FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on steps to promote development of generic versions of opioids formulated to deter abuse

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Summary

FDA issues guidance on development of generic abuse-deterrent opioids

Statement

As we continue to confront the staggering human and economic toll created by opioid abuse and addiction, we're focused on taking actions that reduce the scope of new addiction by decreasing unnecessary exposure to opioids. At the same time, we also must take steps to help those with acute and chronic pain who need access to medicines, including opioids, get access to improved alternatives. Until we're able to find new non-opioid forms of pain management for those who need treatment for pain, it's critical that we also continue to promote the development of opioids that are harder to manipulate and abuse, and take steps to encourage their use over opioids that don't offer any form of abuse deterrence.

Opioids with abuse-deterrent formulations (ADFs) are intended to make certain types of abuse, such as crushing a tablet to snort or dissolving a capsule to inject, more difficult or less rewarding. To date, the U.S. Food and Drug Administration has approved 10 opioid drugs with these properties. But their uptake has been slow among doctors who are treating patients in pain. The reason for their more limited use is likely multifold. We know there can be a learning curve that comes with new technologies. Some prescribers may not be aware of the existence of these drugs, or may be uncertain of when to prescribe the abuse-deterrent versions. But we also know a significant barrier to use can be price. Because these new formulations are currently only available as brand-name products, they're inherently more expensive than the numerous non-abuse deterrent formulations that are also available in generic formulations.

Transitioning from the current market, dominated by conventional opioids, to one in which most opioids have abuse-deterrent properties, holds significant promise for a meaningful public health benefit. But to transition this market more quickly to the ADFs, and consider permanently withdrawing the older formulations that lack abuse-deterrent

features in the event these products were judged to be less safe – there are a number of factors we must consider. One of the factors that the FDA would consider relates to generic access. We must have the potential to improve access to the newer formulations, for appropriately selected and monitored patients, through the introduction of generic competitors.

In order to support this transition and encourage advancements in this area, today the FDA **issued a final guidance (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM492172.pdf)** to assist industry in their development of generic versions of approved ADF opioids. This guidance includes new recommendations about the type of studies companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. We're also taking additional steps beyond the new guidance to help developers of generic ADFs navigate the regulatory path to market as quickly as possible and make the review process more efficient and predictable. For example, we're developing appropriate, improved testing methodologies for evaluating complex features like abuse deterrence for both brand name (innovator) and generic opioid drug products. In addition, we're also taking a flexible, adaptive approach to the evaluation and labeling of ADF opioids.

These efforts also include the development of new tools for expediting the generic development of complex products. The same features that make drugs hard to manipulate and abuse also make these formulations more complex, and therefore harder to develop generic versions of. To provide a more efficient pathway for the generic entry of these and other complex formulations, the FDA is advancing new review policies. For example, the new guidance will now assist generic drug developers who meet with the agency to discuss scientific and regulatory issues before submitting their applications. These meetings will enable the FDA to clarify the agency's expectations early in the development process with the goal of reducing the time it takes to obtain approval. We'll be taking additional steps to facilitate the efficient entry of complex generic drugs in the near future.

Together, all of these efforts are aimed at creating a more robust path for applicants who plan to develop and seek approval of generic ADF opioids. Our goal is, when the use of any opioid drug product is appropriate, to make prescribing of these new formulations more commonplace. But let us be clear on one point. While these innovative formulations are designed to make it harder for people to manipulate the opioid drug so they can't be abused, it's important that prescribers and patients understand that these drugs are not "abuse-proof," and they do not prevent addiction, overdose, or death. To address these issues, among other steps, we're currently conducting a study to evaluate whether the nomenclature we use to describe these drugs, by labeling them "abuse deterrent," is accurately conveying their benefits.

We also recognize that the science of abuse deterrence is relatively new. Both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. That's why we're also focusing our efforts on determining how effective the current abuse-deterrent products are in the real-world setting and better understanding the attitudes and beliefs of health care professionals and those who are prescribed these products.

Further, all of these steps shouldn't be mistaken as an effort that will encourage more opioid use. Our goal is to decrease the rate of new addiction, and thus any unnecessary legitimate and especially illicit use of opioids. Rather, this is an effort designed to encourage the shift – only when opioids are clinically appropriate – from existing, easily abused products to those that are harder to manipulate.

This final guidance is one piece of the FDA's ongoing work aimed at finding solutions to combat the opioid crisis. This effort must include treatments for those who are already addicted. That's why we are also focusing new efforts on the development and promotion of medication-assisted treatments for addiction. As we balance the need to effectively treat pain with the public health emergency related to opioid addiction, we must find creative ways to prevent new cases of abuse and addiction.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, 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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Related Information

- **Guidance for Industry: General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products (PDF - 520KB) (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM492172.pdf)**
- **Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling (PDF - 226KB) (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf)**
- **Opioid Medications (/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm)**

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