

State of West Virginia
Office of the Attorney General
Patrick Morrisey
Attorney General

May 8, 2024

The Honorable Anne Milgram
DEA Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

The Honorable Gina M. Raimondo Secretary of Commerce U.S. Department of Commerce 1401 Constitution Ave., NW Washington, DC 20230

Dear Administrator Milgram and Secretary Raimondo:

As the Attorney General of one of the opioid epidemic's hardest-hit States, I know too well the devastating consequences rampant overprescription has had for hundreds of thousands of families in West Virginia and across the country. As leaders of the Drug Enforcement Administration and the Department of Commerce, both of you do, too. West Virginia's drug overdose mortality has been the highest in the country—90.9 deaths per 100,000 total population in 2021. Nationwide, over six times as many people died from drug overdoses in 2021 than in 1999. And more than three in four of those deaths involved opioids.

I've been deep in the fight against this crisis throughout my years as West Virginia's Attorney General—including getting at its root causes. Part of that effort included my Office's multi-year investigation into federal regulators' role in allowing excessive over-production of the prescription opioids that helped fuel the fire.⁴ For too long, an ever-growing supply of legal opioids made it

¹ NAT'L CTR. FOR HEALTH STATISTICS, CTRS. FOR DISEASE CONTROL & PREVENTION, *Drug Overdose Mortality by State*, https://bit.ly/4a3HJch (last visited May 7, 2024).

² CTRS. FOR DISEASE CONTROL & PREVENTION, *Understanding the Opioid Overdose Epidemic*, https://bit.ly/44vvcwS (last visited May 7, 2024).

³ *Id*.

too easy for drugs initially obtained through lawful prescriptions to be diverted to illicit—and deadly—ends. My Office repeatedly pushed DEA for information about its role in approving annual production quotas for opioids based on legitimate "medical, scientific, research, and industrial needs." Two Freedom of Information Requests and a federal lawsuit⁶ later, my Office released a report showing that DEA spent years acquiescing to providers' requests for increasingly higher opioid production quotas. With little-to-no consideration of the documented and serious threat from prescription-drug diversion, DEA kept increasing drug quotas by broadly accepting industry sales projections even over warnings from other federal agencies like the FDA.⁷ My Office was not the only one highlighting these systemic failures, either—DOJ's Office of the Inspector General issued a report in late 2019 highlighting many of the same issues we uncovered.⁸

I was encouraged in some ways by DEA's ultimate response to these serious issues. The agency started improving how it managed drug quotas by making substantial cuts to overall opioid quotas. And as a result of my Office's lawsuit, DEA adopted a new rule that requires it to affirmatively account for diversion in its drug quotas, as well as to solicit input from the States and other federal agencies. Even so, you both know as well as I do that much remains to be done.

That's why I was so concerned to learn that DEA and the Department of Commerce have worked together to hide an important database on opioid provider registrations from public view.

Last week, Dr. Art Kleinschmidt, former Deputy Director of the White House Office of National Drug Control Policy and founder of the Recovery for America Now Foundation, wrote to let me know that a database originally available to anyone by subscription is now accessible on a case-by-case, agency-approved basis only. Because opioids are controlled substances, healthcare providers must have an active DEA registration to write opioid prescriptions. The Controlled Substances Act Registration Information Database used to provide "real time" information about active and retired DEA registrations the was an essential tool for pharmacies checking a provider's registration status before dispensing opioids, as well as for public accountability when

⁴ See Office of the West Virginia Attorney General's Investigation into the DEA's Failure to Combat Diversion Cost Lives: Results from the West Virginia Attorney General's Investigation into the DEA's Catastrophic Failure to Manage the National Drug Quote System from 2010-2016 (June 4, 2020) ("WV Report"), https://bit.ly/4bshnS6.

⁵ 21 U.S.C. § 826(a)(1).

⁶ West Virginia v. DEA, No. 17-1256 (D.C. Cir., filed Dec. 8, 2017).

⁷ WV Report, *supra* note 4, at 12-15, 17-23.

⁸ See Office of the Inspector General, U.S. Dep't of Justice, Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids (Sept. 2019) ("OIG Report"), https://bit.ly/44tPK9c.

⁹ WV Report *supra* note 4, at ES-3.

¹⁰ 21 C.F.R. § 1303.13(b)(1), (c).

¹¹ 21 U.S.C. § 822(a)-(b).

¹² Molly Giammarco, GATEWAY, *DEA Now Accepting Applications to Access Controlled Substances Act Registration Information Database* (Jan. 22, 2021), https://bit.ly/4b5xC7V.

it comes to who DEA grants or refuses a registration. I understand that a Commerce Department service used to manage the database, and that access used to be available to the public with readily available subscriptions and through open sources like LexisNexis.

Now, though—assuming the database even still exists—it lives behind a firewall under DEA's sole control. It appears DEA and the Department of Commerce agreed to this change. Though DEA did not say what kind of showing members of the public would have to make to prove they should be able to access this critical information going forward, it emphasized that it would approve applications "on a case-by-case basis" only.¹³ Applicants must also comply with DEA's rules as a condition for access, and DEA forbids "unauthorized distribution" as an unauthorized use that could lead to "civil and/or criminal prosecution."¹⁴

I'm deeply troubled by that decision. DEA and Commerce made it at a time when opioid-related overdose deaths were still skyrocketing (DEA's website reports that opioid deaths increased 38% from the year ending January 31, 2020 to January 31, 2021—right when the database went under wraps). Pulling down the public database came in the wake of my Office's and the Inspector General's reports exposing DEA's repeated failures in fulfilling its statutory duties to the public. And the database concerns an issue that the Inspector General report specifically called out: DEA's years long failure to issue enough Immediate Suspension Orders, its "strongest enforcement tool ... to stop registrants from diverting prescription drugs." 16

Each of these realities should have been a reason to *increase* transparency, not to hide away DEA's registration decisions from public review. Broad access to registration information is critical not just for pharmacies making sure a prescription is legitimate, but for journalists and watchdog advocacy groups holding our government accountable. In short, more eyes on DEA's registration decisions are vital to make sure DEA is doing its job by denying or suspending registrations for providers who add to the opioid epidemic's death toll. *Especially* after the critiques DEA weathered for its practices at earlier stages of the crisis, keeping Americans from being able to see exactly how DEA is dealing with pill mills and reckless providers is wrong.

So I'm writing to demand answers for the people of West Virginia. Why did DEA and the Department of Commerce limit access to the Controlled Substances Act Registration Information Database? How many applications has DEA denied, and on what basis? What criteria does DEA use when issuing access? And what is DEA doing to advertise that this information exists—in whatever form it may live now—and make it easier for third parties to access it?

I also urge you to take immediate action to address these concerns. This information must be freely available to the public, not just those entities DEA believes will use it in a way the agency approves. The federal government's response to reports exposing its failures that contributed to

¹³ *Id*.

¹⁴ *Id*.

¹⁵ Facts About Fentanyl, U.S. Drug Enforcement Admin., https://bit.ly/3y8izMb (last visited May 6, 2024).

¹⁶ OIG Report, *supra* note 8, at 15.

the opioid crisis's breathtaking loss of life cannot be to hide what our public servants are doing about it now. Your agencies should welcome public accountability, not hide from it. I trust you will do the right thing. And I look forward to your fast response explaining how you plan to do just that.

Sincerely,

Patrick Morrisey

West Virginia Attorney General

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