Opioid Prescribing Might Require Special Training

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.

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

In February 2009, the FDA 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 abuse, misuse, overdose, and addiction associated with the use of the products, and to ensure that their benefits outweigh their risks.

Under one element of the plan under consideration, 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, a physician can obtain DEA registration without a training requirement. Giving the DEA such authority would require an act of Congress, according to one of the industry working group representatives.

Voluntary programs could be developed, possibly with medical specialty societies, while legislative efforts are underway, the working group noted.

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' benefits exceed their risks, while providing 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 nonopioid tolerant or otherwise inappropriately selected, as well as misuse and abuse of the drugs.

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 were not discussed, but meeting participants expressed concern that an effective REMS for long-acting products could shift misuse and abuse to shorter-acting agents.

The working group also proposed these ideas:

►**A patient-prescriber agreement.** This would serve as a tool to facilitate discussion between the physician and patient.

►**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 working group made no definitive conclusions at the meeting and 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 product in this drug class. ■

Pain Treatment Could Be Restricted

MY TAKE

Requiring physicians to undergo training in order to prescribe opioids would be a major impediment to the care of patients. Most of the physicians I have spoken to say they would not take such training and would instead simply stop prescribing the related drugs. The problem is that most of us have a few patients requiring long-term narcotics, but just a few, and most narcotic use in rheumatology is short term or limited long-term use (e.g., 20 tablets for 3-6 months).

The patient-prescriber agreement is important but is really only needed for patients using continuous long-term narcotics. The medication information sheet is a good idea, but what is the role of the pharmacist? In many states, the pharmacist has access to electronic records of narcotic prescriptions. Shouldn't they have the responsibility of notifying physicians of misuse?

It seems to me that the imposition of training and compulsory use of forms would not reduce the risk of addiction or improve detection of abuse, but it would add another layer of rules and make it more difficult to practice medicine and provide appropriate patient care.

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Adverse Event Reporting Criticized

Little information is made public about adverse events in hospitals, even though public disclosure can help clinicians improve patient safety, according to a government report. After reviewing 8 federally approved patient safety organizations and 17 systems that collect adverse event information for states, the Department of Health and Human Services Inspector General found that only 7 state systems passed along to providers adverse event analyses that led to changes in practice. The other states passed along reports without any analysis. A nationwide database of adverse events collected by the patient safety organizations won't be operational until at least 2011, the report said.

Tobacco Act Takes a Hit

A federal district court has struck down parts of the Family Smoking Prevention and Tobacco Control Act of 2009, saying that some of the landmark law violates tobacco makers' free speech rights. The U.S. District Court for the Western District of Kentucky ruled it unconstitutional to ban color and images in tobacco advertising. But the court upheld provisions requiring large, strongly worded warnings on tobacco packaging, prohibiting companies from making health claims about tobacco products without Food and Drug Administration review, and banning tobacco-branded events and merchandise, such as T-shirts. American Thoracic Society president Dr. J.R. Curtis said in a statement that the society is "confident that the FDA will exercise its new authority to reduce tobacco use in the U.S. by stopping the efforts of big tobacco to market its dangerous products to minors, and by giving current smokers more motivation to stop smoking."

New York Limits Its Salt

The New York City Health Department said it will ask restaurants and producers of packaged food to voluntarily reduce sodium in their meals and products by 25% over 5 years in an effort to curb high blood pressure and heart disease. The department acted as leader of the National Salt Reduction Initiative, a partnership of cities, states, and health organizations. The New York agency said that nearly 80% of the sodium in Americans' diets is added to foods before they are sold. After a year of consultation with food industry leaders, the coalition has developed targets for salt reductions in various foods. In a statement following the New York announcement, Centers for Disease Control and Prevention director Dr. Thomas Frieden endorsed such efforts: "The majority of Americans are consuming about twice the recommended limit of sodium each day, and not by choice. Achieving substantial reductions in sodium levels by incremental decreases in sodium content across the food supply can save many lives while maintaining good taste."

Few Drug-Safety Data Are Online

Safety and efficacy information collected as part of the federal drug approval process is not available online for 9 of the top 25 prescribed brand-name drugs in the United States, according to the Sunlight Foundation, which advocates for transparency in government. The foundation's report found that the FDA makes background documents available online only for drugs approved since 1997. Information for drugs approved earlier is online only in response to a formal request. Safety and efficacy information for Lipitor (atorvastatin), Plavix (clopidogrel), and Synthroid (levothroxine) is not available online, according to the foundation. In addition, the information that is online is in a format that's difficult for researchers and the public to use, according to the report.

FDA Okayed 26 Meds in 2009

The FDA approved 19 new chemical entities and 7 new biologic agents in 2009, according to Washington Analysis, a Washington, D.C.–based investment adviser. Among the new biologics were Medicis's injectable wrinkle fighter Dysport. In the report, Washington Analysis's Ira Loss said he had expected more approvals last year because the agency claimed it wouldn't let statutory approval dates be overridden and it received more money for reviews. In 2008, the FDA approved 21 new chemical entities and 4 new biologics, the report said.

CMS Launches Provider Survey

The Centers for Medicare and Medicaid Services kicked off its fifth annual survey to determine provider satisfaction with Medicare fee-for-service contractors. The contractors process and pay more than $370 billion in Medicare claims each year. The Medicare Contractor Provider Satisfaction Survey offers physicians and other providers a chance to say how well their contractor handles inquiries, outreach, education, claims processing, appeals, reviews, and audits. The CMS said it is sending the 2010 survey to approximately 30,000 randomly selected providers, including practitioners, suppliers, and institutions. Participants can submit their responses confidentially online or via mail, fax, or telephone, the CMS said. Results of the survey, which will take several months to complete, will be released on the CMS Web site this summer, the agency said.

—Jane Anderson