Controversy over the FDA’s effort to finalize a Risk Evaluation and Mitigation Strategy (REMS) for opioids injects some spice into an effort by Congress to reauthorize the drug safety provision of the Prescription Drug User Fee Act (PDUFA). One of the highest-profile amendments in the 2007 version of the PDUFA gave the FDA new authority to require every pharmaceutical manufacturer to develop a REMS for drugs that have value but whose risks could outweigh those benefits if these medications are not used carefully.

REMS are typically multifaceted programs for physicians and pharmacists. A REMS can be as simple as a patient medication guide (MedGuide), or the REMS might contain requirements in seven or eight areas (e.g., record keeping, patient monitoring, and certification). Those additional areas, specified in the 2007 PDUFA law, are called Elements to Assure Safe Use (ETASU).

Since the 2007 PDUFA was enacted, the FDA-required REMS programs have resulted in multiple drug manufacturers producing different REMS for the same agents. That has led to confusion among pharmacists, not to mention complaints from drug companies about a high regulatory burden. That is why revising the 2007 REMS provisions is the pharmacy industry’s top legislative goal for Congress in 2012 as the House and Senate decide that changes are needed. So far, however, the draft opioids REMS addresses only education for health care providers, which is only one of the ETASUs. Even here, the draft applies only to physicians, not pharmacists.

Peter W. Jackson, President of Advocates for the Reform of Prescription Opioids, thinks that pharmacists should be included in an opioids REMS strategy. He maintains that there should be mandatory patient counseling by prescribers (namely physicians, nurse practitioners, and physician assistants), as well as pharmacists, to explain the risks of respiratory depression and addiction that can occur with the long-term use of opioid medications.

Ronna Hauser, PharmD, Vice President for Policy and Regulatory Affairs at the National Community Pharmacists Association, adds that whichever components of REMS are provided to patients by prescribers should also be made known to pharmacists. Pharmacists can offer valuable reinforcement of the physician’s education through appropriate counseling.

The FDA’s Blueprint addresses only physician education, which is voluntary. Any provider education module agreed to by manufacturers of a specific drug class would have to be approved by the FDA and presented by an independent continuing education (CE) company. The programs would be free to health care providers and funded by unrestricted grants from the drug manufacturers. The drug companies would be required to establish goals for all prescribers trained, collect information about the number of prescribers who took the courses, and report the information to the FDA as part of the required periodic assessments.

When the FDA produced an earlier draft in April 2011 of what it expected to be the components of an educational course on opioids, the drug manufacturers argued that the FDA plan would require 30 hours of instruction. In the new Blueprint draft published last November, the FDA says that its syllabus requires 2 or 3 hours of course work for providers.

Suggestions for improving the Blueprint draft have been numerous and have come from all affected parties. Herbert Neuman, MD, Vice President of Medical Affairs and Chief Medical Officer of Mallinckrodt, calls the Blueprint a “comprehensive outline” that contains a good mixture of conceptual and clinical topics. However, he notes that the core training requirements cannot be addressed in 2 or 3 hours, as the FDA purports. A group called Physicians for Responsible Opioid Prescribing identifies what it believes are “unaddressed safety issues” in the Blueprint.

Peter Jackson has a much more negative view of the draft. He says that he and others, including members of an FDA advisory committee, urged the FDA to develop a REMS that went beyond provider continuing education, by including, for example, other ETASUs, such a requirement that patients receive laboratory tests. As for the draft education proposal, he states:

“This weak and timid proposal is shocking after all the [drug-related] deaths.”

REFERENCES