**PROFESSION**

**Prescription drug overdose cases skyrocket at emergency departments**

An FDA proposal could require opioid manufacturers to do more to educate physicians and patients on the potential dangers of their products.

*By KEVIN B. O'REILLY, amednews staff. Posted July 12, 2010.*

With newly released data showing that prescription drug misuse now rivals illicit drug use as a cause of emergency department visits, the Food and Drug Administration in June released a long-awaited proposal aimed at curbing recreational use of opioid analgesics.

Physicians and advocates for pain patients hailed the FDA's proposal for addressing the growing opioid abuse problem while not impeding legitimate access to pain treatment.

Fatal poisonings from opioid overdoses tripled to nearly 14,000 deaths from 1999 to 2006, the Centers for Disease Control and Prevention reported in September 2009. The tally of near-deadly incidents involving opioids is far higher and growing rapidly, as revealed in the CDC's June 18 *Morbidity and Mortality Weekly Report.*

Emergency department visits related to misuse of prescription or over-the-counter drugs doubled from 500,000 in 2004 to 1 million in 2008, said the report, based on estimates from the Substance Abuse and Mental Health Services Administration's Drug Abuse Warning Network. DAWN generated the estimates by reviewing data and medical charts submitted by 231 U.S. emergency departments.

Illegal drugs such as cocaine and heroin were involved in 1 million ED trips annually, a figure that stayed flat over the time period.

Opioids were the prescription drugs most likely to land users in the emergency department, accounting for an estimated 305,885 visits in 2008, more than double the 2004 estimate of 144,644. People who misuse opioids are vulnerable to respiratory depression and can become unresponsive quickly, experts said. They eventually may stop breathing and experience cardiac arrest.

As physicians have moved to treat acute cancer and chronic pain more aggressively using opioids, the opportunity for recreational use of the drugs has grown, said Susan E. Foster, vice president of policy research and analysis at the National Center on Addiction and Substance Abuse at Columbia University in New York.

**ED visits from prescription drug misuse grew from 500,000 in 2004 to 1 million in 2008.**

"Availability and access, we know, leads to misuse," Foster said. "These drugs are there for the taking in medicine cabinets across the country. ... People seem to be more comfortable using prescription drugs than street drugs because they are prescribed by a doctor and approved by the FDA. But the logic isn't good, because the safety doesn't extend to their misuse."

In February 2009, the FDA announced that for the first time it would require manufacturers of an entire class of drugs -- long-acting and extended-release opioids such as fentanyl and oxycodone -- to comply with plans known as Risk Evaluation and Mitigation Strategies to ensure that their products are used safely.

"The misuse and abuse of long-acting and extended-release opioid drug products has resulted in a widespread and serious public health crisis of addiction, overdose and death," wrote Bob A. Rappaport, MD, director of the FDA Division of Anesthesia and Analgesia Products, in a letter in June to two agency advisory committees that will meet publicly July 22-23 in Adelphi, Md., to consider the proposal. The agency declined an interview request.

The FDA plan would require manufacturers to step up their efforts to educate physicians and patients about the dangers of the drugs through medication guides, patient education sheets and continuing medical education courses. The companies would be responsible for working with independent CME providers to offer training for physicians and other prescribers on "appropriate patient selection, dosing and patient monitoring," as well as "patient counseling on the safe use, storage and disposal of opioids."

Drugmakers would be required to survey doctors to show that their knowledge of appropriate opioid prescribing practices has improved. However, the plan does not require physicians to receive training or take opioid-related testing before prescribing the drugs, an idea the FDA had considered previously. The plan also rejects a proposal to require that manufacturers develop registries to track patients who take opioids.

America's top-selling opioid, the extended-release form of oxycodone marketed as OxyContin, recorded $2.9 billion in 2009 sales for Stamford, Conn.-based manufacturer Purdue Pharma, according to the prescription data analysis firm IMS Health. A Purdue Pharma spokeswoman declined to comment on the FDA's proposal, saying the company is part of an industry-wide group reviewing the plan.

**Avoiding obstacles**

Pain specialists responded with relief that the FDA proposal does not mandate opioid training for physicians.

"I'm quite impressed with how thoughtful and circumspect the FDA has been with an issue that is highly charged and highly polarized," said Scott M. Fishman, MD, who chairs the American Academy of Pain Medicine's Legislative & Regulatory Affairs Committee.

**Opioid abuse accounted for 306,000 ED visits in 2008.**

A training mandate would have created "a new obstacle to care for people who need pain management because of the tendency of doctors to opt out of that kind of system," said Dr. Fishman, chief of the pain medicine division at the University of California, Davis, Health System.

"It's important that all clinicians who use opioids have a certain level of knowledge on how to use them appropriately," said Seddon R. Savage, MD, president of the American Pain Society, a multidisciplinary group of 3,500 physicians and other...
pain specialists. "But I also think it's important that it's a professional standard, and not something that's legislated, because it's our responsibility as a medical community to uphold our standards."

The American Pain Society worked with AAPM to release the first comprehensive guidelines on treating chronic noncancer pain in the Feb. 6, 2009, *Journal of Pain*. The society recently convened several other organizations to develop a consensus on opioid-prescribing educational content that could help drugmakers meet the FDA's proposed training requirement.

Since 2003, the American Medical Association has offered a 12-module accredited CME series on pain management and handed out more than 220,000 module certificates to more than 20,000 physicians who completed the online classes. The AMA is working with the National Institute on Drug Abuse to develop CME this year on substance addiction treatment.

In a June 30, 2009, letter sent jointly with 14 other physician organizations, the AMA said mandatory certification for opioid prescribing should be used only as a "last resort." The Association said it plans to file comments in response to the FDA's proposal.

Will Rowe, executive director of the American Pain Foundation, a nonprofit advocacy group for pain patients, said the FDA has taken a "reasonable, rational route" to reducing opioid abuse while protecting access to pain care. "They have emphasized prescriber and patient education in a way that it should be emphasized, and they have limited the restrictions and the mandates that could have been in there," he said.

The foundation in August will launch a $1-million-a-year initiative called PainSAFE (Safe Access for Everyone) aimed at educating patients on proper use and disposal of opioids and other drugs and devices used to treat pain.

Experts noted that just a small fraction of opioid abusers get medicines directly from physicians. According to the 2008 National Survey on Drug Use and Health, only 7% of people who misused oxycodone in the past year said they got it from a doctor. Seventy-six percent of users bought or stole the drugs from a friend or relative, or received the opioids as gifts.

Physicians and other health professionals should do more to tell patients, especially parents, about the dangers of letting their opioids get into others' hands, said Columbia University's Foster. "There is a role for the public health community," she said. "You, as a parent, may safeguard your gun or your alcohol from your kids in order to protect them, yet you are just leaving your prescription drugs out there for the taking."

This content was published online only.

### ADDITIONAL INFORMATION:

#### Rising toll

The number of emergency department visits related to abuse of prescription drugs doubled between 2004 and 2008. It now rivals the number of ED trips caused by illicit drug use.

<table>
<thead>
<tr>
<th>Type of drug misused or abused</th>
<th>2004</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Illicit drugs</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>All prescription or OTC drugs</td>
<td>500,000</td>
<td>1.0 million</td>
</tr>
<tr>
<td>Opioid analgesics</td>
<td>144,644</td>
<td>305,855</td>
</tr>
<tr>
<td>All drugs</td>
<td>1.6</td>
<td>2.0</td>
</tr>
</tbody>
</table>


#### Where abusers got their drugs

Only a small fraction of people who misuse opioids such as oxycodone secure them directly from physicians.

- 34% - Gift; friend/relative got from physician(s)
- 31% - Bought/took from a friend/relative
- 13% - Bought from drug dealer or other stranger
- 11% - Gift; friend/relative got from elsewhere
- 7% - Got from physician(s)
- 4% - Stole from pharmacy/wrote fake prescription/Internet pharmacy
- 100%

Source: “2008 National Survey on Drug Use and Health: National Findings,” Dept. of Health and Human Services Substance Abuse and Mental Health Services Administration Office of Applied Studies, September 2009 ([www.oas.samhsa.gov/nsduh/2k8nsduh/2k8results.cfm](http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8results.cfm))

**WEBLINK**

"Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs, United States, 2004-2008," *Morbidity and Mortality Weekly Report*, June 18 ([www.cdc.gov/mmwr/preview/mmwrhtml/mm5923a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5923a1.htm))

"Briefing Information for the July 22-23, 2010, Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee," Food and Drug Administration ([www.fda.gov/advisorycommittees/committeesmeetingmaterials/drugs/anestheticandlifesupportdrugsadvisorycommittee/ucm217507](http://www.fda.gov/advisorycommittees/committeesmeetingmaterials/drugs/anestheticandlifesupportdrugsadvisorycommittee/ucm217507))


Pain management CME series, American Medical Association (www.ama-cmeonline.com/pain_mgmt)


"2008 National Survey on Drug Use and Health: National Findings," Dept. of Health and Human Services Substance Abuse and Mental Health Services Administration Office of Applied Studies, September 2009 (www.oas.samhsa.gov/nsduh/2k8nsduh/2k8results.cfm)

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