3Qs: When painkillers kill

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The U.S. Food and Drug Administration recently introduced a series of safety measures designed to reduce the risk of extended-release and long-acting opioid medications, the abuse of which led to nearly 16,000 deaths in 2008. Northeastern University news office asked drug policy expert Leo Beletsky, an assistant professor of law and health sciences at Northeastern University, to expound upon the threat posed by opioid analgesics, 22.9 million prescriptions of which were dispensed last year.

The number of Americans who died from extended-release and long-acting opioid overdoses nearly quadrupled between 1999 and 2008, according to figures compiled by the Centers For Disease Control and Prevention. Why has opioid abuse increased over the last decade?

Starting in the 1980s, several major studies and reports shed light on the fact that far too many Americans suffered from unnecessary pain. This led to a growing recognition of inadequate access to effective pain medications, especially among cancer, AIDS and other seriously ill patients. Calls by professional organizations, policymakers, patient advocates and others raised awareness about this important problem, while the pharmaceutical industry invested heavily in formulating and marketing powerful pain medications to help meet patient needs. Opioids — drugs derived from, or synthetically mimicking the properties of the ancient drug opium — collectively serve as the best tool available to modern medicine in treating pain.

Over the intervening years, a steep rise in the prescription of now ubiquitous drugs such as OxyContin, fentanyl and Vicodin were critical to reduce the number of Americans living with pain. As they worked to expand opioid access, however, manufacturers, clinicians and policymakers failed to adequately recognize and mitigate the risks inherent to wider availability of these useful and powerful medications. One major risk is that these medications are very addictive to some people. The other is that they are incredibly efficient at slowing down our breathing, which in some cases can lead users to slip into a coma-like state and die.

The rise in fatal overdose documented in the CDC report clearly parallels the steep increase in the number of prescriptions issued for powerful opioid medications. There is a similar pattern reflecting the contemporaneous increase in pain medication access and abuse. Yet we have to be careful not to oversimplify the conclusions we draw from these trends.

When talking about this issue, I like to use the analogy of automobile safety. Over the course of the 20th century, the rise in car ownership led to radical improvements in our quality of life and economic prosperity, while making us increasingly dependent on (some would even say "addicted" to) automobiles. The number of car crash injuries and fatalities also rose sharply to become the leading cause of accidental death in the U.S. For a long time, this was seen simply as an unavoidable collateral cost of the "automobile revolution." But legislation, lawsuits and voluntary industry action have been very effective in curbing these risks through a number of mechanisms like speed limits, strict drunk driving policies, driver education, seatbelts and airbags. At a time when fatal opioid overdose is quickly overtaking car-related fatalities as the leading cause of death in many U.S. jurisdictions, coordinated policy, industry and health-care practitioner action is critical to mitigating the risks created by the wider availability of critically useful, but dangerous opioid drugs.

How has President Barack Obama's 2011 Prescription Drug Abuse Prevention Plan fared in curbing the abuse of prescription drugs, the second-most abused category of drugs after marijuana?

Clear signs of the prescription drug "problem," including prescription drug abuse and overdose, first emerged around 2007, but it took years for many public health agencies to mount any kind of meaningful response. The federal government has been especially sluggish, but the president's 2011 plan was a definitive step to recognizing these problems as a national crisis. The plan's focus areas (education, monitoring, medication disposal and enforcement) closely parallel the cocktail of strategies that have long formed the pillars of national drug policy for decades. Certainly, much of what is in this document makes sense and is long overdue. The plan, for example, argues that medical providers should be more educated about substance abuse problems, better-equipped to conduct screening and prepared to (and compensated for) engaging their patients on this topic.

But many of the tactics that are used to implement these strategies have yet to be shown to affect drug abuse because they are not sufficiently tailored to accomplish the stated goals (e.g., to reduce prescription drug overdose by 15 percent in five years). One example for this is the emphasis on prescription drug monitoring programs, which are systems (usually computer databases) that allow medical providers to track their patients' prescription and dispensing history for certain medications. Although they are possibly useful to help prevent "doctor shopping" and are certainly needed to address other systematic problems such as medication errors, these programs are probably not capable of making a significant dent in overdose rates. Public health data suggest that only a small fraction of overdose victims acquired their drugs through "doctor shopping."

It is also notable that the plan omits any discussion of overdose education, prevention and treatment. It also does not address any of the "root" consequences of prescription drug abuse and overdose, including poor access to—and inadequate quality of—healthcare and drug treatment services in many communities. Given Obama's stated interest in advancing a "public health approach" toward drug abuse, I think more work needs to be done in clarifying how this new approach differs from the ineffective strategies of the past and what innovative approaches are being proposed to address this emerging epidemic.

The Food and Drug Administration's plan to curb opioid abuse includes developing an education program for prescribers and updating the opioid medication guide for consumers. What would be your strategy for improving the safe use of opioids while ensuring access to prescription drugs for patients in pain?

Unfortunately, there are no simple answers to addressing opioid abuse and overdose. Strategies to combat these problems have to take a short-, medium– and long-term view. In the realm of opioid abuse, one key short– and medium-term strategy would be to increase funding for substance abuse screening and for short interventions in primary healthcare settings. A longer-term strategy would be to improve access to and quality of drug treatment services, which is something the present administration is working toward. We also have to acknowledge that a substantial portion of opioid drug abuse stems from unaddressed mental health, pain management, and healthcare access needs, as well as larger social problems such as underemployment. Such issues require big investments and broader political will that is in short supply as of late.

In the realm of overdose, the key short-term strategy is increasing public awareness about the risk factors of opioid abuse, signs and symptoms of an overdose, and what to do when an overdose occurs. Symptoms of overdose include blue lips and nails, shallow breathing, pinpoint pupils and slow or undetectable pulse. Unlike people who are merely nodding off, overdose victims do not wake up when their name is called or when shaken vigorously.

Among the medium-term strategies to address overdose is increasing availability of naloxone — an opioid inverse agonist drug — through pharmacies and its prescription by healthcare providers. Long-term strategies include the creation and distribution of a naloxone nasal spray or auto-injector device similar to an EpiPen. These kinds of user-friendly devices can facilitate wider availability and usability of naloxone (which is now only approved for intramuscular injection with a syringe). Ideally, naloxone should be available in all first aid kits, and certainly just as accessible as automated external defibrillators.

Opioid pain medications are an important medical tool, but they do not come without risks. Mitigating these risks will take a combination of policy, educational measures, changes in our health care and substance abuse treatment sectors and financial investments. As key stakeholders, drug companies should play an active role in addressing the social and public health "side-effects" that result from wider availability and popularity of their products.

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