

STATEMENT
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BEFORE THE
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES

**“COMBATTING THE OPIOID CRISIS:
PREVENTION AND PUBLIC HEALTH SOLUTIONS “**

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Good morning Chairman Burgess, Ranking Member Green, and members of the subcommittee. Thank you for the opportunity to be here today to discuss the Food and Drug Administration's (FDA or the Agency) role in combating our nation's ongoing crisis of opioid addiction. This is one of the most profound public health challenges facing our country. We need to work together, and consider more active and creative steps, if we're going to make significant inroads against this tragic epidemic.

The issue of opioid misuse and abuse remains one of my highest priorities. We believe it will take carefully developed, sustained, and coordinated action by everyone involved to adequately address the addiction and death afflicting our communities. At the same time that we take steps to reduce the rate of new addiction and address the medical needs of those currently addicted, we also need to make sure that our regulatory steps maintain appropriate prescribing for patients in medical need. We recognize both the urgency and complexity of this crisis. We are committed to reexamining all of our authorities as FDA considers what further steps the Agency can take.

Steps to Address Abuse and Misuse of Prescription Opioid Analgesics

The scope of the epidemic is much larger than FDA's purview, but we know FDA has a critical role to play. We have asked ourselves how our authorities can be used most effectively to address this unprecedented problem. This is especially true when it comes to helping make sure that fewer people become addicted through the medical use of these drugs. It's true that the epidemic is shifting to street drugs. A growing number of people will have their first exposure to opioids through heroin, illicit fentanyl, or other illegal drugs. But a large percentage of people who will become addicted to opioids will still have their first exposure through a lawful medical prescription. Often that first prescription will be for an immediate release formulation of these drugs. At FDA, we can impact both routes to new addiction. On the one hand, our regulatory oversight of lawfully prescribed drugs gives us some important opportunities to impact prescribing in ways that can reduce the rate of new addiction while making sure patients with medical needs have access to appropriate therapy. FDA also plays an important role in the interdiction of unlawful drugs, in particular, illegal drugs that are shipped through International

Mail Facilities. We want to make sure that across the full scope of our portfolio, we are doing everything we can to vigorously address this public health crisis.

Some percentage of patients who are prescribed opioids will develop an addiction to these drugs. Addiction is characterized by a pronounced craving for the drug, obsessive thinking about the drug, erosion of inhibitory control over efforts to refrain from drug use, and compulsive drug taking. This is very different than physical dependence on opioids. The repeated administration of any opioid almost inevitably results in the development of tolerance and physical dependence. These short-term results of physical dependence from repeated opioid administration require dose tapering. We have taken steps to address both the risk of addiction and physical dependence. We recently announced our intention to expand our risk management plans, known as Risk Evaluation and Mitigation Strategies or REMS, to incorporate, for the first time, all opioid analgesics that are intended for use in the outpatient setting, including the immediate-release formulations. We have revised the associated Blueprint¹ for how providers should be educated about pain management in general, and prescribing opioid analgesics specifically. And we are requiring that this training be extended to all providers likely to come into contact with patients who are prescribed these medicines, including nurses and pharmacists.

FDA also is taking immediate action when needed, as we did with FDA's first-of-its-kind request to remove a marketed opioid pain drug from sale due to the public health consequences associated with the product's abuse. We are also looking closely at certain opioids that may have a higher abuse potential. This includes oxycodone, an active ingredient in certain opioid drugs. If we were to determine, through a scientific process, that a particular opioid drug was more prone to abuse, and addiction, we would consider taking additional regulatory steps.

We believe one key to reducing the rate of new addiction is to rationalize prescribing, to help make sure that patients are prescribed opioids only when medically indicated. When a prescription is written, it should be for a dose and duration of use that comports closely with the clinical purpose. We are considering several potential strategies to promote proper opioid

¹ <https://www.regulations.gov/contentStreamer?documentId=FDA-2017-D-2497-0683&attachmentNumber=1&contentType=pdf>.

prescribing and dispensing that involve new measures with respect to how opioid products are packaged and labeled, and how providers are educated about their proper prescribing.

In December, FDA hosted a public workshop on the role of packaging, storage, and disposal options within the larger landscape of activities aimed at addressing abuse, misuse, or inappropriate access of prescription opioids. We discussed, among other topics, how new types of packaging, such as unit dose blister packs, could encourage prescribers to opt for shorter durations of use, thereby limiting the number of opioids dispensed to patients. This could reduce overall exposure, and potentially the rate of new addiction. This could also address the problem of excess supply in the U.S., as there would be fewer pills left in medicine cabinets that could be inappropriately accessed by family members, including children. Moreover, provided FDA concluded there was sufficient scientific support for shorter durations of use, this could provide the basis for further regulatory action to drive more appropriate prescribing.

Such measures would have a goal of reducing the number of doses dispensed, and reducing the risk of leftover pills that can be inappropriately diverted. Using our Sentinel database and contracts with external researchers, FDA has assessed opioid analgesic dispensing and refill patterns by medical indication and provider specialty. This analysis is still ongoing, but preliminary results give FDA some important insight into the amount of opioid analgesic that patients appear to need to control acute pain, by medical indication. FDA also reviewed published literature to get additional insights into the number of pills dispensed, used, and left over by patients who are prescribed opioid analgesics for different medical indications. These analyses are important applications of the resources dedicated to our post market safety efforts, including use of the Sentinel database to answer questions to inform regulatory policy. We will aim to make our findings available in future publications, but the operative point is that FDA can pursue analyses to guide policy making. Resources dedicated to more routine analyses of this kind could allow us to more carefully tailor our policy efforts to avoid – although not eliminate – the risk that we create some unintended obstacles for patients who have an appropriate medical purpose for a longer duration of opioid analgesic use; and some unfortunate obstacles for the doctors and pharmacists who need to prescribe and dispense these medications. But we all must

come together and accept that there are no easy options and that properly addressing this crisis is going to require some shared commitments and sacrifice.

We are also considering the feasibility of incorporating new prescribing information in opioid analgesic labeling. If, for example, medical professional societies (the dental association, for example) were to create evidence-based guidelines on appropriate prescribing for different medical needs, and FDA reviewed the scientific support for these guidelines and determined that it was sufficient to support updates to product labeling, we could potentially use our current authority to adjust product labeling. If this type of information were incorporated into product labeling, it could be used as part of a framework for helping to ensure more appropriate prescribing and dispensing. In addition to labeling changes, if FDA determined that packaging opioid analgesics in blister packs in certain quantities was necessary to ensure safe use, FDA could also potentially require manufacturers to implement these packaging changes. We also recently requested that manufacturers of over-the-counter loperamide – an FDA-approved product to help control short-term symptoms of diarrhea – make packaging changes, such as the use of blister packs, in order to address issues related to the abuse and misuse of that product.

FDA is considering other new steps to better confront this crisis. Among other actions under consideration: Earlier this year, FDA held a public hearing to explore ideas for using our REMS authority to impact opioid prescribing practices. One idea under consideration by our Opioid Policy Steering Committee is requiring sponsors to ensure that prescribers provide specific documentation for a prescription above a specified quantity, such as a statement that the quantity prescribed is medically necessary for the patient. The Steering Committee is exploring evidence-based approaches that would encourage electronic prescribing as a mechanism for the prescriber to provide documentation of medical necessity before the drug is dispensed by the pharmacy, as well as how to leverage the current system of prescription drug monitoring plans (PDMPs) to improve safe opioid prescribing.

Steps to Address Illegal Narcotics and Interdiction

On the issue of illegal narcotics, such as illicit fentanyl, that are coming into the U.S. via international mail, FDA has taken action to enhance our operations at international mail facilities (IMFs). FDA plays an important role related to the interdiction work that takes place in the IMFs. When an illegal controlled substance is identified in the IMFs, our partners at Customs and Border Protection (CBP) will immediately seize it, such that products readily and initially identified as controlled substances will not come to the FDA investigators in these facilities. Instead, what FDA is tasked with opening, inspecting, and sometimes testing include products that are perceived to be illegally-imported FDA-regulated drug products; for example, if they are believed to be counterfeit drugs or unapproved drug products like kratom. But as part of our work to examine what initially are believed to be non-opioid drug products, we still identify a large amount of controlled substances, in some cases because they might be disguised as other kinds of drug products. To give you some statistics on the scope of the risk: From the end of September 2017 through January 2018, of about 5,800 suspicious packages that FDA was tasked with inspecting because they were suspected of containing illegal prescription or counterfeit drugs or dietary supplements, 376 were controlled substances, including opioids, and were referred back to CBP for seizure. In some measure, the FDA investigators are a last line of defense in the IMFs, working closely with CBP. As the sophistication of those trying to penetrate our mail facilities continues to increase, this represents a growing vulnerability.

To address these risks, last year, we tripled the number of import investigators we have in the IMFs, allowing us to nearly quadruple the number of suspicious packages that we're able to open and inspect. This has taken our footprint from 8 to 22 full time employees (FTEs), the maximum capacity that our space in these facilities allows. We took these steps by allocating additional resources to this mission that we were able to redeploy from other parts of our critical enforcement mission as part of our Office of Regulatory Affairs (ORA). As part of this effort, we also doubled the number of our Port of Entry Special Agents, our criminal investigators who cover ports and the IMFs, from 6 to 12.

Our aim is to stop, inspect, and test more packages that contain suspicious drugs.

As part of these efforts, we also increased our CyberCrime Investigative Unit. This unit now consists of 11 criminal investigators. This special team has specialized training in disrupting and dismantling the large online networks that manufacture and sell foreign unapproved and counterfeit drugs, including opioids, to the U.S.

Last spring, FDA's Office of Criminal Investigations announced a major takedown of a drug trafficking organization for involvement in manufacturing fake prescription drugs with fentanyl. FDA's CyberCrime unit assisted with this investigation and plays an integral role in a large percentage of all of FDA's criminal investigations. They are a critical and unique asset that we have already, and will continue to, invest in.

As the committee continues its efforts to address the opioids crisis, FDA looks forward to providing whatever support we can. Thank you again for the opportunity to testify today.