

Is the DEA Branching Out Into Regulating Medicine?

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The Drug Enforcement Administration, having virtually eliminated the diversion of prescription pain relievers into the underground market for nonmedical users, appears to be setting its sights on regulating the medical management of pain, a mission not suited for law enforcement. Acting under the authority of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), the DEA [announced](#) [2] a proposal to reduce, once again, the national production quotas for fentanyl, morphine, hydromorphone (Dilaudid), oxycodone, and oxymorphone, bringing the production levels down 53 percent from 2016 levels.

The September 12, 2019 new quota [proposal](#) [3] from the DEA states (Federal Register page 48172):

*As a result of considering the extent of diversion, DEA notes that the quantity of FDA-approved drug products that correlate to controlled substances in 2018 represents **less than one percent** of the total quantity of controlled substances distributed to retail purchasers.(emphasis added)*

The ostensible purpose of the production quotas is to reduce the amount of prescription opioids

that get diverted into the underground market. As has been clearly [demonstrated](#) [4], the overdose rate from the nonmedical use of licit and illicit drugs has been on a steady, exponential increase since at least the late 1970s, with the only variation being the particular drug in prominence at any given period. As opiophobia receded in the 1990s, opioid prescribing increased, with prescription volume tripling from 1999 to 2015. The drug of choice for nonmedical users during the early part of this century became diverted pain relievers, which then became a dominant component of the opioid-related overdose statistics. Concerted efforts by policymakers to reduce opioid production and prescribing led to a 58 percent reduction in per capita high-dose opioid prescription volume from [2008 to 2017](#) [5] while total opioid prescription volume dropped [29 percent](#) [6] from 2010 to 2017. Despite these reductions, the overdose rate continued to surge. It increased [13 percent](#) [7] between 2016 and 2017, although preliminary data suggests the overdose rate might be starting to [level off](#) [8].

[Overdose deaths soared while prescription volume dropped](#) [9] as nonmedical users migrated to cheaper and more readily available heroin and now fentanyl. Between 2011 and 2017 the proportion of opioid-related overdose deaths due to prescription pain relievers dropped precipitously while those due to heroin and fentanyl surged. Preliminary data for 2018 point to this trend continuing. The share of opioid-related deaths involving [fentanyl](#) [7] rose from 14 percent in 2010 to 60 percent in 2017. Based on [data](#) [10] from the Centers for Disease Control and Prevention, fentanyl or heroin was involved in 75 percent of opioid-related deaths in 2017. Just 30 percent involved prescription opioids, down from 52 percent in 2010, but 68 percent of those cases also involved heroin, fentanyl, cocaine, barbiturates, benzodiazepines, or alcohol—meaning *fewer than 10 percent* of opioid-related deaths involved prescription opioids without those other dangerous substances.

Set aside the evidence that reducing the amount of prescription opioids available for diversion helped drive up the overdose rate by driving nonmedical users to more dangerous substances. With the DEA telling us that less than 1 percent of prescription opioids are currently diverted into the black market, why is it necessary for the DEA to tighten quotas even further?

Aside from the apparent desire of law enforcement to regulate the practice of medicine, there can be no justification for the continued reduction in opioid manufacturing --unless it is based upon the belief that the prescription opioids are producing all of the heroin and fentanyl addicts by "hooking" patients on opioids.

Such a belief ignores the evidence. According to data from the CDC and the National Survey on Drug Use and Health there is [no correlation](#) ^[11] between prescription volume per capita and “past month nonmedical use of prescription pain reliever” or “pain reliever use disorder in the past year” among persons aged 12 or above. The NSDUH repeatedly reports [that less than 25 percent](#) ^[12] of nonmedical users of prescription opioids get them through a doctor—most get them from a friend, relative or dealer. And a classic [study](#) ^[13] in 2007 that examined OxyContin addicts admitted to rehab between 2001 and 2004 found 78 percent claimed the drug had never been prescribed for them, and 92 percent used OxyContin in conjunction with multiple other drugs—cocaine being the drug 66 percent of the time. Also notable is that 78 percent reported previous treatment for substance use disorder.

The continued clampdown by the DEA also shows a complete lack of understanding about the nature of [addiction](#) ^[14]. Addiction is a disorder characterized by compulsive use despite negative consequences. The etiology and pathogenesis of addiction involves psychological trauma during early development, and a significant association with psychoneurological comorbidities, often with genetic and epigenetic connections. Addiction is not the same as physical dependence. And addicts are not “[possessed](#) ^[15],” i.e., their [brains](#) ^[16] are not “[hijacked](#) ^[17]” by the drug to which they are addicted. As Drs. Nora Volkow and Thomas McLellan of the National Institute on Drug Abuse have [pointed out](#) ^[18], addiction to opioids is very uncommon, “even among those with preexisting vulnerabilities.”

Highly rigorous and respected Cochrane systematic studies in [2010](#) ^[19] and [2012](#) ^[20] of chronic pain patients found addiction rates in the 1 percent range, and a [report](#) ^[21] on over 568,000 patients in the Aetna database who were prescribed opioids for acute postoperative pain between 2008 and 2016 found a total “misuse” rate of 0.6 percent.

The DEA is tasked with the impossible assignment of determining just how many opioids, of all types, are needed to treat pain or provide anesthesia to roughly 325 million Americans in any given year, and to apportion specific production quotas to individual manufacturers. As the central planners of the former Soviet Union—and the countless Russians who stood in long queues to buy necessities—would attest, it is impossible to plan how much of any product consumers need in a given year, let alone predict needs in the future.

An [acute national hospital shortage of injectable opioids in 2018](#) ^[22] was largely the result of DEA production quotas set for that year along with an unanticipated shutdown, for quality control purposes, of a major manufacturing plant. This caused many postoperative patients to suffer from under-medication of their pain and caused the cancellation of numerous elective surgeries. There is also evidence that many chronic pain patients, suddenly cut off or abruptly tapered from long-term opioid therapy, have turned to the [dangerous black market](#) ^[23] in search of relief. Worse, many have turned to [suicide](#) ^[24].

A strong case can be made that the clampdown on prescription opioids has only served to drive up the overdose rate among nonmedical users while inflicting unintended harm on patients. The management of acute and chronic pain—as well as substance use disorder—is not in law enforcement’s wheelhouse. If relaxing the quotas is not in the cards politically, then the least the DEA can do is to stop making matters worse.

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