Do stricter controls curb opioid abuse?

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Credit: AI-generated image (disclaimer)

Americans consume a staggering amount of the opioid painkiller hydrocodone - about 99% of the world's supply. In October, after 10 years of debate the Drug Enforcement Agency (DEA) reclassified medications like Vicodin, and products that combine hydrocodone with other drugs, as Schedule II controlled substances.

This means that the DEA can regulate them like almost all other prescription opioids, such as oxycodone and morphine. Doctors and other licensed subscribers must now write a new prescription each month for patients who need these drugs.

Before doctors could call prescriptions in by phone and could prescribe refills beyond a 30 day supply.

Debates about whether or not "rescheduling" of hydrocodone is a smart policy move depend upon who you ask, and what you believe, about the overall effects that this policy change will have on patients, providers and health systems.

Does reclassification curb abuse?

The general facts are clear. There have been unprecedented increases in opioid use and abuse. Hydrocodone sales increased 280% from 1997 to 2007. From 1999 to 2007, the number of unintentional overdose deaths involving opioid painkillers quadrupled.

In an epidemic of prescription painkiller addiction and abuse it seems odd that some painkillers are less strictly regulated than others. However, it is unclear how reclassifying opioid painkillers such as hydrocodone will affect rates of abuse and addiction, or injuries and deaths.

Surveillance data suggest abuse of hydrocodone combination products, like Vicodin, are less likely to result in death compared to other prescription opioids.

From 1998 to 2002 the rate of emergency department (ED) visits and deaths related to oxycodone, per 1 million prescriptions was up to three times higher than the rate for hydrocodone. Similarly, in 2004-2006 the rate of ED visits and deaths per 1 million prescriptions of oxycodone

was about 3.5 times higher than the rate for hydrocodone combination products. However, this doesn't refute arguments for stricter reclassification.

Vicodin, for instance, has been the top selling drug by volume in the United States for years and many abusers may transition from fixed-dose combination hydrocodone to stronger forms of prescription opiates, like oxycodone.

Whether or not reclassifying hydrocodone curbs abuse and addiction depends on a variety of factors. Our prior work suggests that the impact of the FDA's regulatory actions is unpredictable.

For example, some information released by the FDA in its so-called "drug risk communications" has had immediate and strong impacts. These communications are meant to help prescribers make more informed decisions, but many of these risk communications had either delayed or no impact on health care behaviors. With reclassification, we'd expect to see some decrease in the distribution and sales of hydrocodone relative to other painkillers. What we don't know is how significant that decrease will be.

There are many alternative drugs that might be more appropriate to treat certain kinds pain instead of hydrocodone products – from opioids such as tramadol (Ultram) to non-opioid pain treatments.

The effect of rescheduling on other significant and long-term outcomes, such as injuries and deaths from prescription opioids, is even more difficult to know, due to the number of factors that drive such phenomena.

Limiting access?

Given the limitations imposed on Schedule II controlled substances, one natural concern is that hydrocodone will be harder to access for patients who legitimately need it.

This argument has been used against nearly all efforts to date to rein in epidemic rates of abuse and death from prescription opioids. In January last year a representative from the Generic Pharmaceutical Association told the FDA Drug Safety and Risk Management Advisory Committee that placing drugs in Schedule II could significantly impact patients by making these medications less accessible.

But, the DEA highlights the sheer volume of opioids prescribed and consumed by Americans, and the rising number of overdoses and deaths related to prescription opioids. For example, by 2008, the annual number of fatal drug poisonings surpassed those of motor vehicle deaths. In public hearings held by the FDA, the strength of these counter-points is only magnified by tearful pleas of parents who have lost children to opiate addiction.

Because of these important perspectives from so many different stakeholders, it is critical that public health agencies and researchers closely track and assess the real impact of hydrocodone's rescheduling on the opioid epidemic, as well as pain treatment. The stakes couldn't be higher.

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