Office of the Attorney General
State of West Virginia

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December 23, 2019

The Honorable Uttam Dhillon
Acting Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Submitted Electronically via Regulations.gov

Re: Comments by the States of West Virginia, Arkansas, Florida, Kentucky, Missouri, and Nebraska, on the request for comment entitled, *Management of Quotas for Controlled Substances and List I Chemicals* (Docket No. DEA-455)

Dear Acting Administrator Dhillon:

The undersigned States submit the following comments in response to the request for comment of the Drug Enforcement Administration ("DEA") regarding its proposed revisions to the process of setting annual production quotas for controlled substances. 84 Fed. Reg. 56,712 (Oct. 23, 2019) ("Proposed Rule"). Broadly speaking, the Proposed Rule will help the DEA account for diversion of controlled substances through more precise adjustments to annual quotas, and we applaud the significant improvements the DEA has made in reducing opioid production quotas over the past several years. That being said, we recognize that this work remains ongoing, particularly as the agency has historically missed or underutilized several valuable sources of information when calculating quotas. The undersigned States write to draw attention to these opportunities and urge the DEA to continue accounting for them and other sources as the agency continues to refine the quota-setting process in this and future years.

BACKGROUND

With all the attention appropriately given to the illicit drug trade when combatting our nation's opioid crisis, it is easy to forget another fire fueling the epidemic: the availability of controlled substances diverted from *legitimate* uses. Indeed, diverted drugs—that is, drugs manufactured and sold legally, but that make it into the hands of users who do not have a

prescription—factor in a substantial percentage of opioid deaths and instances of abuse. In West Virginia, diverted drugs factored in roughly one-third of all fatal drug overdoses in 2016 involving state residents. *See* West Virginia Department of Health & Human Resources, *2016 West Virginia Overdose Fatality Analysis* 4 (Dec. 20, 2017), *available at* https://dhhr.wv.gov/bph/Documents/ODCP%20Reports%202017/2016%20West%20Virginia%20Overdose%20Fatality%20Analysis_004302018.pdf. And nationwide, of the 5 million Americans who reported having recently abused opioids, 71% obtained those drugs through diversion, not prescriptions. *See* Maureen V. Hill et al., *Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures*, 265 Annals of Surgery 709, 709 (2017).

The Controlled Substances Act should be a critical check against diversion. The Act authorizes the Attorney General of the United States to regulate the "manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. § 821. Pursuant to this authority, the Attorney General has tasked the DEA Administrator with setting limits on the amount of Schedule I and Schedule II controlled substances that may be produced each year. 21 C.F.R. § 1303.11. These "aggregate production quotas" are intended to prevent unjustified increases in the supply of potentially dangerous drugs, including highly addictive and frequently abused opioids like oxycodone and hydrocodone. To that end, the DEA has a duty to limit the production of controlled substances to levels sufficient for—and not beyond—"the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks." *Id.* § 1303.11(a). Accordingly, the "gold standard" for these quotas is that, when set correctly, controlled substances at levels above those required for legitimate ends—and thus vulnerable to illicit diversion—are never produced in the first place.

This laudable goal has unfortunately been subverted by loose regulatory language and lax enforcement in past years. As originally drafted, the regulations creating the aggregate quota system required the DEA to account for only the sales, consumption, existing inventories, and projected market demand for each controlled substance. 36 Fed. Reg. 7786, § 303.11(b) (Apr. 24, 1971); *see also id*. at § 303.02(c) (defining "net disposal" of a substance as the amount "sold, exchanged, given away, used in the production of another substance . . . or otherwise consumed by the registrant"). The DEA *could* consider "other factors . . . as the Director considers relevant," but was not required to do so. *Id*. at § 303.11(b)(5). The quota-setting process thus shifted over time from identifying the amounts of controlled substances actually necessary to meet legitimate medical and scientific needs toward considering the amounts that were *in fact* sold or that *could* be sold—without accounting for the drugs diverted to illicit use *after* sale.

The prior administration, in particular, was asleep at the switch when it came to tailoring production quotas to legitimate medical need. A recent report by the Inspector General cites the runaway growth in production quotas over those years as evidence that the "DEA did not use its available resources, including data systems[,] . . . to detect and regulate diversion effectively." Office of the Inspector General, U.S. Dept. of Justice, *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids* ("Inspector General's Report") i, (2019). From 2009 to 2016, for example, the DEA's quota-setting process focused on comments and requests from pharmaceutical manufacturers and trade groups—and these interested parties expressed a near-uniform desire to produce and sell more

drugs. *See*, *e.g.*, 74 Fed. Reg. 54,077 (Oct. 21, 2009) (describing comments on proposed quotas as coming from "seven companies," all seeking increases); 75 Fed. Reg. 55,828 (Sept. 14, 2010) (14 companies seeking increases in 28 quotas); 76 Fed. Reg. 77,016 (Dec. 9, 2011) (six companies seeking increases in 22 quotas); 77 Fed. Reg. 55,500 (Sept. 10, 2012) (nine companies seeking increases in 25 quotas); 78 Fed. Reg. 48,193 (Aug. 7, 2013) (six companies seeking increases in 30 quotas); 79 Fed. Reg. 53,216 (Sept. 8, 2014) (five companies seeking increases in 32 quotas).

Predictably, unchecked deference to industry demands led to skyrocketing increases in aggregate production quotas. Take hydrocodone for example. In 2010 the DEA capped production of hydrocodone for sale at 55,000 kilograms. U.S. Dept. of Justice, Aggregate Production Quota History for Selected Substances (Nov. 15, 2017), *available at* https://www.deadiversion.usdoj.gov/quotas/quota_history.pdf. By 2014 the quota had ballooned to over 99,000 kilograms. *Id*. As for oxycodone, the quota more than doubled during the same period, from 70,000 kilograms in 2008 to over 149,000 kilograms in 2014. *See* Inspector General's Report at 14. Critically, these soaring amounts were not justified by corresponding increases in medical, scientific, or other legitimate need for opioids: Although opioid production expanded dramatically between 2008 and 2014, the proportion of Americans with opioid prescriptions actually *decreased*. Centers for Disease Control, U.S. Opioid Prescribing Rate Maps, https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html (last accessed Oct. 11, 2019). Even more sobering, opioids were allowed to proliferate even as overdose deaths more than doubled nationwide over these same years. Rose A. Rudd, et al., Centers for Disease Control and Prevention,*Increases in Drug and Opioid Overdose Deaths—United States, 2000-2014*, 64 Morbidity & Mortality Weekly Report 1378, 1379 (Jan. 1, 2016); *see also* Inspector General's Report at 7, 13-14 (contrasting 71% annual increases in overdose deaths from 2013 to 2017 with contemporaneous 400% increases in opioid production quotas).

Neither the excess drugs produced during this era nor the human costs associated with their abuse were distributed equally. As a growing opioid supply descended on narrowing segments of the population, ever-increasing rates of drug abuse and addiction followed—and these injuries were inflicted disproportionately on some of the most vulnerable members of society. In particular, opioid abuse is more likely to affect senior citizens, women, and Medicaid recipients. Beth Han, et al., *Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health*, 167 ANNALS OF INTERNAL MEDICINE, 293, 296 (2017). Similarly, some states have been hit harder than others. From 2010 to 2016, the rate of drug overdose deaths nearly doubled in West Virginia, and nearly tripled in Ohio. Centers for Disease Control and Prevention, *Underlying Cause of Death 1999-2017*, http://wonder.cdc.gov/controller/saved/D76/D72F779 (last accessed Oct. 11, 2019). And although not all of these deaths are attributable to diversion, prescription opioids have been a dominant driver in the growing crisis. In 2016, for example, opioids obtained through a prescription were a factor in over 66% of all drug overdose deaths. *Id*.

In the face of these sobering realities, the States have worked to pioneer robust responses to opioid over-prescription. Along with over 25 national and state partners, the Office of the West Virginia Attorney General announced best practices for prescribing and dispensing opioids in early 2016. West Virginia Attorney General, *Best Practices For Prescribing Opioids In West Virginia*

(Jan. 2016), *available at* http://bit.ly/2bHACNH. This project's goal is to increase patient safety and reduce opioid dispensing by 25 percent in the State. Soon after, all West Virginia doctors prescribing opioids for Medicaid patients or public employees with state health insurance were required to follow opioid prescribing guidelines developed by the Centers for Disease Control. U.S. Department of Justice, Office of the Inspector General, *Factsheet: West Virgnia's Oversight of Opioid Prescribing and Monitoring of Opioid Use* 5 (Mar. 2019), *available at* https://oig.hhs.gov/oas/reports/region3/31803302_Factsheet.pdf. West Virginia also passed legislation limiting opioid prescriptions for acute pain to between three and seven days, depending on the circumstances. 2018 W. Va. Acts ch. 46. And the West Virginia Attorney General worked with the state Board of Pharmacy to develop a "morphine milligram equivalents" calculator, which determines the total strength of opioids a patient is prescribed and displays it on the Board's Controlled Substances Monitoring Program ("CSMP"). Together with other efforts to encourage increased use, this tool has caused the number of CSMP users to quadruple. W. Va. Bd. Pharmacy, *Controlled Substance Monitoring Program: 2018 Annual Report* 1 (2018), *available at* https://www.wvbop.com/download_resource.asp?id=274. It has also spurred an additional 120,000 CSMP queries since 2015, which in turn led to an 85 percent reduction in doctor-shopping between 2014 and 2017. *Id*. at 8-9.

All of these actions have contributed to a dramatic decrease in the amount of opioids prescribed in West Virginia. Hydrocodone pills dispensed in the State dropped from nearly 100 million in 2011 to just under 38 million in 2018, and oxycodone pills dropped from nearly 44 million in 2012 to under 25 million. *Id*. at 5. And West Virginia is just one example of the States' individual and collective efforts to respond to the opioid crisis and its disastrous effects on our residents. Florida, for instance, passed a law in 2018 that (like West Virginia's law passed the same year) limits opioid prescriptions to between three and seven days depending on the circumstances. Fla. Stat. § 456.44. Nevertheless, even aggressive efforts on the state level can only go so far—particularly in light of an ever-increasing supply of opioids entering the States from both illegal and legal sources.

Since taking office, President Trump has made it a priority to stem the opioid crisis's flow of senseless death. In March of 2018, President Trump announced his Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand. *President Donald J. Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand* (Mar. 19, 2018), *available at* https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-initiative-stop-opioid-abuse-reduce-drug-supply-demand/. This plan approaches the opioid crisis from multiple angles, including education initiatives aimed at reducing the demand for drugs, and a crackdown on the supply of illegal drugs entering the country. *Id*. The plan also focuses on scaling back the over-prescription of opioids through the "Safer Prescribing Plan," which aims to cut nationwide opioid prescription fills by one-third within three years. *Id*.

The "Safer Prescribing Plan" is a vitally important measure, but it is limited to the extent that it targets the prescribing practices of federally funded providers only, not the prescription drug industry as a whole. With respect to that broader issue, we have also been encouraged to see the DEA begin making significant momentum toward reforming the annual quota process. Consistent with the President's directive, the DEA has proposed reductions in controlled substance quotas in

recent years. U.S. Dept. of Justice, *Justice Department, the DEA Propose Significant Opioid Manufacturing Reduction in 2019* (Aug. 16, 2018), *available at* https://www.dea.gov/press-releases/2018/08/16/justice-department-dea-propose-significant-opioid-manufacturing-reduction. Nevertheless, decades of unchecked quota increases are not undone overnight. Although we applaud the DEA's decision to stop increasing aggregate quotas, the statistics from our States make plain that there is much more to be done. Specifically, although the DEA has started the process of reversing unjustified growth in controlled substance quotas, it has not yet determined the amounts necessary to meet legitimate medical, scientific, and industrial needs.

In light of this concern, the State of West Virginia challenged the DEA's 2018 controlled substance quotas in court. *See West Virginia v. DEA*, No. 17-1256 (D.C. Cir. filed Dec. 8, 2017). This lawsuit sought reform to the quota-setting process that would adjust sales figures to account for the rate at which opioids are diverted from legitimate medical uses. And as a result, the DEA undertook regulatory modifications designed to correct past practices: On April 19, 2018, the DEA proposed adding new factors to the quota-setting calculation. 83 Fed. Reg. 17,329 (Apr. 19, 2018). These requirements became effective August 15, 2018. 83 Fed. Reg. 32,784 (July 16, 2018) ("Quotas Rule"). Under the new Quotas Rule, the DEA is now *required* to account for the rate of diversion every year when formulating aggregate production quotas, and must seek out and incorporate input from States and federal agencies on whether the proposed quotas are "excessive" under the statutory criteria. *Id.* at 32,793.

A federal statute enacted later that year addressed similar concerns. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act") codified the Quotas Rule as part of a broader series of reforms. *See* Pub. L. No. 115-271, 132 Stat. 3893, 3954-56 (Oct. 24, 2018); *see also* Inspector General's Report at 43 ("the SUPPORT Act codifies the new quota regulation"). Yet while the Quotas Rule applies to the entire quota process, the SUPPORT Act applies these changes with respect to five enumerated controlled substances only: "fentanyl, oxycodone, hydrocodone, oxymorphone, [and] hydromorphone." 132 Stat. 3954.

The DEA proposed new production quotas for 2020 on September 12, 2019. The new quotas would cut the 2020 production quota for hydrocodone by over 20 percent, and oxycodone by nine percent. 84 Fed. Reg. 48,170. 48,177 (Sept. 12, 2019).) ("Proposed Quotas"). This proposal shows that the DEA has moved in the right direction; the Proposed Quotas for many controlled substances have been reduced for the third year in a row. *Compare* 84 Fed. Reg. at 48,177, *with* 83 Fed. Reg. 67,348, 67,354. The DEA's explanation of these reductions also charts a promising path for the future. The proposal noted that the Quotas Rule and the SUPPORT Act make it a legal duty to account for diversion in calculating controlled substance quotas, and outlines the data sources the DEA used when striving to meet this requirement. 84 Fed. Reg. at 48,171-72. Nevertheless, as West Virginia and several other States pointed out, the DEA did not use a consistent methodology when accounting for diversion of different controlled substances, and did not consider the full range of data that would be helpful in making these determinations. West Virginia Attorney General, *Comments of West Virginia and Six Other States on the Proposed Annual Production Quotas for 2020*, Doc. ID. No. DEA-2019-0008-0662 (Oct. 16, 2019), *available at* https://www.regulations.gov/document?D=DEA-2019-0008-0662.

The DEA subsequently published the Proposed Rule on October 23, 2019. 84 Fed. Reg. 56,718 (Oct. 23, 2019). This rule would allow the DEA to set quotas at a more precise level for all controlled substances, both by measuring quotas in terms of dosage units and setting distinct quotas for each stage of the sales process. 84 Fed. Reg. 56,721-22.

DISCUSSION

Overall, we applaud the DEA's efforts to correct the systemic flaws in the national drug quota system and to end the somber role that system has played in the opioid epidemic's growth. Although many opioid quotas still remain higher than they were in 2009, there has been marked improvement since 2017 that reflects more precise metrics and a broader perspective on the problem. We are especially encouraged by the Proposed Rule's reduction in allowable drug inventories. Nevertheless, there remains room for improvement as the DEA continues to implement the new statutory and regulatory requirements governing the quota-setting process. The remainder of these comments address two such areas. *First*, the DEA should consider a broader range of data when calculating diversion. It can accomplish this goal by considering sources that are already available (while continuing to push for ever-better data sources for future years), and by adopting a uniform method of accounting for diversion under the Quotas Rule and the SUPPORT Act. *Second*, the DEA should analyze overprescribing of controlled substances when determining quantities that are "medical[ly] and scientific[ally]" necessary. 21 C.F.R. § 1303.11(a) The DEA can begin this process by considering data and best practices of healthcare providers, and by collecting information from the Prescription Drug Takeback Program and similar sources.

I. The DEA Should Expand The Universe Of Data Sources It Uses To Account For Illicit Diversion.

There are many tools available to the DEA to help determine the amount of diversion occurring each year, or at the very least, trends in the amount of diversion. The DEA has acknowledged that some of these sources are valuable, but that the agency does not currently use them in a uniform way. Other sources are housed within the DEA and are readily available, but have not been part of the DEA's quota analysis. Other national databases track outcomes such as individuals in treatment, drug poisoning episodes, overdose deaths, and the rates of misuse and abuse of prescription drugs. States can also provide valuable information about the drugs involved in overdose deaths and emergency room visits, and may even be able to link these episodes to diversion by highlighting those without an active prescription. While acknowledging that none of these databases are perfect, together they can provide a more complete account of diversion of controlled substances throughout the United States.

A. The data and analysis used to estimate diversion under the SUPPORT Act should be used to set quotas for all controlled substances.

Both the Quotas Rule and the SUPPORT Act require the DEA to determine the extent to which controlled substances are diverted from legitimate uses, and to reduce those substances' quotas accordingly. The Quotas Rule added the "extent of any diversion of the controlled substance in the class" to the "factors that must regularly be considered in setting the aggregate production quotas." 83 Fed. Reg. at 32,784. This change was designed to ensure that quota

amounts are "limited to that needed to provide adequate supplies for the United States' legitimate needs." *Id.* Similarly, the SUPPORT Act requires that "after estimating the amount of diversion of a covered controlled substance, the Attorney General shall make appropriate quota reductions, as determined by the Attorney General, from the quota the Attorney General would have otherwise established had such diversion not been considered." Pub. L. No. 115-271, § 3282(a)(4), 132 Stat. 3955.

Notwithstanding the similar language and purposes behind these two reforms, the DEA has taken different approaches when accounting for diversion under the SUPPORT Act and the Quotas Rule. For the five controlled substances covered by the SUPPORT Act, the DEA has estimated diversion using databases of theft reports and seizures of controlled substances by law enforcement. 84 Fed. Reg. at 48,172-73. The DEA then made a straightforward reduction in these substances' aggregate quotas "by the corresponding quantities." *Id.* at 48,173. When applying the Quotas Rule to substances not covered by the SUPPORT Act, however, the DEA noted that these theft and seizure databases contained "usable information"—but stopped short of conducting the same division calculations for other controlled substances. at 48,172. Indeed, the agency did not even give a rough estimate of diversion for the other controlled substances, nor any corresponding decrease in their quotas. *Compare* 84 Fed. Reg. at 48,177, *with* 83 Fed. Reg. at 67,354 (proposing 2020 production quota of amphetamine (for sale) that is identical to the quota for 2019).

The DEA has not explained the logic behind these divergent approaches. If the DEA assumes that if must use different methodologies because of different wording in the Quotas Rule and SUPPORT Act, it is missing the forest for the trees. True, the SUPPORT Act is more pointed, directing that a quota "shall" be reduced from the amount that "would have otherwise been established had diversion not been considered," whereas the Quotas Rule requires only that the DEA to make a "determination" related to diversion. Pub. L. No. 115-271, § 3282(a)(4), 132 Stat. 3955; 21 C.F.R. § 1303.11(b). Yet in both contexts, the agency is required to make a determination regarding diversion. It is unclear why the DEA would choose to ignore the "usable" information contained in these databases for controlled substances outside the SUPPORT Act's purview—particularly when the DEA does not believe any other sources of information provided to it are usable, 84 Fed. Reg. 48,172—nor why its conclusions under the SUPPORT Act do not support similar quota decreases for all affected substances. After all, any diversion of controlled substances is *per se* not medically or scientifically necessary, and the new statute and rule *both* require taking diversion into account.

If the DEA believes it has developed a sound method to estimate diversion under the SUPPORT Act, then it is unreasonable and arbitrary and capricious not to apply that methodology to all diversion-related inquires. The agency's refusal to consider other existing sources underscores this point: Without anything else to rely on when considering other controlled substances, the appropriate response should be to give *greater* deference to the data sources and methodology for substances covered by the SUPPORT Act, not to decline to make any determination. At a minimum, the DEA should explain why it believes that the Quota Rule and SUPPORT Act mandate different treatment and results. Transparency regarding the DEA's findings and analysis, including disclosure of the formulae upon which the agency relies, is essential to provide all relevant parties the ability to thoroughly evaluate any DEA quota.

B. The DEA should include existing national and state databases in its analysis to develop a broader picture of diversion.

Even for those controlled substances the SUPPORT Act covers—and thus that the DEA used law enforcement databases to analyze—the most recent Proposed Quotas provided a surprisingly low figure for estimated diversion. For example, the agency's metric captured only 57 kilograms of oxycodone in 2019, out of a total 82,500 kilograms produced. *Compare* 84 Fed. Reg. 48,173 (estimated 2019 diversion), *with* 83 Fed. Reg. 67,354 (approved 2019 production quotas). After accounting for recent reforms, the trends discussed above still make it unlikely that diversion accounts for less than 0.007% of oxycodone produced. We recognize that accounting for diversion accurately is a difficult task given the limitations of current data sets, but the DEA can—and should—expand the universe of sources it considers when setting aggregate production quotas. We recommend three specific steps to incorporate information that is currently within the agency's reach, but that requires additional effort to bring together. *First*, the DEA should improve usability of the ARCOS and the SORS databases to allow for greater insight into prescribing practices. *Second*, it should look to other national databases that track drug abuse patterns, poisonings, emergency room visits, and individuals in treatment. *Third*, it should consider state databases that track drug overdoses and emergency room or hospital visits. If adopted together, these changes would allow the DEA to develop a much more comprehensive picture of legitimate and illegitimate prescription drug consumption—and tailor the annual quotas accordingly.

1. ARCOS and SORS should be valuable resources in estimating the extent of diversion. ARCOS is the repository for reports of all acquisitions and distributions of many controlled substances, including all Schedule II opioids and many other frequently abused drugs. 21 C.F.R. § 1304.33(d). The aggregation of these reports is intended to capture the full universe of controlled substance transactions, down to the individual dosage unit. *Id.* § 1304.33(e). SORS also provides a mechanism for wholesalers to report "orders of unusual size, . . . deviating substantially from a normal pattern, [or] of unusual frequency." *Id.* § 1301.74(b).

The previous Proposed Quotas did not indicate whether the DEA used SORS, and refered to ARCOS only in noting that it "was determined to contain identical information to the Theft Loss Report Database" and therefore not considered. 84 Fed. Reg. at 48,172. Choosing not to rely on SORS may be understandable as a practical matter, as the Inspector General noted that DEA field offices are extremely unlikely to retain or help centralize suspicious orders reports. *See* Inspector General's Report at 30-32. Specifically, the report notes that the "DEA has not created a system whereby [SORS] reports sent to its field divisions are uploaded into the SORS database." *Id.* at 31. Reforming this process to capture all suspicious orders would be an important and straightforward fix to allow the DEA to capture more information about "red flags" for diversion. *Id.* at 30. We echo the Inspector General's call for prompt change in this area. Especially given the DEA's lament about the lack of useful data to account for diversion, 84 Fed. Reg. 48,173, we fully expect that the administration will act quickly to reform the SORS reporting process so that the DEA will be in position to harness what should be a critically important source of information.

The DEA's decision to discount ARCOS is harder to rationalize. In the Proposed Quotas, the DEA explained that overdose data received from States and the Centers of Disease Control cannot be used to estimate diversion because that data is imprecise; it does not distinguish between

"illicit" and "FDA-approved" opioids, nor between the "basic class" of opioids causing an overdose (for example, hydrocodone versus oxycodone). 84 Fed. Reg. at 48,172. Yet this shortcoming could be mitigated by cross-referencing this existing overdose data with ARCOS, which does identify the specific forms and quantities of controlled substances sold in a given area. Thus, although there would not be a 1:1 match between a specific ARCOS transaction and a specific reported overdose, the ARCOS data would provide context that could and should inform the quota-setting process. If, for example, Centers for Disease Control data shows a State has a disproportionately high opioid overdose rate, and ARCOS data shows that State also has disproportionately high sales of prescription opioids, then the DEA could conclude that a larger share of that State's overdoses are attributable to diversion of prescription opioids rather than use of illegal opioids. The ARCOS data accordingly has value beyond what is already captured by the Theft Loss Report database, and the DEA should not have disregarded it entirely.

To be sure, ARCOS data is often reported in inconsistent ways and at varying times, which may prevent the DEA from having a complete picture of distribution patterns at the time the DEA sets quotas for the next year. Inspector General's Report at 28-29. Standardizing these reporting procedures—including through monthly reports from all registrants—would allow the DEA to maintain an updated year-to-date estimate of controlled substance sales. And even if this estimate lags behind the quota setting process by a year or two, the DEA can compare these results to its projected quotas for that year to determine if and where it is overestimating legitimate demand.

2. Other national databases, while not perfect, should be an additional tool for the DEA when accounting for diversion in the annual quotas. While acknowledging the shortcomings of some of these databases—including lag time, sample size, and breakdown of drugs into classes—there is still plenty of available material that can help put a number on diversion by shining a light on it from different angles. A selection of examples include:

- **National Poison Data Center (NPDC)**, *American Association of Poison Control Centers*: This is the data warehouse for the nation's 55 poison control centers. It tracks calls as anonymized, individualized data in near real-time and by specific drug type (*e.g.*, oxycodone, hydrocodone, and hydromorphone).

- **Treatment Episode Data Set (TEDS)**, *Substance Abuse and Mental Health Services Administration*: This database collects treatment data for individuals 12 years or older from state agency data systems. It records admissions and discharges along with what substances were used, route of use, frequency of use, and number of previous admissions.

- **Researched Abuse, Diversion and Addicted-Related Surveillance (RADARS)**, *Denver Health and Hospital Association*: This is a database of diversion poisonings, and non-medical use of prescription drugs by specific drug, along with the street price of specific prescription drugs.

- **National Survey on Drug Use and Health (NSDUH)**, *Substance Abuse and Mental Health Services Administration*: This is an annual survey of nearly 70,000 people in all 50

States and the District of Columbia. It is conducted to monitor substance use trends and breaks down the number of people who report misusing specific drugs.

3. Similarly, a number of States have their own databases that can be helpful in determining the extent of diversion of controlled substances. Not only do many States track drug overdose deaths by specific drug—which is one of the weaknesses the DEA noted in the national databases it considered, 84 Feg. Reg. 48,172—using data from state-based prescription drug monitoring programs may make it possible to determine how many of these individuals had an active prescription for any of the drugs at issue. For example:

- **Overdose Surveillance Summary**, *Alabama Department of Public Health*: This summary shows the number of deaths where specific drugs—oxycodone, hydrocodone, methadone, and others—were reported on the death certificate.

- **Opioid Overdose Surveillance Dashboard**, *California Department of Public Health*: This dashboard is able to show overdose deaths, emergency department visits, hospitalizations and prescriptions for prescription opioids in each county.

- **Florida Drug-Related Outcomes Surveillance and Tracking System (FROST)**, *University of Florida College of Medicine*: FROST is an interactive, publicly available data dissemination tool for researchers, public health professions and the general public to quickly explore Florida drug-related outcomes by aggregating and presenting data from a variety of state and federal data sources.

- **Overdose Fatality Report**, *Kentucky Office of Drug Control Policy*: This report lists all drugs broken out by the number of deaths each was associated with in the State.

- **Opioid Data Dashboard**, *New Jersey Department of Health*: This dashboard shows deaths attributed to oxycodone and other opioids by county, and inpatient or outpatient hospital visits for prescription opioids by county.

- **State Opioid Data Dashboard**, *New York Department of Health*: This dashboard shows overdose deaths, emergency department visits, and hospital discharges with the ability to view through the lens of all opioids, synthetic opioids excluding methadone, or opioids excluding heroin.

- **Fatal Unintentional Poisoning Surveillance System**, *Oklahoma State Department of Health*: This database lists the top drugs and number of deaths each was associated with in the State.

- **Prescribing and Overdose Data**, *Oregon Health Authority*: This dashboard show overdoses, EMS naloxone administration, overdose hospitalization, and risky prescribing measures for opioids excluding heroin.

- **State Resident Drug Overdose Quarterly Report**, *Washington Department of Health*: This dashboard shows overdose deaths and hospitalizations by county and can be broken down by a number of drug classes.

While not an exhaustive list, these resources—and the underlying state-level data collection tools they rely on—provide a starting point for quantifying diversion. They are able to get at diversion from a wide variety of angles: overdose deaths, reported poisonings, individuals in treatment, abuse and misuse, and emergency room visits. Especially where comprehensive national sources are lacking, the DEA should not discount state-specific sources when fulfilling their statutory mandate to account for diversion in setting quotas.

II. The DEA Should Account For Over-Prescribing As Part Of Its Diversion Analysis.

Theft and seizure records are important data points for the DEA, but they paint an incomplete picture of diversion. Drug abusers can obtain prescription opioids through legal channels, either directly from irresponsible physicians or from family members or friends with excess medication. Indeed, one of the central factors that has made diversion possible on such a massive scale in our country is the systemic overprescribing of opioids. By definition, opioids prescribed in quantities above what patients need for pain management are not "necessary to be manufactured . . . to provide for the estimated medical, scientific, research and industrial needs of the United States." 21 C.F.R. § 1303.11(a). More concerning, overprescribing also feeds directly into diversion: More than half of prescription opioid abusers report that they obtain drugs "from a friend or relative for free"—and an additional 15% either buy or steal drugs from their friends and relatives. *See* Rachel N. Lipari & Arthur Hughes, *How People Obtain the Prescription Pain Relievers They Misuse*, Substance Abuse and Mental Health Services Administration (Jan. 12, 2017), *available at* https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html. Neither is this trend isolated to one-time or infrequent abuse; family and friends remain the most common source of narcotics for even habitual opioid abusers. *Id*.

A. The DEA should use medical professionals' "best practices" to help account for overprescribing at the physician level.

There is abundant evidence that the amount of opioids prescribed in recent years has been excessive, far above the amount necessary to support legitimate medical need. Numerous studies, for example, demonstrate that opioids are commonly dispensed in excessive quantities after surgeries and hospital stays. A recent study conducted by the University of Michigan analyzed post-surgery opioid use among 89 hysterectomy patients. It showed that patients consumed, on average, less than half of the hydrocodone pills they were prescribed—leaving a surplus equivalent to 22 hydrocodone tablets per patient. *See* Sawsan As-Sanie, et al., *Opioid Prescribing Patterns, Patient Use, and Postoperative Pain After Hysterectomy for Benign Indicators*, 130 OBSTETRICS & GYNECOLOGY 1261, 1264 (2017). Yet even with this consistent underuse of prescribed pain medication, 97% of the women in the study reported adequate pain control, and 40% believed they received more opioids than necessary. *Id*. This data shows that even in the limited context of one specific surgery, overprescribing contributes to a massive increase in the opioid supply—with roughly 600,000 hysterectomy procedures performed each year, an average of 22 surplus pills per patient corresponds to the equivalent of 13 million medically unnecessary hydrocodone pills prescribed every year. *See* Beata Mostafavi, *Study: Patients Use Only About Half of Opioids*

Prescribed After Hysterectomy, Univ. Mich. Health (Dec. 4, 2017), *available at* https://labblog.uofmhealth.org/rounds/study-patients-use-only-about-half-of-opioids-prescribed-after-hysterectomy.

Similar patterns have been observed across a wide range of other procedures—mastectomies, cholecystectomies, hernia repairs, and others. Hill, *et al.*, at 710. Other examples abound. A survey of 210 urologic surgery patients revealed that two-thirds of patients received medically unnecessary opioids—and over 90% of them saved their extra pills. Core Bates, et al., *Overprescription of Postoperative Narcotics: A Look at Postoperative Pain Medication Delivery, Consumption and Disposal in Urological Practice,* 185 J. UROLOGY 551, 551 (2011). A study of 250 upper-extremity surgery patients showed that most patients received a prescription for 30 opioid pills, but 77% took less than half that amount, and 45% took only five pills or less. Jeffery Rodgers, et al., *Opioid Consumption Following Outpatient Upper Extremity Surgery*, 37 J. HAND SURGERY AM. 645, 645 (2012). A survey tracking 343 children who were discharged from a hospital with an opioids prescription discovered that the patients never took 58% of the prescribed doses, yet only 4% of the excess medication was disposed of properly. C.L. Monitto, *et al.*, *Opioid Prescribing for the Treatment of Acute Pain in Children on Hospital Discharge*, 125 Anesthesia & Analgesia 2113, 2113 (2017). Circumstances like these are a perfect recipe for diversion.

Finally, another University of Michigan study revealed that after gallbladder removal patients were generally prescribed 250 milligrams of opioid pain medication, or about 50 pills, but only used the equivalent of 6 pills. Ryan Howard, *et al.*, *Reduction in Opioid Prescribing Through Evidence-Based Prescribing Guidelines*, 153 JAMA SURG. 285, 286 (2017). This study also highlights the aftermath of using data like this to reduce future prescriptions. The University's academic medical center reported that the average prescription after gallbladder removal surgery dropped by two-thirds after this study—and importantly, "requests for opioid refills didn't increase." *Id*. To the contrary, patients who received the smaller prescriptions took even fewer pills than the patients in the study, yet reported *the same level* of pain control. *Id*.

Medical experts are addressing over-prescription concerns like those highlighted by these studies by crafting "best practices" for opioid prescribing—which in turn can provide the DEA with further insight into the true quantities of "medically necessary" opioids. For example, Johns Hopkins University's recent review of 20 common surgical procedures provides guidance on medically advisable amounts of opioids for opioid-naïve patients. *See* Heidi N. Overton, et al., *Opioid-Prescribing Guidelines for Common Surgical Procedures: An Expert Panel* Consensus, 2 J. AM. COLL. SURG. 411, 411 (2018). This analysis found that none of the procedures in question typically warrant prescribing more than 20 oral oxycodone tablets, or their equivalent, and half of the procedures warrant prescribing no more than 10. *Id.* at 413. Nevertheless, some procedures were treated with prescriptions five times larger than what the panel recommended—another indication that the agency's view of "medically necessary" quantities may no longer align with best practices. *Id.* at 412 (finding that post-operative pain after laparoscopic cholecystectomy has been treated with prescriptions ranging from "0" to greater than "50" tablets, while in the panel's view a dose of only "0 to 10" was warranted).

B. The DEA can account for overprescribing at the patient level by incorporating data collection into its prescription drug takeback program.

The DEA should also expand its prescription drug takeback programs to capture more precise data on overprescribing rates. The DEA administers a network of Authorized Collection Sites and organizes biannual "National Take Back Days" through which patients can return unused medication for safe disposal. U.S. Drug Enforcement Administration, *Disposal Act: General Public Fact Sheet* at 2 (June 1, 2018), *available at* https://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_public_06222018.pdf. Many state Attorneys General offices participate in these takeback opportunities. These programs capture large quantities of unused medications—937,443 pounds during a one one-day event, and nearly 12 million pounds just through biannual Take Back Day programs. U.S. Drug Enforcement Administration, *17th National Take Back Day* at 4-5, *available at* https://takebackday.dea.gov/sites/default/files/NTBI%2017%20Totals-April2019.pdf. And there is good reason to believe that drugs returned in takeback events skew heavily towards dangerous controlled substances that are frequently overprescribed and targeted for diversion. For example, a review of medication returned at 80 Take Back Days locations across six States found that hydrocodone accounted for 37% of returned dosage units, with opioids overall accounting for 66%. Jeanie E. Jaramillo-Stametz *et al.*, *Multi-state Medication Take Back Initiative: Controlled Substances Collected From 2011 to 2015*, 23 J. SUBSTANCE USE 36, 39 (2017).

As a general rule, these takeback programs do not track the types and quantities of drugs returned. This limitation limits—although does not reduce entirely—their value in measuring overprescribing. The DEA should thus modify existing and future take back programs to ensure that this critical source of information does not go unused. More than sales data, overprescribing data directly speaks to the question of medical and scientific necessity. It should be axiomatic that medications voluntarily disposed of were not part of the "medical, scientific, research and industrial needs" of the United States. 21 C.F.R. 1303.11(a).

The results from drug take back programs that *have* tracked disposed medications shows how powerful a tool these programs could be for monitoring the scope of opioid overprescribing. For example, analysis by Wisconsin's MedDrop™ program showed that Schedule II opioids accounted for over 47% of pills returned for disposal. Grace C. Welham, et al., *Type and Frequency of Opioid Pain Medications Returned for Disposal*, 2 DRUGS-REAL WORLD OUTCOMES 129, 132 (2015). The average prescription returned through this program had more than half the prescribed dose remaining, *id.*—results that track the studies discussed above about overprescribing to post-operative patients. A similar study reviewed results from 11 drug take back programs in Maine over a three-year period, and found that most Schedule II opioids returned had an average of 69% remaining from the originally prescribed dose. *See* Heather Stewart, et al., *Inside Maines's Medicine Cabinet: Findings From the Drug Enforcement Administration's Medication Take-Back Events*, 105 AM. J. PUB. HEALTH e65, e66-e67 (2015).

The results from drug take back programs are important not only for what they show about the widespread trend of prescribing opioids in excessive amounts, but also because the numbers of returned drugs represent only a small fraction of excess drugs overall. Patients with excess opioids are far more likely to save excess pills, rather than turn them over for disposal. A 2011

study, for instance, found that 91% of patients with leftover opioids kept them for later use. *See* Cory Bates, *et al.*, at 551. And a 2016 study found that 47% of parents saved their children's leftover pain medication, and another 15% either gave away the excess pills or could not remember what happened to the excess. *See* C. S. Mott Children's Hospital, *Narcotics in the Medicine Cabinet: Provider Talk is the Key To Lower Risk* (May 16, 2016), *available at* https://mottpoll.org/sites/default/files/documents/051616_painmeds.pdf. In keeping with the sobering statistics about diversion, there is every reason to believe that these leftover pills are a ripe source for eventual diversion to family and friends.

* * *

The opioid crisis is one of the preeminent tragedies facing our country today, and the DEA's annual quotas are an essential tool in our continued fight against senseless deaths from opioid abuse and overdoses. It is certainly helpful to account for diversion by capturing theft and seizures from crime scenes, as the DEA's current methodology considers in part. But relying exclusively on evidence of illegal activity is not only myopic, but dangerous: It reinforces the error that underscored years of prior quota calculations by assuming that controlled substances legally sold are part of the "medical [and] scientific" needs of the United States. The reality is that opioids are often prescribed *legally* but *unnecessarily*—and the excess too often becomes part of the tragic statistics that define our national opioid crisis. We applaud the DEA's renewed commitment to responsible annual opioid quotas and to continuing to develop the data sources needed to regulate with precision, and consistent with a holistic vision of what constitutes legitimate need. We appreciate the opportunity to provide input as the DEA continues this process for 2020 and the years to come. We look forward to the DEA's attention to the questions raised in these comments, and welcome further opportunities to provide insight into the realities of opioid over-prescription and abuse in our States.

Sincerely,

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