keeping out questionable ingredients manufactured abroad is the focus of the FDA Globalization Act of 2009 (H.R. 759), sponsored by Representative John Dingell (D-Mich.). H.R. 759 would require the FDA to develop risk-based inspection schedules; originate quality risk-management plans for business establishments, especially manufacturers of pharmaceutical ingredients; implement country-of-origin labeling; and use its authority to recall new drugs. At the hearings, Congressman Dingell said that Representative Joe Barton (R-Tex.), the top Republican on the committee, was working with him on refining the bill. That bill came about because of deaths in the U.S. caused by a contaminated raw heparin ingredient imported from China a few years ago.

More recent events are likely to give a push to the second “in waiting” bill, which will be the 2010 version of 2008’s Safeguarding America’s Pharmaceuticals Act. This legislation, sponsored by Representatives Jim Matheson (D-Utah) and Steve Buyer (R-Ind.), also has bipartisan support; it is apt to get some added lift-off help because of the theft of antipsychotic agents and antidepressants from an Eli Lilly & Co. warehouse in Connecticut on March 16 and because of the discovery of $10 million in stolen prescription drugs at the home of a Florida man on March 22.

The counterfeit problem has been a concern for the FDA for at least five years, and the FDAAA had a requirement that the agency develop a unique identifier for each drug package as a way to track a package from manufacturer to pharmacy shelf. The FDA issued final guidance on an identifier on March 26 and will also be rolling out some parallel guidelines in the near future.

The Safeguarding bill goes farther than the FDAAA; it calls for a national... continued on page 254
electronic pedigree system (a shipping document), allows for interoperable technologies to track those e-pedigrees, and requires that a standardized numerical identifier be used on individual packages. (The FDAAA simply specifies that the FDA define the characteristics of an identifier but does not require companies to use an identifier.) At the March 10 hearings, Dr. Sharfstein stated that the FDA currently lacks the authority to require pharmacists to ensure that the package they receive, stamped with a unique number, is the correct one (the pedigree requirement in the Safeguarding Act).

The FDA has escaped the attention of Congress for the past 15 months, at least in terms of drug safety, which is probably fine with Dr. Sharfstein and his boss, FDA Commissioner Margaret Hamburg, MD. But that is about to change, as congressional proposals push the agency out from the shadows into the limelight on Capitol Hill.

REFERENCES