

# Attorney General Morrisey Remarks – March 1, 2018

## As prepared for delivery

Today, I am pleased to announce a major national development in our plan to address one of the root causes of the opioid epidemic and stem the unrelenting tide of death in West Virginia and across the country. Today, we believe we will begin seeing a major change to the failed drug supply system and federal government policies that have fueled the opioid epidemic and helped lead to the death of hundreds of thousands of Americans nationwide.

In December of 2017, after years of my office's efforts to get to the bottom of the massive oversupply of opiates in our country, I filed a lawsuit unilaterally against the DEA to begin initiating major changes to the failed drug quota system that has helped caused so much senseless death.

For far too long, going back over the past decade and longer, the DEA maintained drug quota regulations that were fatal and dangerously flawed.

Unfortunately, my efforts to get to the bottom of this catastrophe – which were initiated by my office during the Obama Administration -- were originally stymied, as the Obama-era DEA was clearly asleep at the switch and unwilling to recognize the fatal nature of this failed system. That is now changing under President Trump and Attorney General Sessions. I believe that the Trump Administration and Attorney General Sessions agree with me that the system should serve patients' needs instead of industry wants.

As we all know, prescription opioids can be dangerous, addictive, and ultimately deadly.

When the government allows the industry to manufacture and distribute too many opioids, it creates absolutely unacceptable opportunities for criminal, reckless, and negligent conduct – with deadly consequences.

Unfortunately, the drug quota system did just that.

The DEA quota program is completely broken because it confuses market demand for dangerous narcotics with the amount of legitimate medical need.

DEA's quota program relies far too much on just a single piece of dangerously deceptive information: the estimated amount of the drugs the industry can sell.

Let me be clear: the DEA effectively helps determine how many drugs can be manufactured based upon how many drugs pharmaceutical companies can sell.

The regulations provide that “[i]n order to determine the estimated needs” for drugs manufacturers submit requests stating the “quantity desired” by them for the following year, the amounts that they sold for prior years, and their inventory.

As long as these numbers indicate that the drug manufacturers are likely to be able to sell all of the drugs they “desire[],” DEA adds up the requests and arrives at a national total for each controlled substance. [21 C.F.R. § 1303]

This process serves what industry wants instead of patients’ needs.

This quota process failed to include critical information in the hands of the States, the CDC, and the Department of Health and Human Services that would have shown that the increases industry requested each year were not necessary to meet legitimate medical need.

This quota process resulted in the unconstrained, unvalidated, and deadly increases each year for the past decade that helped fuel the drug epidemic and helped cause senseless death.

Think about the issue this way. Imagine if the agency charged with protecting our citizens from illegal drug diversion stood by and allowed our nation to be soaked with gasoline while criminals and unscrupulous actors of the pharmaceutical supply chain lit a match. The DEA's actions were beyond reprehensible – they were deadly.

While my office has been aggressively going after negligent actions committed up and down the supply chain, the underlying circumstances of this deadly crisis were firmly rooted in part, by the abject failure of Washington bureaucrats and their leaders.

It's long been a goal of mine to fix an important part of the source of the excess drug supply in our country: the DEA's fundamentally broken drug quota system.

I began these efforts during the Obama Administration in September of 2015 when I first demanded information on the drug quota system under FOIA. The Obama DEA effectively stonewalled my office in response.

When President Trump and Attorney General Sessions took office, I renewed my efforts and I spent the past year working with them and DEA on this critical issue.

Then, on December 8, 2017, in order to draw a line in the sand and make absolutely one hundred percent crystal clear to career employees at DEA that the status quo is not acceptable and to support the Trump Administration and Attorney General Sessions in their efforts to address my concerns, I filed a lawsuit in the United States Court of Appeals for the District of Columbia Circuit against the DEA challenging the latest drug quotas for opioids.

While I was required to file my lawsuit on December 8 to meet a statutory deadline, I remained confident President Trump, General Sessions, and Acting Administrator Patterson would continue our progress toward reform and I knew that my lawsuit would help them overcome any potential bureaucratic inertia and complacency.

Accordingly, I did not announce or publicize my lawsuit on behalf of West Virginia against the DEA, and today is the first time I am discussing the case in public.

I am speaking about my lawsuit today for the first time because I can report some very good news for the people of West Virginia and all Americans.

I have here in my hand an advance directive from Attorney General Sessions to the DEA that instructs them to immediately move forward with critical reforms to the nation's drug quota regulations.

After my close collaboration with the Department of Justice and DEA, I am hopeful the resulting changes will include several key reforms.

First, DEA will reduce reliance on market demand estimates by seeking input each year from the States, the CDC and the Department of Health and Human Services. DEA will also continue to consult with the FDA and now make FDA's input public.

Second, DEA will also discount market demand estimates by the amount of that demand that has been and would be diverted into illicit use. This will both eliminate existing excess opioid supply and prevent future excess opioid supply. We believe this has been one of the biggest problems with the quota system.

Third, DEA will also give States the right to obtain formal administrative hearings to consider concerns and provide evidence of excess opioid supplies.

I am also hopeful that DEA will improve its regulations by distinguishing between prescribed doses and consumed doses. This will help eliminate dangerous excess quantities of pills prescribed to patients that end up in medicine cabinets where they are often diverted to illicit use by young people.

I am also confident that DEA will conduct an additional notice and comment rulemaking to address the many other shortcomings with the drug quota regulations.

I heartily applaud Attorney General Sessions for the major step he is taking today and for his continued collaboration with me to protect our citizens from this deadly scourge of opioid excess. The President and Trump Administration deserve praise for this bold move.

Given the urgency of the opioid crisis and the need to put these reforms in place before DEA begins the process of setting drug quotas for next year, I have urged DEA to promulgate these reforms as an interim final rule with immediate effect.

We must have a far better drug quota system that responds to the legitimate medical needs of patients so they obtain the medications they require, yet reduces the massive oversupply and deaths caused in part by the current system.

In view of the progress we have made and the significant step that General Sessions has just taken, I am asking the D.C. Circuit Court of Appeals to put my lawsuit against DEA on hold while progress continues, with a view toward hopefully being able to dismiss the case in the near future once we have achieved our objective of obtaining vital reforms of the drug quota system.

We should all applaud Attorney General Sessions for the step he has taken today and all of the other critical work he is doing to address the opioid crisis.

Every West Virginian should know that today marks an important step forward. In the Mountain State, we are all seeing first-hand a tremendous amount of death. West Virginia leads the nation, per capita, in drug overdose deaths at 52.5 deaths per 100,000 people. We must turn this around.

Small communities have been engulfed in an inferno of opiates and addiction and we have seen unfathomable numbers of pills prescribed and supplied in our communities. Kermit, West Virginia, for instance, a town of 392 people, received 9 million hydrocodone pills. That's 23 thousand pills per person. Every man, woman, and child in Kermit would have had to consume 31 pills a day to use everything shipped to Kermit.

I've taken action and acted as aggressively as any Attorney General in the country to bring accountability to the pharmaceutical supply channel and advance holistic policies that address the opioid epidemic from a supply, demand, and educational perspective. My office reached the largest drug settlements in state history, instituted a best practices program designed to dramatically curb supply and reduce opiate prescriptions, introduced a new faith-based initiative to combat addiction and spur community involvement in fighting this epidemic, and is educating many, many thousands of students, seniors, and community leaders about the perils of the opiate problem.

This is the challenge of our time in West Virginia. I want to commend my office and our team for all they are doing to stop the senseless death in our state. We must win this fight and prevent another generation of West Virginians from falling victim to these deadly drugs.



But we still need more help. I have called on our Legislature to devote appropriate resources to fund our state police, equip an enforcement surge, and make the state policy changes necessary to further limit oversupply. I have asked for more assistance on the treatment side of the equation to ensure those who are addicted get the help they need to get better in the head and the heart. We also need authority to help local prosecutors criminally prosecute the drug kingpins who are poisoning our citizens – unfortunately, to date, this request has been denied and criminal elements are escaping accountability.

Today marks an important but preliminary step. We cannot and will not let up.

The era of unlimited supply must end and never return because we are losing too many neighbors, too many friends, too many sons, too many daughters: Too much senseless death. And government shouldn't be part of the reason for it.