Working Together to Reduce the Devastating Effects of Opioid Misuse

February 6, 2017 By Robert M. Califf

The public health crisis of opioid misuse, addiction and overdose is one of the most challenging issues the U.S. Food and Drug Administration has faced during my time as FDA commissioner. Solving this issue is critical to our future.

The issues cut across every socioeconomic level and geographic boundary. It would be difficult to identify any community in America that has not been touched by friends, family members or colleagues suffering from addiction, and far too often, losing their lives to it. As I leave the agency as part of the presidential transition, I have reflected on what I have seen, how far the nation has come, and the important work that remains for both the public and private sectors.

I've made it a point to see affected communities, first-hand, because interventions and national policy solutions work best when they are well informed by what communities actually need. Just last week, I visited Baltimore to better understand how our cities are being affected – in this case, by an inflow of illicit fentanyl, a synthetic opioid that is about 100 times more potent than many other prescription opioids, and can be deadly on its first use. I have also visited the neonatal intensive care unit, or "NICU" of a Tennessee hospital where babies were screaming and shaking in the pain of withdrawal because they were born with Neonatal Opioid Withdrawal Syndrome. I have met people in West Virginia who did back-breaking work in power plants or in coal mines; after suffering on-the-job injuries they were first afflicted with pain, then by addiction. They got prescription pain relief but, too often, it wasn't accompanied by the proper support and counseling. In Kentucky, I spoke to spouses and families whose lives have been forever changed by addiction, even as the community rallied together to fight it. And, much closer to home, I have heard personal stories from FDA employees and providers in local health care facilities, whose families and friends are not immune.

We have taken a number of actions at the FDA over the past several years to help reduce the number of people who become addicted, or who ultimately overdose from prescription opioids. We've improved product labeling, pushed for prescriber education, and encouraged the development of abuse-deterrent formulations. In addition, we have approved new intranasal and auto-injector forms of naloxone — products to reverse opioid overdoses, which can be administered by laypersons and are, therefore, better available able to save lives.

I'm also proud of the partnerships we have formed with other federal Agencies and the work that

has resulted from them. But the latest data, including data from the Centers for Disease Control and Prevention (CDC) remind us that while some progress is being made, there is more to do. For example, it is promising to see that the nationally estimated number of outpatient prescriptions dispensed for Schedule II opioids decreased by 10 percent in 2015 compared to the previous year, according to IMS Health. However, the CDC reports that while the rate of overdose deaths associated with prescription opioid use increased by just 4 percent instead of by 9 percent the previous year, deaths associated with heroin use have skyrocketed. Clearly, more work needs to be done.

As I prepare to turn over the awesome responsibility of FDA commissioner to the next Administration, I feel compelled to point out that public and private sector efforts in this area must be continued and strengthened. In particular, I want to call on the pharmaceutical companies that manufacture and sell these drugs to dig deeper into their expertise and resources to prioritize finding solutions to this public health problem. I have consistently been impressed that the motivation to cure disease and improve quality of life for patients is shared across the spectrum of federal agencies, public health workers, health care providers and scientists within the pharmaceutical industry. However, the financial incentives in the industry can lead to a focus on short-term profits instead of patient well-being.This is the time for both branded and generic drug companies to go beyond marketing and distribution plans and instead commit their expertise and resources to confronting the devastating negative consequences of a class of drugs that brings much needed pain relief, when used appropriately.

Specifically, I urge us all to focus on the following priorities:

1. Encouraging appropriate prescribing by healthcare practitioners. Too many people become addicted from unnecessary prescriptions for minor pain or injury. And even appropriately prescribed opioids can lead to addiction, so careful monitoring of patients prescribed these powerful drugs is needed. While there are situations where opioids are appropriate, there are also situations where other alternatives can be effective. Therefore, conversations between provider and patient about the pain treatment plan are imperative. If an opioid is appropriate, CDC guidelines and FDA labeling emphasize the need to start on the lowest dose and minimum time necessary, and carefully monitoring patients for signs of addiction and inadequate pain control.

2. Considering the family as well as the patient. Pain treatment, and use of opioid drugs, will be more successful when the family is involved. It will result in fewer drugs diverted from the medicine chest, fewer babies born addicted to opioids and better treatment of pain. Women who use or abuse opioids, or who are in treatment for opioid addiction, should talk to their health care provider before considering pregnancy.

3. Finding better ways to treat pain with new medications and with more holistic pain management. It’s time to put more resources into the development of non-opioid, non-addictive medications to help people who are in serious, debilitating pain. We need more research to define the most effective non-medication approaches to pain and how to deliver them in a complex and financially constrained healthcare system.

4. Improving how companies, professional societies and academics communicate about their activities in this area. I urge companies to commit to transparent and appropriate company communications and to work with government and others in the community to do a better job in

educating the medical professionals responsible for treating our nation's pain, as part of the overarching effort to do everything possible to help prevent addiction. Professional societies and academic medical centers also need to continue their efforts at educating their members and examining their practices to find ways to improve. For example, the education of the next generation of physicians about how best to manage pain is critical.

5. Finding new ways to curb diversion and misuse of opioids. In addition to our continuing efforts to help support the development of abuse-deterrent formulations, the FDA is exploring potential packaging, storage, delivery, and disposal solutions that companies and other stakeholders might consider that would prevent opioids from being diverted to those without a legitimate prescription for these powerful drugs. I implore companies to conduct research and offer their creative ideas and resources to innovate in this area.

6. Increasing pragmatic research to better understand how to implement appropriate pain therapy in general and use of opioids in particular. Post-market requirements from FDA that mandate industry-funded studies and recent pragmatic research efforts by the Patient-Centered Outcomes Research Institute and the NIH and Department of Defense are expected to provide important data, but we need more robust evidence to better guide practice. Pain is a vexing issue that seems to fall between the cracks in research funding; we need to keep the pressure on funding entities to move pain to the forefront as a research issue.

7. Treating addiction as a disease, not as criminal behavior. We have the tools to treat addiction and reverse overdose from opioids and are working to develop more of them. But there's a lot we don't know about the drivers for drug abuse, and scientific knowledge will help us make better decisions. This is one reason why we need companies with products on the market to monitor the safety of those drugs and make their data public. We have mandated post-market studies to define major questions about chronic use of opioids, and it is essential that industry fulfills these requirements.

I am proud to have been part of the effort that's changing the tide on this epidemic, but the nation has a long way to go.Government, companies, healthcare systems and healthcare providers all have important roles to play. The most recent data reminds us it's time to double down on these efforts. While I won't have the good fortune of leading this fight in an official capacity, I'm proud of the work the FDA and others have done so far. I leave FDA's efforts to the many leaders at the agency who have been working tirelessly on this issue — and will continue doing so — and look forward to supporting public and private efforts to bring this epidemic to an end.

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