FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to help prevent new addiction, curb abuse and overdose related to opioid products

For Immediate Release

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Statement

The issue of opioid misuse and abuse remains one of my highest priorities and we believe it's going to take carefully developed, sustained, and coordinated action by everyone involved to reduce the tide of opioid addiction and death afflicting our communities; while maintaining appropriate prescribing for patients in medical need. We recognize both the urgency and complexity of this crisis and are taking several steps today toward these goals.

Today, at a **Part 15 hearing (/NewsEvents/MeetingsConferencesWorkshops/ucm583543.htm)** on this issue, we're gathering a broad group of stakeholders, both private and public, to seek feedback on how the agency can strengthen our oversight of opioids.

I'm encouraged that we have voices representing patients, industry, academia, and advocacy organizations, as well as provider groups and professional societies. I'm deeply committed to helping families, caregivers, and patients grapple with this crisis.

That's why today we also took a fairly unprecedented and novel action regarding an over-the-counter (OTC) product that we're concerned is contributing to the death toll associated with the opioid epidemic.

Since establishing the Opioid Policy Steering Committee in May, senior FDA leaders across the agency have been hard at work to ensure that we're leaving no stone unturned in our efforts to combat this immense public health emergency. With **11.5 million Americans (https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm#opioid3)** misusing prescription opioids in the past year and **more than 40 people dying every day (https://www.cdc.gov/drugoverdose/opioids/prescribed.html)** from overdoses involving prescription opioids, it has become abundantly clear that more vigilant action is needed from the FDA and others to get ahead of this crisis.

At the FDA, we believe one of our key roles in addressing the opioid epidemic is to reduce new addiction. We're exploring ways we can reduce exposure to opioids through our influence on prescribers, particularly through our Risk Evaluation and Mitigation Strategy (REMS) authorities. We're also actively exploring how we can use changes in packaging as a way to give providers better options for tailoring how much they prescribe to the clinical need. This is especially true when it comes to immediate release formulations of opioid drugs like Vicodin and Percocet, which are typically meant for short-term use.

If more immediate release opioid drugs, in particular, were packaged in three or six-day blister packs; then more doctors may opt for these shorter durations of use. Additionally, provided the FDA concluded that there was sufficient scientific support for these shorter durations of use, this could provide the basis for further regulatory action to drive more appropriate prescribing.

To illustrate the point: Suppose the dental community developed an expert guideline that said that no routine dental procedure should require more than a three or five-day initial fill of an immediate-release opioid, and the FDA reviewed and determined that blister packs in these quantities were necessary to ensure safe use. If the drugs were then packaged in blister packs that comported with these durations of use, it could help reduce overall dispensing. More doctors might more readily opt to prescribe these blister packs instead of other treatment options.

Today, toward these goals, we have taken a new action related to how one opioid product is packaged as a way to help address a growing problem of abuse and misuse of this product. The FDA is requesting that sponsors of OTC loperamide – an FDA-approved product to help control short-term symptoms of diarrhea, including Travelers' Diarrhea – change the way they label and package these drugs to stem abuse and misuse that leaves us deeply concerned.

Abuse of loperamide has been increasing in the United States. When used at extremely high and dangerous doses, it's seen by those suffering from opioid addiction as a potential alternative to manage opioid withdrawal symptoms or to achieve euphoric effects of opioid use. The maximum approved daily dose for adults is 8 milligrams per day for OTC use and 16 milligrams per day for prescription use. It's sold under the OTC brand name Imodium A-D, as store brands, and as generics.

Loperamide is safe at these approved doses. But when higher than recommended doses are taken we've received reports of serious heart problems and deaths with loperamide, particularly among people who are intentionally misusing or abusing high doses. The majority of reported serious heart problems occurred in individuals who were intentionally misusing and abusing high doses of loperamide.

The FDA added a warning to the product label in the spring of 2017 to warn of ingesting high doses of loperamide, including from abuse and misuse. Evidence suggests that package limitations and use of unit-dose packaging may reduce medication overdose and death.

Today we sent letters to the OTC manufacturers requesting that they implement changes consisting of packaging limitations and unit-of-dose packaging. We're requesting that packages contain a limited amount of loperamide appropriate for use for short-term diarrhea according to the product label. One example is a single retail package containing eight 2-milligram capsules in blister packaging. We asked the manufacturers to take the necessary steps to implement these changes in a timely fashion to address these public health concerns.

I also plan to reach out to those who distribute loperamide online, through retail web sites, to ask them to take voluntary steps to help us address this abuse issue. The new packaging should help make limits on sales more easily achieved. The abuse of loperamide requires the purchase of extremely large quantities. Often this is done through the purchase of large bottles of loperamide, which is a common configuration in which the pill form of the medication is currently packaged. Today's action is intended to change how the product is packaged, to eliminate these large volume containers. We know that many of the bulk purchases of these large volumes are being made online through major online web retailers.

I believe anyone who is distributing health care products has an obligation to be a partner in helping address the most pressing public health challenges like opioid abuse. If you're selling a drug with the potential for abuse and misuse through an online website, you're no longer in the business of selling widgets, or books. You have a social contract to take voluntary steps to help address public health challenges.

But this isn't our only action today. I'm also pleased to announce that we posted the revised and updated Blueprint, "**Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (https://www.regulations.gov/contentStreamer?documentId=FDA-2017-D-2497-0683&attachmentNumber=1&contentType=pdf)**," which contains core educational messages for health care providers involved in the treatment and monitoring of patients with pain. It also includes more information on pain management, including the principles of acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic).

All of these steps are meant to help ensure appropriate use of opioids as they're intended. But there is much more to do and we are mindful that any intervention the FDA considers should minimize the burden on appropriate patient access and, to the extent practicable, on the delivery system – which brings me back to today's hearing and why stakeholder feedback is so important.

Engaging with stakeholders is critical to our success. That's why, following the hearing and discussion today, we welcome and strongly encourage the public to submit electronic or written comments to the docket until March 16, 2018. Many already submitted comments to our previous Federal Register notice, and we're currently carefully reviewing the more than 900 comments received. We look forward to reviewing the submitted comments from this meeting. Our discussion will also continue on Feb.15 in collaboration with the Duke Margolis Center for Health Policy, through a **public workshop (https://healthpolicy.duke.edu/events/public-workshop-strategies-promoting-safe-use-and-appropriate-prescribing-prescription)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** exploring strategies for promoting the safe use and appropriate prescribing of prescription opioids. This feedback, and continued engagement, will inform what more the FDA could be doing to stem the opioid crisis while helping to maintain safe, effective, and appropriate prescribing for patients who need it.

Appropriate prescribing practices, better packaging, and education are important steps within our statutory authority to help address the human and financial toll of opioid addiction. They can reduce harm while still providing effective pain management protocols. Today's Part 15 hearing, and the new actions I mentioned, are indicative of the kinds of steps we need to take as we confront this epidemic.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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