Docket No. DEA-480

Before the Drug Enforcement Administration

STATE OF WEST VIRGINIA,

to

DRUG ENFORCEMENT ADMINISTRATION,
ROBERT W. PATTERSON, Acting Administrator of the
Drug Enforcement Administration, and
JEFFERSON BEAUREGARD SESSIONS III, Attorney General

On Rulemaking

STATE OF WEST VIRGINIA COMMENT ON CONTROLLED SUBSTANCES QUOTAS RULEMAKING

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The State of West Virginia, by and through Attorney General Patrick Morrisey, respectfully submits these comments on the Drug Enforcement Administration's Controlled Substances Quotas proposal. Finalizing this proposal will address one of the root causes of the opioid epidemic and stem the unrelenting tide of death in West Virginia and across the country.

General Comments

Prescription opioids are dangerous and addictive euphoria-inducing drugs. The addictive high that prescription opioids produce ensures that the demand for these drugs always far outstrips legitimate medical need. Even though federal and state law limit the use of opioids to legitimate medical use, any excess in the supply of these drugs that is produced will inevitably end up diverted into illicit and unlawful use. As a result, excess opioid supplies create unacceptable opportunities for criminal, reckless, and negligent conduct.

Accordingly, federal law requires the Attorney General of the United States to limit the total amount of scheduled opioids produced to the quantity necessary "to provide for the estimated medical, scientific, research, and industrial needs of the United States." 21 U.S.C. § 826(a). In other words, the federal government must cap production of drugs each year to match legitimate needs to prevent illicit and unlawful use and to keep Americans safe, healthy, and productive.

The Attorney General has delegated responsibility to establish drug quotas to the Administrator of the Drug Enforcement Administration and the regulations defining how they are established are in Part 1303 of Title 21 of the Code of Federal Regulations. Unfortunately the Part 1303 quota regulations are fatally flawed, and the Obama-era DEA was asleep at the switch on a runaway train of death. DEA's quota program was utterly broken because it conflated market demand for narcotics with the amount of legitimate medical need by relying almost entirely on just a single piece of dangerously deceptive information: the estimated amount of the drugs the industry can sell. The regulations provide that "[i]n order to determine the estimated needs" for drugs the DEA has drug manufacturers submit requests stating the "quantity desired" by them for the following year, the amounts that they sold for prior years, and their inventory. 21 C.F.R. § 1303.12. As long as these numbers indicate that the drug manufacturers are likely to be able to sell all of the drugs they "desire," DEA simply adds up the requests and arrives at a national total for each controlled substance.

DEA's Obama-era quotas unlawfully, arbitrarily, and capriciously conflated what industry wants with what Americans need and the Obama DEA's process neglected vital information in the hands of other federal agencies and the States that would have shown that the increases industry requested each year were not necessary to meet legitimate need. The Obama DEA's broken quota system resulted in unconstrained and unvalidated increases each year for the past decade that fueled the drug epidemic. The excess narcotics supply naturally flowed to the devastated coal fields of West Virginia and other communities that were hardest hit by the recession. It is as if the Obama DEA soaked our nation with gasoline that puddled and pooled in vulnerable communities where rampant criminal and negligent conduct ignited this dangerous excess opioid supply into a raging inferno of tragic destruction and death.

While the State of West Virginia has been aggressively going after criminal and negligent wrongs committed up and down the supply chain, the underlying circumstances of deadly motive, opportunity, and reckless corporate oversight were firmly rooted in abject failure by Washington bureaucrats and their leaders in the Obama administration.

This proposal by President Trump's Justice Department and DEA marks a dramatic step forward to fix the broken drug quota process. First, DEA will discount market demand estimates by the amount of that demand that has been and would be diverted into illicit use. Second, DEA will reduce reliance on market demand estimates by formally seeking input each year from other federal agencies and the States. Third, DEA will give each State the right to obtain formal administrative hearings in Washington to consider concerns and evidence of excess opioid supplies.

The State of West Virginia heartily applauds Acting Administrator Patterson and Attorney General Sessions for the steps they are taking to protect our citizens from this deadly scourge of opioid excess.

The era of unlimited supply must end and never return because we are losing too many neighbors, too many friends, too many sons, and too many daughters. The State of West Virginia therefore urgently requests that DEA promptly finalize the proposed rule.

SPECIFIC COMMENTS

THE CURRENT DRUG QUOTA SYSTEM IS LEGALLY FLAWED.

The DEA has been delegated the statutory responsibility to set quotas at levels no greater than required "to provide for the estimated medical, scientific, research, and industrial needs of the United States." 21 U.S.C. § 826(a). Unfortunately, the current drug quota system is woefully deficient. The current system relies almost entirely on drug manufacturers requests stating the "quantity desired" for the following year, the amounts that they sold for prior years, and their current inventory. 21 C.F.R. § 1303.12. But this information translates to the amount of drugs that can be sold rather than the amount of drugs that are required for the "medical, scientific, research, and industrial needs of the United States." 21 U.S.C. § 826(a). Opioids prescribed by drug pushing doctors and dispensed by pill mill pharmacies supplied by negligent distributors are abused, not used for legitimate and statutorily relevant purposes.

The current quota system effectively presumes drugs are needed for one of the four statutorily specified purposes so long as they are procured from the DEA-registered distribution chain. This implicit presumption is specious, as illustrated by *United States v. Moore*, 423 U.S. 122 (1975), the seminal case defining the scope of the Controlled Substances Act. In *Moore*, the Supreme Court held a DEA-registered doctor who "act[s] as a large-scale 'pusher'" and "not as a physician" violates the Controlled Substances Act notwithstanding the fact that the doctor is registered and the drugs are not dispensed "outside the 'legitimate distribution chain.'" *Id.* at 130, 143. The Court found that Congress sought to prohibit and severely punish distribution for illegitimate purposes irrespective of whether "the 'transaction' falls within or without legitimate channels." *Id.* at 135. With respect to drug quotas, Congress specifically ordered the quotas be set at levels required only for statutorily specified purposes—"medical, scientific, research, and industrial." 21 U.S.C. § 826(a). Other purposes are not legitimate and the diversion of opioids and other drugs for these purposes must be excluded from the quota setting process.

To put the matter simply, drugs that addicts "want" for abuse are not drugs that United States "needs" for legitimate purposes. Thus, DEA must dramatically reform the broken drug quota system by finalizing the proposal.

THE STATE OF WEST VIRGINIA HAS BEEN DEVASTATED BY A DRUG EPIDEMIC FUELED BY THE BROKEN QUOTA SYSTEM.

Over the past two decades prescription opioids have flooded our State. West Virginia was especially vulnerable to this assault because of the despair and hopelessness that accompanied a dwindling job market resulting largely from the Obama War on Coal.

Where these excess pills flooded and pooled in the State, addiction soon followed. As every West Virginian now knows, next came overdoses, recoveries, and overdoses where no recovery was possible. All of this was made possible because of a broken quota system that failed to protect the public from euphoria producing drugs that also had the power to kill.

This tragedy infamously played out in Kermit, West Virginia, where a single pharmacy was flooded with 12 million hydrocodone pills over a six year period, and Williamson, West Virginia, where two pharmacies received over 20 million narcotics over a single decade.

Because the quota system was almost entirely based on the number of pills drug manufacturers estimated they could sell into the registered chain, manufacturers, wholesalers, and pharmacies had no incentive to report the suspicious orders and prescriptions. There was no incentive to report drug pushers such as doctors Michael Kostenko and Jorge Gordinho who fueled the opioid epidemic and contributed to hundreds of deaths and thousands of overdoses in West Virginia. There was no incentive because there was always remaining pills available for patients in actual need of narcotics. In fact, there was a perverse incentive to manufacture, distribute, and dispense these unwarranted narcotics because there was profit to be made. For individuals and companies in the supply chain, it was better that they profit than their competitors.

For instance, Crab Orchard Pharmacy in southern West Virginia alone allegedly filled over 6,000 opioid prescriptions from Dr. Kostenko from 2010 to April 2016. Kostenko pleaded guilty to distributing oxycodone not for legitimate medical needs and was sentenced to twenty years in prison. Likewise, Crab Orchard allegedly filled over 1,000 prescriptions from Dr. Gordinho from 2010 to January 2016. Gordinho pleaded guilty to charges of distributing oxycodone, oxymorphone, hydrocodone, and morphine not for legitimate medical needs and beyond the bounds of medical practice.

Another pharmacy, Larry's Drive-In Pharmacy, dispensed nearly 10 million doses in just 11 years in a county with fewer than 25,000 residents.

Pill mill pharmacies dispensing prescriptions written by well-known pill pushing doctors and rogue pain clinics were supplied with unlimited supplies of opioids by allegedly negligent distributors like McKesson and other negligent companies that failed to detect and report suspiciously large orders of controlled substances. McKesson alone allegedly delivered nearly one hundred million doses of hydrocodone and oxycodone into the State of West Virginia from 2007 to 2012.

All of these opioids dispensed by pill mill pharmacies and supplied by drug distributors contributed to the ever-increasing aggregate production quotas because the quotas were based on sales through the registered chain for any purpose, not just medical needs.

The quota system was put in place to ensure that drugs would not be produced and available for drug pushers like Kostenko and Gordinho. Congress entrusted the Attorney General and DEA to ensure that only those drugs that were needed for legitimate purposes are produced. But the quota system was broken and allowed unchecked and unvalidated increases in the supply of deadly prescription narcotics, and States have been largely unable to completely check the inevitable resulting harms posed by pill pushing doctors, pill mill pharmacies, and negligent drug distributors. This left States like West Virginia unable to successfully serve and protect their citizens.

Although all states have been affected by this cycle, West Virginia has been hit like no other state in the nation. Two decades ago, West Virginia had a drug overdose rates below the national average; sadly, over the last few years, West Virginia has led the nation in that same rate.

This is in part because the State has consistently ranked in the top ten in the opioid prescribing rate largely because of the activities of dozens of pill pushing doctors. In fact, the drug overdose rate has closely followed the opioid prescribing rate by county, and hundreds of overdoses can be tied directly to pill pushing doctors who were enabled by pharmacies and distributors who looked the other way while supplying the excess opioids that were able to be produced as a result of the broken quota system.

Thus, the broken quota system has led to a number of problems for West Virginia. It has contributed to increased crime, medical costs, emergency services, and need for foster care, at the same time reducing the employment rate and draining the state's tax base. We also cannot forget the friends, family, and neighbors we have lost to the opioid epidemic.

Accordingly, DEA must finalize the proposed changes to fix the broken quota system to prevent this senseless tragedy and death in West Virginia.

PROPOSED REFORM: CONSIDERING DIVERSION

§ 1303.11(b)(5)

"<u>The extent of any diversion of the controlled substance in the class</u>"

§ 1303.13(b)(1)

"<u>changes in the extent of any diversion in the class</u>"

STATE OF WEST VIRGINIA COMMENT:

The DEA must finalize the proposed addition of the extent of diversion of controlled substances to the factors considered in setting and adjusting annual aggregate production quotas. By definition, controlled substances that are diverted for illicit use are not required "to provide for the estimated medical, scientific, research, and industrial needs of the United States." 21 U.S.C. § 826(a). Diverted controlled substances are abused rather than used for "medical, scientific, research, and industrial needs." 21 U.S.C. § 826(a). Thus, DEA cannot lawfully and reasonably ignore diversion when setting drug quotas without setting drug quotas at levels that are higher than required to meet such needs.

Evidence of diversion is evidence of excess production and quotas that have been set at levels that are greater than the "needs of the United States." 21 U.S.C. § 826(a). Therefore, ignoring diversion results in unlawful quotas.

DEA cannot continue the Obama-era practice of ignoring widespread diversion of opioids across the United States that demonstrates the quotas are currently set far in excess of quantities required to meet the "needs of the United States." 21 U.S.C. § 826(a).

PROPOSED REFORM: CONSULTING FEDERAL AGENCIES

§ 1303.11(b)(6)

"Relevant information obtained from the Department of Health and Human Services, including from the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Centers for Medicare and Medicaid Services"

STATE OF WEST VIRGINIA COMMENT:

DEA must finalize the proposed requirement for DEA to consult with federal agencies that possess critical information necessary for DEA to lawfully and reasonably set aggregate production quotas. DEA cannot lawfully and reasonably determine "estimated medical . . . needs of the United States" without consulting the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Centers for Medicare and Medicaid Services. 21 U.S.C. § 826(a).

The Food and Drug Administration already identifies drug shortages, as provided by Congress, and validates claimed drug sales by manufacturers.

The Centers for Disease Control and Prevention tracks opioid overdoses and deaths. This data and its institutional expertise and focus gives CDC keen insight that can assist DEA in setting drug quotas and identifying excess quotas that are resulting in pill dumping and death.

The Centers for Medicare and Medicaid Services is the largest medical payer in America and has extensive data that can be leveraged to assess claims by manufacturers that more drugs are required to meet legitimate medical needs. In effect, CMS can validate or refute whether there is any underlying increase in medical needs. If there is no increase in population or claims for relevant treatments and care and there are no documented drug shortages, increases in drug quotas produce excess pills that fuel diversion. One of the key flaws in the current system is that perceived ability to sell out and sell more drugs was allowed to justify quota increases without evidence of increased legitimate medical need. CMS can play a vital role in providing a crucial check and balance in the drug quota system to prevent deadly excess opioid production.

PROPOSED REFORM: CONSULTING STATES

§ 1303.11(b)(6)

"relevant information obtained from the states"

§ 1303.11(c)

"A copy of said notice shall be mailed . . . to each state attorney general"

"A copy of said order shall be . . . transmitted to each state attorney general"

§ 1303.13(c)

"A copy of said notice shall be mailed . . . to each state attorney general"

"A copy of said order shall be . . . transmitted to each state attorney general"

STATE OF WEST VIRGINIA COMMENT:

DEA must finalize the proposed requirement for close consultation with the States in setting aggregate production quotas to avoid dangerous excess quotas that lead to devastation and death. Excess quotas will first result in localized instances of pill dumping that State governments are best equipped to identify early when overdoses turn up in emergency rooms and local and state police find the tell-tale signs of the presence of pill pushing doctors and pill mill pharmacies. Finalizing the proposal will require DEA to consider relevant information submitted by States in setting quotas so that quotas will be lowered rather than increased when the first signs of pill dumping arise. Increasing the participation of States in setting quotas will be a critical improvement to the drug quota system and help prevent dangerous excess opioid production.

PROPOSED REFORM: MANDATORY EXCESS PILL HEARINGS

§ 1303.11(c)

"The Administrator may, but shall not be required to, hold a public hearing on one or more issues raised by the comments and objections filed with him <u>except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed quantity for the class as excess for legitimate United States need</u>"

§ 1303.13(c)

"The Administrator may, but shall not be required to, hold a public hearing on one or more issues raised by the comments and objections filed with him <u>except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed quantity for the class as excess for legitimate United States need</u>"

STATE OF WEST VIRGINIA COMMENT:

DEA must finalize the proposed requirement for mandatory excess pill hearings requested by States. States will be far more likely to invest the effort necessary to assemble the evidence of excess controlled substance production when they have confidence that they will be able to receive formal public hearings. Providing for mandatory hearings requested by States that wish to present evidence of excess controlled substance supplies will provide a safeguard to protect the public and ensure swift corrective action if quotas dangerously exceed the amount required "to provide for the estimated medical, scientific, research, and industrial needs of the United States." 21 U.S.C. § 826(a)

PROPOSED REFORM: DIVERSION DETECTION

§ 1303.12(b)

"<u>The administrator may require additional information from an applicant which, in the Administrator's judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer</u>"

§ 1303.22(d)

"<u>The Administrator may require additional information from an applicant which, in the Administrator's judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer</u>"

STATE OF WEST VIRGINIA COMMENT:

DEA must finalize the proposed additional authority to require relevant information from applicants for procurement quotas and from applicants for individual manufacturing quotas. Currently, DEA only obtains information representing sales volumes in the registration chain. But DEA does not obtain additional information to identify whether multiple applicants are relying on perceived legitimate demand from the same customers. In other words, some anticipated legitimate demand may be double counted in the quota process, leading to an excess quota level for a given year. Greater information will allow DEA to better evaluate individual quota requests and result in more sound drug quotas.

THERE IS A STATUTORY PROCESS FOR PREVENTING SHORTAGES OF DRUGS FOR LEGITIMATE MEDICAL NEEDS.

The State of West Virginia understands that many individuals have submitted comments indicating concerns over whether the reforms to the broken drug quota system will lead to shortages of drugs that are required to meet legitimate medical needs. But the proposed reforms are aimed squarely at reducing the production of excess pills for drug abuse that are obtained through pill dumping, pill mill pharmacies, and negligent drug distributors. While there is rampant overprescribing of opioids to meet legitimate needs, addressing this issue is the domain of the States, not the federal government. Thus, any concerns over efforts to reduce legitimate prescribing rates are not relevant to this proceeding. And at any rate, Congress enacted a statutory process to address any drug shortages that arise as a result of drug quotas. 21 U.S.C. § 826(h). Where any shortages to occur, the statutory mechanism will address the issue. Accordingly, the comments relating to shortage fears do not provide any basis to delay or decline to finalize the proposed reforms.