Balancing Treatment for Chronic and End-of-Life Pain With Steps to Stem Opioid Misuse

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The opioid epidemic continues to take an emotional, physical and financial toll on Americans. The U.S. Food and Drug Administration is committed to taking every possible step to address the many facets of this complex public health crisis.

While we work to ensure appropriate and rational prescribing of opioids, we won't lose sight of the needs of Americans living with serious chronic pain or coping with pain at the end of life. They too face significant challenges.

So, as we consider new policy steps to address the opioid addiction crisis, the FDA remains focused on striking the right balance between reducing the rate of new addiction by decreasing exposure to opioids and rationalizing prescribing, while still enabling appropriate access to those patients who have legitimate medical need for these medicines.

Today, the FDA is holding a Patient-Focused Drug Development meeting to gather additional viewpoints directly from adult and pediatric patients living with chronic pain. We've asked them to share their perspectives on the impact of chronic pain on their everyday lives; treatment approaches using medications such as opioids, acetaminophen, non-steroidal anti-inflammatory drugs, antidepressants, as well as other medications; and non-pharmacologic interventions or therapies, including medical devices that can deliver local analgesia and reduce or obviate the need for systemic therapy.

We want to better understand the challenges or barriers patients face accessing various treatments for pain. We're hopeful that this meeting will provide valuable insights to inform our opioid policies and advance our efforts to develop better therapies.

Unfortunately, the fact remains that there are still too many prescriptions being written for opioids, and too many prescriptions written for long durations of use that aren't appropriate for the medical need for which the opioid is being prescribed. This presents a difficult challenge both for the FDA and for providers. We don't want to perpetuate practices that led to the misuse of these

drugs, and the addiction crisis. At the same time, we don't want to act in ways that are poorly targeted, and end up disadvantaging legitimate patients.

In most circumstances, opioids should only be used for the treatment of acute pain and prescribed for short durations of time. However, the FDA is aware that there are certain circumstances – such as in the treatment of metastatic cancer pain and the episodic treatment of migraine pain – where the drugs are administered over longer periods. In select patients and for certain medical conditions, opioids may be the only drugs that provide relief from devastating pain. We've heard from some of these patients, and listened carefully to their concerns about having continued access to necessary pain medication. We've heard their fear of being stigmatized as a person with addiction, and the challenges they face in finding health care professionals willing to work with patients with chronic pain. Tragically, we know that for some patients, loss of quality of life due to crushing pain has resulted in increased thoughts of or actual suicide. This is unacceptable. Reflecting this, even as we seek to curb overprescribing of opioids, we also must make sure that patients with a true medical need for these drugs can access these therapies.

At the FDA, we're taking a number of new steps to address the need to aggressively confront the epidemic of addiction, while advancing policies to help make sure that patients with pain have access to appropriate, evidence-based care.

Balancing the need to maintain access with the mandate to aggressively confront the addiction crisis starts with good medical management. All patients in pain should benefit from the skillful and appropriate care of their pain. It's also critical that we take this same aggressive approach to changing the culture of medicine around treating pain. The roots of this crisis are embedded in the practice of medicine, and prescribing practices that were at times too cavalier. A generation of providers dispensed these medicines too liberally, and were slow to address the signs of misuse and addiction. At the same time, we know that some manufacturers inappropriately promoted these drugs for unapproved uses. Patients in pain deserve thoughtful, careful and tailored approaches to the treatment of their medical conditions.

For example, we recently released the revised Blueprint of the core content for training that opioid drug manufacturers are required to make available to prescribers. This Blueprint includes information on acute and chronic pain management, safe use of opioids or other non-opioid or non-drug treatments, as well as material on addiction medicine and opioid use disorders. For the first time, we're requiring training to be offered on non-opioid alternatives for the treatment of pain, and extending this educational material to other health care professionals who participate in the treatment and monitoring of pain, such as pharmacists and nurses, in addition to prescribers. Once finalized later this year, together with the Opioid Analgesic Risk Evaluation and Mitigation Strategy, the Blueprint will apply – for the first time – to manufacturers of both immediate-release opioid analgesics intended for use in the outpatient setting and extended release and long-acting formulations of these drugs.

We're also taking new steps to encourage medical professional societies to develop evidence-based guidelines on appropriate prescribing of opioids for different medical indications. The FDA

will be working with these important stakeholders to help advance the development of these new, evidence-based prescribing recommendations.

Such guidelines can be used to inform providers about the appropriate duration of use for opioids for different common, acute indications such as their use as analgesics following different post-operative surgical procedures. Once these guidelines are available, they can help make sure that opioid prescribing more closely comports with clinical need. This can help reduce overall dispensing and, in turn, also limit exposure to opioids and reduce the rate of new addiction.

The guidelines developed by the U.S. Centers for Disease Control and Prevention (CDC) also provide helpful guidance to prescribers. The CDC guidelines reinforce the need to treat pain carefully and adopt opioids as a last resort medication for most conditions.

Additionally, the FDA recently launched an innovation challenge to spur development of medical devices – including digital health and diagnostics – that could provide novel solutions to treating pain. The agency also is planning to create a new series of guidance documents aimed at promoting the development of new drugs targeted to the treatment of various types of pain. This is in addition to efforts we're undertaking with the National Institutes of Health as part of a public-private partnership to identify areas of opportunity to advance pharmacological treatments for pain and addiction.

This work, which includes meetings with experts from across government, industry and academia, prioritizes efforts to: facilitate sharing data to focus future resources and research and spur innovation in developing new pain medications, including those that are non-addictive, as well as develop methods to objectively measure pain in patients.

Many say that we find ourselves in the situation we're in today – facing an epidemic of addiction – because as providers, we didn't sufficiently inform ourselves as a profession in the study and treatment of pain. We thought these drugs were less addictive than they turned out to be. And once we had evidence that they were fueling a crisis of addiction, we didn't act swiftly and forcefully enough. We need to be mindful of this history, learn from it and make sure that we act aggressively to confront new trends that may continue to fuel the current crisis or lead to a new epidemic of addiction.

This is why the FDA has taken steps to address the misuse of kratom and stem the flow of illegal opioids like illicit fentanyl that are being shipped through the mail. We have evidence that we'll release soon showing that based on a measure of morphine equivalents, the flow of illicit opioids, particularly fentanyl, dwarfs the entire market for prescription drugs. These statistics suggest that more of the new addiction is going to rise out of the use of illicit drugs, and more of those who become addicted following a lawful prescription could more quickly migrate onto illegal formulations such as fentanyls.

Given the magnitude of the current epidemic, we must act forcefully to confront these new turns in this crisis.

Our goal is to support more rational prescribing practices, as well as identify and encourage development of new treatment options that don't have the addictive features of opioids. In this way, we'll help ensure that we're not unnecessarily putting patients as risk of addiction by overprescribing opioids, while also maintaining appropriate access to care for patients with serious pain. In pursuing these goals, we must make sure that patients inform our work.

We thank the patient community for sharing their perspectives as we continue to confront this crisis. I look forward to hearing the insights from today's meeting, and will continue to take steps to help advance care for patients with pain.

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