

# New FDA program adds to tools to curb opioid abuse in United States

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A new risk management plan from the U.S. Food and Drug Administration to help clinicians properly prescribe drugs with addiction potential aims to help reduce the growing epidemic of opioid abuse in the United States. With deaths associated with these drugs, often sold illegally, now reaching toward 14,000 each year – including the fatal shootings of two Philadelphia teenagers last week in a house where police found large quantities of Percocet and morphine, prescription drug pads, and more than \$100,000 in cash -- the authors of a Viewpoint piece in the new issue of the *Journal of the American Medical Association* say the new plan represents a promising opportunity to cut the amount of addictive prescription drugs in circulation for sale and abuse.

The authors, medical toxicologists Jeanmarie Perrone, MD, an associate professor of Emergency Medicine in the Perelman School of Medicine at the University of Pennsylvania, and Lewis S. Nelson, MD, a professor of Emergency Medicine at the New York University School of Medicine, highlight the FDA's new Risk Evaluation and Mitigation Strategy (REMS), which seeks to manage and prevent the serious risks of misuse and addiction associated with long-acting and extended-release opioids such as OxyContin.

The plan, adopted in early July, includes requirements for prescriber continuing education and patient counseling. A separate REMS for fentanyl lozenges and nasal sprays has also been implemented, requiring a patient-prescriber agreement outlining the expectations and

responsibilities for using the drugs safely.

In addition to rolling out the new REMS in a way that's easy and quick for prescribers to use, the authors support a closer look at evidence associated with the true efficacy and risks associated with using opioids for chronic noncancer pain, which has been a large driver of increased prescriptions for these medications over the past 20 years. They also call for a revision of drug labeling to reflect the latest science about risk-benefit information and the most appropriate uses of the medications, a move that was also urged in a petition to the FDA signed by physicians and public health activists last week. The authors also suggest the creation of a REMS for short-acting opioids, which studies have shown is widely associated with nonmedical use.

"There is no single magic bullet for addressing opioid abuse in the community, which has become an enormous public health problem. But we are optimistic that this is the first of several steps needed to enhance safe prescribing of these powerful drugs," Perrone says.

Dr. Perrone is available to discuss opioid abuse and misuse, proper prescribing methods and indications for use of these drugs, and efforts to curtail the [epidemic](#) of opioid abuse and deaths, such as REMS and state-run prescription [drug](#) monitoring programs.

Provided by University of Pennsylvania School of Medicine

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