Congress Passes Unambitious User Fee Reauthorization and Expansion

Act Omits Key Provisions Sought by Pharmacy Groups

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ongress passed, and President Barack Obama signed, the FDA Prescription Drug User Fee Act (PDUFA) with only a few muted peeps of pique from pharmaceutical groups after they noted some of the bill’s omissions. The bill’s main goals had been to extend the brand-name user-fee program for 5 years and to establish two new user-fee programs for generic and biosimilar drugs. The legislation accomplishes that, and with the additional new fees—more than $1 billion per year—the FDA will theoretically have more resources to approve new drugs more quickly. A few tag-along provisions, for example, gave the agency new authority to inspect overseas manufacturers of drug ingredients, but whether the agency will have enough money to hire additional foreign inspectors is uncertain.

This reauthorization of the user-fee bill was a much smoother legislative ride than in 2007, when many significant drug safety provisions were added, but drug safety was decidedly not an issue this time around. Provisions on track-and-trace of drugs to prevent counterfeit versions from reaching hospitals, which had been in the Senate version, were dropped from the final bill; in addition, limitations on direct-to-consumer advertising were not considered.

Significant revisions to Risk Evaluation and Mitigation Strategies (REMS), which pharmacy groups had sought, never got off the ground. The uninspiring provisions aimed at preventing drug shortages were mentioned in this column last month.1 Pharmacy groups gave obligatory “commendations” to Congress for passing the bill, which itself was an accomplishment of sorts. But the groups were quick to note the bill’s shortcomings.

“It is important to highlight a critical issue that was not resolved in this legislation—‘downstream’ supply chain security,” said John J. Castellani, President and Chief Executive Officer of Pharmaceutical Research and Manufacturers of America (PhRMA).

Edith A. Rosato, RPh, IOM, Chief Executive Officer of the Academy of Managed Care Pharmacy (AMCP), added, “AMCP is concerned that certain provisions, such as significant enhancements to postmarket risk management and Risk Evaluation and Mitigation Strategies were not included in the final bill. AMCP does acknowledge that the bill includes a more efficient method of allowing minor modifications to REMs.”

The pharmacy organizations had hoped that Congress would come up with a national track-and-trace program that would pre-empt the California e-Pedigree program, which is slated to start in 2015. The California requirement for item-level drug-package serialization and full-scale tracking will be costly for everyone (from manufacturers through pharmacies) to comply with. The Pharmaceutical Traceability Enforcement Code Act (RxTEC) provision in the Senate bill was meant as an alternative to e-Pedigree that would be easier to comply with. However, the House did not include RxTEC in its version of the PDUFA reauthorization, and the Senate was unable to retain its provision when the House and Senate met to reconcile their slightly different bills.

The RxTEC model was developed by the Pharmaceutical Distribution Security Alliance (PDSA), a multi-stakeholder initiative whose membership spanned the drug-distribution channel. This model would have required manufacturers to serialize individual salable units of medications with two-dimensional data matrix bar-code labels and to maintain and manage RxTEC data in their systems so that serial numbers on individual medication bottles would be linked to product lot numbers.

However, the RxTEC system would have been more “reactive” than the California e-Pedigree “preventive” system. Theoretically, e-Pedigree would allow counterfeit drugs to be identified before they arrived in a pharmacy and were dispensed. The RxTEC system, because it would track lot numbers only one step back in the distribution channel (there would be no central data repository), would represent an after-the-fact tool for the most part.

When RxTEC was discussed at a House hearing in March, Janet Woodcock, Director of the Center for Drug Evaluation and Research, noted, “If our goal is to protect patients from receiving counterfeit drugs before they receive them, rather than going back and reconstructing what happened after they have received them, then we need a real-time system that tracks drugs down to the pharmacy level [and] down to the unit level.”

Industry groups, however, clearly preferred RxTEC to e-Pedigree. The Generic Pharmaceutical Association (GPhA) maintains that the RxTEC model offers a better solution than the California law (e-Pedigree), which would require full electronic track-and-trace capabilities to be implemented, hypothetically enabling the entire distribution history and location of every unit in the supply chain to be determined at any time. The GPhA believed that adopting the California model (or one with similar features) would raise the cost of medications by billions of dollars over a period of time; would be prone to error; and would produce results that, at best, would be similar to those of the less expensive, more efficient RxTEC model.

No one seems to know why the RxTEC provision, whatever its shortcomings, never made it into either the House or...
the final bill signed by President Obama. The California Board of Pharmacy wrote to Representative Henry Waxman (D-Calif.), the top Democrat on the House Energy and Commerce Committee, condemning RxTEC. Rep. Waxman, by virtue of his position, had a lot to say, though not the final word, about the contents of the FDA bill coming out of the House.

Representative Brian Bilbray (R-Calif.) was apparently RxTEC’s leading proponent in the House. His office was allegedly unable—more likely unwilling—to shed any light on the opposition that Rep. Bilbray faced. The fact that the 2007 PDUFA reauthorization included a number of provisions on track-and-trace—the 2012 version included none—speaks volumes about the lack of ambition in the 2012 bill.

Reference