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Making Opioid Drugs Less Alluring

Congress should act to continue the manufacture of tamper-resistant pills.

By LYNN WEBSTER

New York Mayor Michael Bloomberg announced last week that the city's emergency rooms will begin restricting patients to a three-day supply of opioid painkillers. The move is meant to counter rampant abuse of OxyContin and other drugs, often by addicts who get pills from family members or friends who receive more than they need from doctors. The Centers for Disease Control and Prevention estimates that 15,000 Americans die annually from opioids, either in suicides or accidental overdoses by addicts and non-addicts.

Given that opioids used in prescription drugs are a mainstay of treatment for millions of Americans with moderate-to-severe pain, how can the drugs be made safer? Part of the answer has to do with formulations of the drugs that are designed to slowly release them over

eight, 12 or 24 hours. Although an extended release has therapeutic value in many situations, until recently the pills could be crushed, making all of the opioid effective immediately and giving abusers the euphoria they sought.

The positive news is that now there are products with tamper-resistant features that make extended-release medication far more difficult to convert to an immediate, full dose of the drug. It is still early, but preliminary reports show that tamper-resistant opioids are less likely to be abused.

The Food and Drug Administration has already proposed that manufacturers be required to cooperate to educate all of the nation's more than 350,000 physicians on how to reduce the potential abuse and lethality of extended-release opioids.

But there is a major hitch. Just as it appears that industry has made some progress, albeit small, toward safer opioid formulations, patents are ending on drugs with tamper-resistant formulas—specifically Purdue's OxyContin and Endo's Opana. If the FDA and Congress fail to act, generic versions of extended-release drugs in their original formulations—without a tamper-resistance formula—are due to hit the market in early 2013.

If easily abusable formulations are made available again, why should users seeking a high not turn to them? Furthermore, what incentives will spur opioid makers to continue to formulate safer products?

Here is where Congress comes in. The Stop Tampering of Prescription Pills Act would prevent generics from being approved that are copies of older, more abuse-prone formulations. In effect, the Stopp Act would sidestep a Catch-22 that now confounds makers of tamper-resistant, extended-release opioids. When the companies developed the new versions, the manufacturers could not legally claim that the new formulas were tamper-resistant—because they had not yet met rigorous and time-consuming FDA testing requirements to prove that claim. Instead the makers of extended-release oxymorphone and oxycodone products simply replaced earlier versions of the medications with the new tamper-resistant ones.

The FDA's rule that reformulated products cannot carry labeling claims of tamper resistance until they have been on the market long enough to be sufficiently studied—plus a lack of clarity on what scientific standards tamper-resistant products must meet—is what allows generics to argue that their products are equivalent. Consider the possible harmful result when insurance companies and government payers inevitably place generics on a less-expensive tier than brand-name products, ensuring that patients and doctors are forced via pricing to use less-safe medications. The Stopp Act was designed to avoid these sorts of dilemmas, while helping prescribers differentiate the potential safety of the varying formulations.

Some argue that pharmaceutical companies wish only to safeguard their profits in blocking generics from issuing

earlier, non-tamper-resistant formulations. Maybe so—but what is the alternative? Allow recreational abuse and addictive behaviors to shift to the "old school" opioids with no attendant responsibility placed on the generic manufacturers?

The makers of certain extended-release opioids have risen to the call for safer formulations. There is wisdom in expecting makers of generics to abide by the same rules of safety.

With the power to relieve pain comes the danger of ending life if medications are improperly consumed or prescribed. Congress has before it a clear path that likely will prevent innumerable deaths. I hope lawmakers will take it.

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