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F.D.A. to Place New Limits on Prescriptions of Narcotics

By [GARDINER HARRIS](#)

WASHINGTON — Many doctors may lose their ability to prescribe 24 popular narcotics as part of a new effort to reduce the deaths and injuries that result from these medicines' inappropriate use, federal drug officials announced Monday.

A new control program will result in further restrictions on the prescribing, dispensing and distribution of extended-release opioids like OxyContin, fentanyl patches, methadone tablets and some morphine tablets.

These products are classified as Schedule II narcotics and already are restricted according to rules jointly administered by the [Food and Drug Administration](#) and the Drug Enforcement Agency. But the current restrictions have failed to "fully meet the goals we want to achieve," said Dr. John K. Jenkins, director of the F.D.A.'s new drug center.

"What we're talking about is putting in place a program to try to ensure that physicians prescribing these products are properly trained in their safe use, and that only those physicians are prescribing those products," Dr. Jenkins said in a news conference on Monday. "This is going to be a massive program."

Hundreds of patients die and thousands are injured every year in the United States because they were inappropriately prescribed drugs like OxyContin or [Duragesic](#) or they took the medicines when they should not have or in ways that made the drugs dangerous. The agency has issued increasingly urgent warnings about the risks, but the toll has only worsened in recent years.

The blame for this is shared among doctors who prescribe poorly, patients who pay little attention to instructions

or get access to the medicines inappropriately, and companies that have marketed their products illegally.

The F.D.A. this year will hold meetings with manufacturers, patient and consumer advocates, and the public to ask for advice on how to carry out the new control program, officials announced. The first meeting will be on March 3, and no immediate changes in access to the drugs is planned.

The 24 medicines under review had 21 million [prescriptions](#) written for them in 2007, to 3.7 million patients, Dr. Jenkins said. They are extremely effective in reducing pain, which many medical studies suggest is widely undertreated in patients suffering serious illness. ([A complete list of the drugs](#) is at www.fda.gov/cder.)

But many doctors prescribe the drugs far too cavalierly, Dr. Jenkins said. The F.D.A. has received reports of patients' being prescribed such medicines to treat something as simple as a sprained ankle, he said. In such patients, the medicines can be dangerous.

Part of the problem is marketing. Several reports, for instance, have suggested that Purdue Pharma, the maker of OxyContin, helped fuel widespread abuse of the drug by aggressively promoting it to general practitioners not skilled in either pain treatment or in recognizing [drug abuse](#).

The company has denied such a connection, but a holding company connected with Purdue and three top Purdue executives pleaded guilty last year to criminal charges that the company had misled doctors and patients by claiming for five years that OxyContin was less prone to abuse because it was a long-acting narcotic.

Doctors are also to blame. A common reason for disciplinary actions at state medical boards is the use of narcotics in patients who show clear signs of addiction or for whom the drugs are obviously inappropriate.

The F.D.A. generally avoids interfering with the practice of medicine because doctor behavior is governed by state medical boards. Instead, the agency usually tries to provide doctors with the best and most current information, and then allows them to decide how to use it.

Most of the drugs withdrawn over the last 20 years, however, were taken off the market because doctors continued to use the medicines in ways that the F.D.A. warned against.

For decades, the agency’s armory in these battles held only a popgun and a cannon — the popgun being the issuance of widely ignored warnings; the cannon being its ability to force a medicine’s withdrawal. But a law passed in 2007 gave the agency a new, intermediate weapon — Risk Evaluation and Mitigation Strategies. Known as REMS, these programs allow the agency to place strong restrictions on the distribution of certain drugs.

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