

HEALTH

Are opioids only for patients with “severe pain”?

A petition that asks the FDA to tighten labeling for opioid analgesics raises questions about appropriate prescribing for moderate chronic pain.

By KEVIN B. O'REILLY, *amednews* staff. Posted Aug. 20, 2012.

A group of 37 physicians in July petitioned the Food and Drug Administration to no longer approve the use of opioid analgesics in patients with moderate noncancer pain. The FDA has until the end of the year to respond to the petition, which is the latest entry in the fierce debate about the proper boundaries of opioid prescribing for patients with chronic pain.

The petition, filed by the New York-based Physicians for Responsible Opioid Prescribing and Washington-based Public Citizen, asks the FDA to change the label for instant-release and extended-release opioids by:

- Striking the term “moderate” from the indication for noncancer pain.
- Limiting the maximum daily dose to the morphine equivalent of 100 mg for noncancer pain.
- Limiting daily use for noncancer pain to 90 days.

“By implementing the label changes proposed in this petition, [the] FDA has an opportunity to reduce harm caused to chronic pain patients as well as societal harm caused by diversion of prescribed opioids,” said the petition, signed by prominent specialists in pain medicine, addiction medicine, occupational health and public health.

The FDA could choose not to take action on the petition, change the labeling as requested or appoint an advisory committee to examine the matter. The agency did not respond to a request for comment by this article’s deadline.

“I think we stand a very good chance of succeeding here,” said Andrew Kolodny, MD, president of Physicians for Responsible Opioid Prescribing and chair of the Dept. of Psychiatry at Maimonides Medical Center in New York. He said evidence of safety and efficacy of opioids for use over a long period in patients with moderate pain is lacking and that the FDA should take action to address a “public health crisis.”

How pain is rated

Several widely used instruments let patients rate pain on a scale of one to 10. The one-to-three range is described as mild, nagging pain that does not greatly interfere with a patient’s daily life. The four-to-six range is “moderate pain” that significantly interferes with a patient’s ability to perform activities of daily living such as working, cooking and doing chores. The seven-to-10 range is “severe pain” that is disabling and renders a patient unable to perform daily-life activities.

Changing opioid labeling to eliminate the indication for moderate noncancer pain would not bar physicians from continuing to prescribe the drugs to such patients off-label. However, the change would prevent drugmakers from marketing the medications for use in such patients and could affect payers’ coverage of the drugs.

The petition comes on the heels of an FDA risk mitigation and evaluation strategy for extended-release and long-acting opioids issued July 9. The program requires drugmakers to fund continuing medical education courses for the 32,000 U.S. physicians and other health professionals who prescribe opioids. The FDA’s goal is for 60% of these prescribers to receive education on proper patient selection, dose titration and management and patient counseling within the next three years.

Jeanmarie Perrone, MD, associate professor of emergency medicine in the Perelman School of Medicine at the University of Pennsylvania in Philadelphia, said the FDA’s voluntary education strategy may not be enough to address what she called the “opioid epidemic” in an Aug. 1 viewpoint article in *The Journal of the American Medical Association*. She said the petition to tighten opioid labeling is a welcome effort to spark more discussion among physicians about painkiller prescribing.

“This expansion of our idea that all pain should be treated immediately and aggressively, and that pain management treatment equals an opioid, needs to change in the public’s expectation and the prescriber’s understanding,” Dr. Perrone said. “We need to rein it all back to something a little more appropriate.”

Nearly 23 million U.S. prescriptions for extended-release and long-acting opioids were dispensed in 2011, the FDA says. More than 15,500 Americans died of overdoses involving opioids in 2009, according to the Centers for Disease Control and Prevention. Many of the overdoses involved patients also using illicit drugs or misusing other prescription drugs that contributed to their deaths.

Physicians should be careful when prescribing opioids, but ruling out their use for patients with moderate chronic pain takes matters a step too far, said James F. Cleary, MD, director of the University of Wisconsin Pain and Policy Studies Group in Madison.

“I don’t think the petitioners or others have given us any evidence that we shouldn’t be using opioids for treatment of chronic noncancer pain in a selected group of patients,” said Dr. Cleary, director of the palliative care program at the University of

Wisconsin Hospital and Clinics. "In some patients, it is actually very effective. That we would, for a so-called public health crisis that we don't fully understand, hurt people who do benefit from these medicines is too bad. That's an immoral step."

The American Academy of Pain Medicine also objected to the Public Citizen petition.

"We believe that [the petitioners'] recommendations for reducing the dosage and duration of prescribed medications fail to take into account the needs of the millions of Americans who are finding relief from the debilitating effects of chronic pain thanks to a long-term care plan that includes the use of appropriately prescribed opioids," the academy's statement said.

Methadone draws special concern

Recommendations issued jointly by the American Academy of Pain Medicine and the American Pain Society in 2009 say, "Clinicians may consider a trial of [chronic opioid therapy] as an option if [chronic noncancer pain] is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh or are likely to outweigh potential harms."

The guidelines, published Feb. 6, 2009, in *The Journal of Pain*, note that patients with poorly defined pain conditions, psychiatric problems or a personal or family history of substance abuse should be considered high risk for chronic opioid therapy. Some physicians argue that the real danger in opioid prescribing is not that patients with moderate pain are getting the drugs, but that doctors too often prescribe methadone. "What gets lost in the mix is that not all opioids are created equal," said Michael Schiesser, MD, an addiction-medicine specialist in Bellevue, Wash., who treats many chronic pain patients.

Although methadone accounts for only 2% of painkiller prescriptions, more than 30% of opioid-related deaths involve the drug, the CDC says. The difference between an effective and a dangerous dose of the drug is small, the agency notes. The drug can quickly build up in a patient's body, suppressing respiration and leading to arrhythmia.

ADDITIONAL INFORMATION:

More people misusing opioids

About 5% of Americans have used opioids recreationally within the previous year, according to an annual survey of people 12 and older by the Substance Abuse and Mental Health Services Administration. Chronic misuse of opioids has increased dramatically since 2002.

Duration of nonmedical use	2002-03 rate per 1,000 people	2009-10 rate per 1,000 people	Rise
Any use in prior year	48.4	49.2	1.6%
30-99 days in prior year	8.8	9.5	8.3%
100-199 days in prior year	4.8	5.1	7.4%
200-plus days in prior year	2.2	3.8	74.6%

Source: "Frequency of Prescription Pain Reliever Nonmedical Use: 2002-2003 and 2009-2010," *Archives of Internal Medicine*, published online June 25 (archinte.jamanetwork.com/article.aspx?doi=10.1001/archinternmed.2012.2533)

WEBLINK

Petition seeking change in FDA labeling for opioid analgesics, Physicians for Responsible Opioid Prescribing, July 25 (www.citizen.org/documents/2048.pdf)

"Frequency of Prescription Pain Reliever Nonmedical Use: 2002-2003 and 2009-2010," *Archives of Internal Medicine*, published online June 25 (archinte.jamanetwork.com/article.aspx?doi=10.1001/archinternmed.2012.2533)

"Curbing the Opioid Epidemic in the United States," *The Journal of the American Medical Association*, Aug. 1 (jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2012.8165)

"Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain," *Journal of Pain*, February 2009 (<http://www.ncbi.nlm.nih.gov/pubmed/19187889>)

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