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FDA Mandates New Warning Labels, but Doctors Want More: Top [2013-09-13]

By John P. Kamin, Reporter

New rules by the U.S. Food and Drug Administration that will require warning labels on all extended-release and long-acting opioid analgesics will limit what pharmaceutical companies can say when marketing the drugs, but the doctors that prompted the change say that the FDA should have done more to control the manufacturers' sales pitches.

The federal agency announced Wednesday that it will require drugmakers to use the new warning labels and will also require manufacturers to perform new post-market studies on all extended-release and long-acting opioid analgesics. The FDA took the action in response to a petition that was filed by Physicians for Responsible Opioid Prescribing in July 2012.

Opioid abuse is thought to be a major cost driver in the workers' compensation industry. The Workers Compensation Research Institute and the California Workers' Compensation Institute have reported increased use of opioids by injured workers for conditions that do not call for the prescription of narcotic drugs. Recent research by CWCI showed that the trend may be leveling off, but that usage rates are still higher than in prior years.

The new labels required by the FDA will warn doctors and patients that extended-release opioids are to be used only for severe pain when alternative treatment is inadequate and presents risks of addiction, abuse, misuse, overdose and death.

Morgan Licinsky, a spokesperson for the FDA, told WorkCompCentral that the agency still has more administrative work to do before it will start requiring manufacturers to affix the labels to prescriptions.

"The FDA is going to be working with the drug sponsors through an established regulatory process for finalizing the labeling changes, and we expect the labeling to be finalized by approximately December of this year," she said. "Once the labels are finalized, the companies would be responsible for getting them onto the products, and into the hands of patients."

Licinsky said that the labeling requirements will apply to OxyContin, Butrans, MS Contin, Kadian, Avinza, Embeda, Exalgo, Duragesic, Nucynta ER, the original Opana ER (for the name drug and three generics), the new formulation for Opana ER, Dolophine, Palladone, three generic drugs for methadone oral solution and one generic drug for methadone oral concentrate.

Physicians for Responsible Opioid Prescribing, or PROP, is a group of doctors and public health officials that has been working to highlight the dangers posed by narcotic painkillers. The petition requested the

labeling, a warning that the drugs be used only for "severe" pain, and sought to establish a maximum daily dose of 100 mg of morphine for noncancer pain. The FDA granted the first two requests, but denied the request for the 100-mg limitation.

Dr. Andrew Kolodny, president of PROP, told WorkCompCentral that the FDA's labeling decision will limit what drugmakers can say in educational conferences that they sponsor. The FDA already requires pharmaceutical manufacturers to provide free educational conferences about "safe and effective" prescribing of the drugs across the country, he said.

"All of these programs now are going to have to change what they are teaching the doctors," Kolodny said. "They are going to now have to teach that extended abuse opioids are a last resort treatment for patients with severe pain. And that is not what they are teaching right now. So I think it will help in terms of the education."

Mark Pew, senior vice president of business development for Prium, said that the FDA originally considered making such seminars mandatory in 2011, but dropped the idea after the American Medical Association opposed it. He cited a "blueprint" from the FDA stating "why prescriber education is important" for extended-release and long-acting opioids as evidence that the federal agency has been wanting to help doctors understand the dangers of the drugs. The blueprint cites statistics about the dangers of opioids and states that education could help prevent the public health problem.

While the FDA may be able to force the drugmakers to host the conferences, the agency has had a more difficult time enforcing how drugmakers communicate government-mandated warnings, Pew said.

"There has been a mandate for big pharma to document side effects for 15 to 20 years," he said. "But big pharma has figured out a really good way to comply with the letter of the rule, but not the intent. They have created these television and radio commercials which show people holding hands, butterflies flying through the air and have soft Yanni music playing in the background − while they talk about side effects like diarrhea, respiratory issues, depression and how you could die from heart failure. They have done a good job of complying with the letter of the law − which is explaining the side effects − but they have figured out a soothing way to present it."

The creation of the soothing environment while describing harmful side effects has helped prevent people from understanding the true implications of taking the drug, Pew said. Because of such tactics, Pew said it will be interesting to see how pharmaceutical companies communicate the new warnings to doctors.

"Just like the television and radio commercials, I do not know if they are going to comply with just the letter of the law, or the intent," he said.

Despite the potentially positive impact on drugmakers' educational conferences, PROP still views the FDA's response to the petition as insufficient because the rules will not prevent drug companies from using allegedly misleading marketing techniques. PROP wanted the FDA to change its labeling regulations to prevent drug companies from marketing the long-term and high-dose use of opioids as safe and effective for conditions such as fibromyalgia, chronic headaches and chronic back pain, he said.

"Where labels have the biggest impact is on claims drug companies can make about their products," Kolodny said. "That is why my organization wanted the labels changed − because right now, drug

companies are permitted to claim that long-term and high-dose use of opioids is safe and effective. They can say 'safe and effective' for anything they want − they can say that it is safe and effective for fibromyalgia, for chronic headaches and for low back pain. These conditions are where their products are most commonly prescribed, and these are conditions where the experts say that opioids are a terrible choice."

Had the FDA agreed to PROP's petition in full, it would have made the marketing of opioids for such uses illegal by classifying them as "off-label" prescribing, Kolodny said. Once the FDA has classified a use of a drug as "off-label" prescribing, it is illegal for drug companies to cite those uses in the drug-marketing campaigns.

"They are sending a sales force in and out of doctors' offices every day, telling doctors that you should be prescribing opioids aggressively for common conditions, where opioids should not be prescribed," he said.

Kolodny noted that even if the FDA had adopted a stance that would have impacted drugmakers' marketing statements, doctors could have still prescribed the opioids for such conditions because the FDA does not regulate doctors themselves.

"If they (the FDA) were properly following federal law, they would not permit the existing label," he said. "They would require a label that is consistent with the scientific evidence. And the scientific evidence is that for most patients, opioids are neither safe nor effective."

Michael Von Korff, the vice president of PROP, told WorkCompCentral via email that he would have liked to see the FDA classify long-term use of opioids as "off label."

"Since there is no evidence that opioids are safe and effective for the long-term management of chronic pain (long-term meaning more than three months), they could have the opioid label indicate the limits of the evidence, so that long-term use of opioids would be off-label prescribing," he said. "This would not prohibit prescribing opioids long term, but it would make it illegal for drug companies to market opioids for long-term management of chronic pain. This should be done for both short-acting and long-acting opioids."

As for the changes the FDA did adopt, Von Korff said the labels will provide more information for treating physicians to consider, but he does not anticipate much change in doctors' actual prescribing habits.

"I would not expect a dramatic, sudden change in opioid prescribing, but it is possible that we will begin to see a leveling off of opioid prescribing and then a gradual decline in the volume of opioids prescribed, because most opioids prescribed are for chronic pain," he said.

Pew said that the labeling changes are unlikely to affect patients or doctors very much, but said the new labels could have an impact on pharmacists.

"The biggest impact is going to be with pharmacists, because they are the ones that are reading the labels," he said. "They are at ground zero trying to determine whether this would be the appropriate prescription for this patient and making sure that this drug combines with the other drugs that the patient is taking."