Mandatory Training Debated for Opioid Safety

BY ELIZABETH MECHCATIE

COLLEGE PARK, MD. — Special training in safe prescription of long-acting opioid drugs, as well as the use of patient-prescriber agreements, could be required to earn federal approval to prescribe such products, under proposals discussed by an industry working group.

The working group presented those and other options at a public meeting held by the Food and Drug Administration. The meeting was part of an initiative to develop a class-wide risk evaluation and mitigation strategy (REMS) for long-acting opioid drugs.

The FDA last February informed manufacturers of long-acting opioid products that they would have to develop a single REMS for the drug class. The FDA wants to reduce the potential for abuse, misuse, overdose, and addiction associated with the use of the products and to ensure that their benefits outweigh their risks.

Some physicians would opt out of training, thus reducing access to the drugs for patients who need them.

DR. JENKINS

Under one element of the plan being-considered, clinicians seeking Drug Enforcement Agency registration to prescribe schedule II controlled substances would be required to certify that they were trained to safely prescribe and choose the appropriate patients for the drugs. Currently, there is no training requirement for a physician to obtain DEA registration. Giving the DEA such authority would require an act of Congress, according to one of the industry working group representatives.

While efforts to pass such legislation are underway, the working group members noted, voluntary programs could be developed, possibly with medical specialty societies.

Requiring such training raises the concern that some physicians would opt out of training—thus reducing access to the drugs for patients who need them, said Dr. John Jenkins, director of the Office of New Drugs, in the FDA's Center for Drug Evaluation and Research.

The REMS program's goals are to ensure that the drugs' risks don't exceed their benefits, while ensuring access for patients who need them, Dr. Jenkins noted during a press briefing after the meeting.

The drugs to be included in the REMS are brand name and generic products that contain fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. Among the problems associated with those products include their use in patients who are non–opioid tolerant or otherwise inappropriately selected, as well as the drugs' misuse and abuse.

Dr. Jenkins cited the example of pain treatment with methadone—which, when taken too frequently, can result rapidly in an overdose.

Short-acting opioid products are not included in the discussion. But meeting participants expressed concern that an effective REMS for the long-acting products could shift misuse and abuse to the shorter-acting agents.

Other ideas proposed by the industry working group for the REMS include:

- A patient-prescriber agreement, which would serve as a tool to facilitate a discussion between physicians and patients.
- A medication information sheet.
- Metrics to assess the impact of the REMS. There should be a measure to determine whether the REMS impedes patients' access to appropriate medication, the working group noted.

The industry working group made no definitive conclusions at the meeting, however, and it has not developed a final plan for the REMS.

Dr. Jenkins said he couldn't predict when the REMS would be finalized. But an FDA advisory panel will meet in the spring to discuss the elements of the proposed REMS, to solicit advice from experts, and to hear public comment, he added. Until a final REMS is approved, Dr. Jenkins said, the FDA will require an interim REMS for any other products in the drug class. ■