Office of the Attorney General
State of West Virginia

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October 15, 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, Idaho, Kentucky, Louisiana, and Nebraska, on the request for comment entitled, *Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020* (Docket No. DEA-508P)

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 the proposed 2020 aggregate production quotas for Schedule I and Schedule II controlled substances. 84 Fed. Reg. 48,170 (Sept. 12, 2019) ("Proposed Quotas"). The DEA is required to consider input from the States when determining whether proposed quantities of controlled substances are "excessive" relative to the amounts necessary to meet the legitimate medical and scientific needs of the United States. 21 C.F.R. § 1303.11(c). The undersigned States submit these comments to explain that the illicit diversion of controlled substances—opioids especially—as a result of over-prescribing is a crucial factor in this analysis. The undersigned States applaud the significant improvements the DEA has made in this regard over the past several years and in the Proposed Quotas, and identify several factors that warrant additional consideration before the DEA calculates the final 2020 quotas.

BACKGROUND

One of the fires fueling the opioid epidemic is the availability of controlled substances diverted from *legitimate* users or 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 were a factor in roughly one-third of all fatal drug overdoses involving state residents in 2016. *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 is intended to operate as a 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 amounts 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 Schedule II 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, the amounts of controlled substances above those required for legitimate ends—and thus vulnerable to illicit diversion—are not produced in the first place.

Unfortunately, this laudable goal has often been subverted by loose regulatory language and lax enforcement. As originally drafted, the regulations creating the annual 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). Thus, the DEA's quota-setting process 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 portions of each category 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") at i, Evaluations and Inspections Division 19-05 (Sept. 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 unsurprisingly, 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 as an 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 this same period, from 70,000 kilograms in 2008 to over 149,000 kilograms in 2014. 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* during this period. 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 between 2008 and 2014. Rose A. Rudd, et al., *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 ANN. INTERNAL MED. 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/ucd-icd10.html (last accessed Oct. 11, 2019). Not all of these deaths are attributable to diversion from legitimate sales, of course. Nevertheless, *prescription* opioids have been a dominant driver in this growing national 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 rampant 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. W. Va. Att'y Gen., *Best Practices For Prescribing Opioids In West Virginia* (Jan. 2016), *available at* http://bit.ly/2bHACNH. The goal of this project was 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. West Virginia also passed legislation limiting opioid prescriptions for acute pain to between three and seven days, depending on the circumstances. S.B. 273, 2018 Reg. Sess. (W. Va. 2018). In 2018, Florida likewise passed a law limiting opioid prescriptions to between three and seven days, depending upon the circumstances. Fla. Stat. § 456.44. 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 double. 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.

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 dispensed dropped from nearly 44 million in 2012 to under 25 million. 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. 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*.

Although a vitally important measure, the "Safer Prescribing Plan" is targeted at 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 forward momentum in 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"). While the Quotas Rule applies to the entire quota process, however, 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. 84 Fed. Reg. 48,170 (Sept. 12, 2019). 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. The Proposed Quotas would cut the 2020 production quota for hydrocodone by over 20 percent, and oxycodone by nine percent. *Compare* 84 Fed. Reg. at 48,177, *with* 83 Fed. Reg. at 67,354. The DEA's explanation of these reductions also charts a promising path for the future. The Proposed Quotas note 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.

DISCUSSION

Overall, we applaud the DEA's recent efforts to correct the systemic flaws in the drug quota system that have played a role in the opioid epidemic's growth nationwide. 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. 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 three such areas. *First*, the agency should adopt a uniform method of accounting for diversion under the Quotas Rule and the SUPPORT Act. The Proposed Quotas use two different methods of accounting for diversion; one for the five specific controlled substances listed in the SUPPORT Act only, and another more broadly under the Quota Rule. *Id*. at 48,173. It is unclear why the DEA interpreted these provisions—which are both aimed at accounting accurately for diversion—to require distinct methodologies. *Second*, the final 2020 quotas should consider both diversion specifically and over-prescribing generally when determining the amount of controlled substances that are "medical[ly] and scientific[ally]" necessary. 21 C.F.R. § 1303.11(a). *Third*, while recognizing the data-related limitations the DEA has identified in the Proposed Quotas, the final quotas should account for additional sources of information—some that are already available to the DEA—that would provide additional help when accounting accurately for diversion.

I. The DEA Must Conduct The Same Diversion Analysis 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. The rule explains that 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 Proposed Quotas take a noticeably different approach when accounting for diversion under the SUPPORT Act and the Quotas Rule. For the five controlled substances covered by the SUPPORT Act, the Proposed Quotas explain that the agency estimated diversion using databases of theft reports and seizures of controlled substances by law enforcement. 84 Fed. Reg. at 48,172-73. The Proposed Quotas then make 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 Proposed Quotas note only that these theft and seizure databases contained "usable information." *Id*. at 48,172. There is no indication that the diversion calculations conducted for the five SUPPORT Act substances were conducted for any other controlled substance. The Proposed Quotas do not even contain 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 Proposed Quotas do not explain the logic behind these divergent approaches. If the DEA assumes that it must use different methodologies because the Quotas Rule and SUPPORT Act are worded differently, 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," Pub. L. No. 115-271 § 3282(a)(4), 132 Stat. 3955, whereas the Quotas Rule requires only that the "extent of diversion" be "consider[ed]," 21 C.F.R. § 1303.11(b)(5). Yet over-prescribed and diverted opioids are *per se* 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). Moreover, while the Quotas Rule does not expressly require the DEA to use the same databases that the SUPPORT Act mandates, it still requires the DEA to make a "determination" related to diversion. 21 C.F.R. § 1303.11(b). It is unclear why the DEA would choose not to draw conclusions from the "usable" information contained in these databases for controlled substances other than those the SUPPORT Act describes—particularly when the DEA does not believe any other sources of information provided to it *are* usable, 84 Fed. Reg. 48,172—or why those conclusions should not translate directly into a quota decrease for all affected substances.

Finally, the final 2020 aggregate production quotas must "include the findings of fact and conclusions of law upon which the order is based." 83 Fed. Reg. at 32,790. Transparency regarding the DEA's findings and analysis—including disclosure of the formulae upon which the agency relies in setting the final numbers—is essential to provide all relevant parties the ability to thoroughly evaluate the DEA's order. Indeed, given the DEA's past failure to account for diversion and the input of States and federal agencies when developing the proposed quotas, full information about the DEA's process is especially needed.

If the DEA believes it has developed a sound method to estimate diversion under the SUPPORT Act, it is unreasonable not to apply that methodology to all diversion-related inquiries. After all, if the DEA believes that there are currently no other sources of useful or useable data from which to account for diversion, then 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 a determination and corresponding quota adjustment for other controlled substances. At a minimum, the DEA should explain why it believes that the Quotas Rule and SUPPORT Act mandate different treatment and results before finalizing the 2020 quotas.

II. The DEA Should Include Methods And Data That Capture Over-Prescribing As Part Of Its Diversion Analysis.

The DEA's current approach to accounting for diversion is a significant improvement from previous years, and we are optimistic that the administration will continue to adjust its methodology so the final quotas more accurately reflect legitimate need. Another important data point in this analysis—and one that the Proposed Quotas do not adequately account for—is over-prescription.

Although drug dealers and unethical physicians are responsible for much of the opioid diversion nationwide, the most common path for diverted opioids to find their way to drug abusers is through friends and family members. More than half of prescription opioid abusers report that they obtain the drugs "from a friend or relative for free"—and an additional 15% either buy or steal drugs from their friends and relatives. *See* Substance Abuse and Mental Health Services Administration, *How People Obtain the Prescription Pain Relievers They Misuse* (Jan. 12, 2017), *available at* https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html.

Moreover, this trend is not isolated to one-time or infrequent abuse—family and friends remain the most common source of narcotics for even habitual opioid abusers. *Id*.

One of the central factors making diversion on this massive scale possible is over-production and over-prescription of opioids—practices that work together to enable legitimate prescriptions to get into the hands of patients' friends and family. Indeed, there is ample 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. This study 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). Significantly, even with this habitual 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.* In other words, the study supported a conclusion that opioids were prescribed at levels well beyond the patients' actual medical needs. And extrapolating this data, with roughly 600,000 hysterectomy procedures performed each year, an average of 22 surplus pills per patient means that this one surgery may correspond to the equivalent of 13 million medically unnecessary hydrocodone pills prescribed every year. *See* Beata Mostafavi, *Study: Patients Use Only About Half of Opiods 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 opioid 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 & Anelgesia 2113, 2113 (2017).

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. This study also highlights the aftermath of using this data to reduce prescription amounts. 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." Ryan Howard et al., *Reduction in Opioid Prescribing Through Evidence-Based Prescribing Guidelines*, 153 JAMA Surg. 285, 285 (2017). 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.*

The results from drug takeback programs, aimed at helping patients dispose of unused and unneeded medication, further underscore the scope of opioid over-prescription. For example, analysis by Wisconsin's MedDrop™ program showed that Schedule II opioids accounted for over 47% of the 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 over-prescription of opioids to post-operative patients. A similar study reviewed results from 11 drug takeback 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 Maine'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 takeback 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., *Overprescription of Postoperative Narcotics: A Look at Postoperative Pain Medication Delivery, Consumption and Disposal in Urological Practice*, 185 J. of Urology 551, 551 (2011). 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.

In short, the Proposed Quotas represent a marked improvement over prior years, particularly as they finally begin to account for diversion. Yet while the theft and seizure records the DEA considered are important data points, they capture a picture of diversion that is far from complete. We recognize that there is no perfect system of measuring other sources of diversion like over-prescription, but the DEA should still strive to use the information that *does* exist—neither the SUPPORT Act nor the Quotas Rule allows for ignoring this important driver of diversion altogether.

III. The DEA Must Consider Additional Information To Properly Calculate Production Quotas.

Finally, although we recognize that current data sets make accounting for diversion fully and accurately a difficult task, the DEA can—and should—expand the universe of sources it draws

from when setting aggregate production quotas. The Inspector General's Report (at 28), comments by States on previous controlled substance quotas, and the Proposed Quotas themselves, 84 Fed. Reg. at 48,172, all note the need for more comprehensive and accurate data to fully capture the scope and magnitude of diversion. Indeed, even where the Proposed Quotas provide a specific figure for estimated diversion, the figure is surprisingly low; this 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). Even on the heels of recent reforms, the trends discussed above make it unlikely that diversion accounts for less than 0.07% of oxycodone produced.

The DEA should take three steps to capture information that *is* currently within its reach, but that requires additional effort to bring together. *First*, it should improve usability of the Automatic Reports and Consolidated Ordering System ("ARCOS") and the Suspicious Order Reporting System ("SORS") databases to allow for greater insight into prescribing practices. *Second*, it should improve data collection in prescription drug takeback programs to capture the quantities and proportions of drugs that are overprescribed in particular areas. *Third*, it should consider medical best practices as part of its holistic diversion analysis. If adopted together, these changes would allow the DEA to develop a much more comprehensive picture of legitimate and illegitimate prescription drug consumption—and better 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 manufacturers to report "orders of unusual size, . . . deviating substantially from a normal pattern, [or] of unusual frequency." *Id.* § 1301.74(b).

The Proposed Quotas do not indicate that the DEA used SORS, and refer 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 order 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 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, we fully expect that the administration will act quickly to modify SORS so that the DEA will be in a position to harness what should be a critically important source of information.

The DEA's decision to discount ARCOS in the Proposed Quotas is harder to rationalize. The Proposed Quotas explain that overdose data the DEA received from States and the CDC 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 (*i.e.*, 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 identifies 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, CDC data shows two States have comparable opioid overdose rates, but one State has disproportionately higher 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. While we encourage the DEA to make these changes to increase information available for future years, we also urge the administration to use the data that *is* available now to fulfill its duty to consider diversion under the Quotas Rule and SUPPORT Act.

2. Similarly, the DEA should expand its prescription drug takeback programs to capture more precise data on over-prescription 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. These programs capture large quantities of unused medications—937,443 pounds during a 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 over-prescribed and targeted for diversion. For example, a review of medications returned at 80 Take Back Days 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. OF SUBSTANCE USE 36, 39 (2017).

As a general rule, these takeback programs do not track the types and quantities of drugs returned, which currently limits—although does not reduce entirely—their value in measuring over-prescription. The DEA should modify existing and future take back programs to ensure that this critical source of information does not go unused. More than sales data, over-prescribing 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). And as noted above, unused

medications are a major contributor to diversion, which the DEA is obligated to consider when setting annual quotas.

3. The DEA could also gain important insight into what opioid quantities are "medically necessary" by studying the best practices developed by the medical community and state regulators. For example, a recent review by Johns Hopkins University of 20 common surgical procedures provides guidance on the suitable amounts of opioids that physicians should prescribe to 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 warranted prescribing more than 20 oral oxycodone tablets, or their equivalent, and half of the procedures warranted prescribing no more than 10. *Id*. at 413; *see also*, *e.g.*, *id.* at 412 (finding that post-operative pain after laparoscopic cholecystectomy has been treated with prescriptions ranging from "0 to greater than 50" tablets, where in the panel's view a dose of only "0 to 10" was warranted).

As noted above, the Proposed Quotas account for diversion by capturing thefts and seizures from crime scenes. 84 Fed. Reg. at 48,172. This is certainly helpful data, 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 any controlled substance that is *legally* sold is part of the "medical [and] scientific" needs of the United States. The reality is that legal sales are outsized in comparison to legitimate need, and legally prescribed drugs are often abused. The information provided in these comments represents only a fraction of the data highlighting the disconnect between the amount of opioids *prescribed* and *sold* each year and the amount actually *used* by their intended patients—much less the amounts that *should be* prescribed. Equating demand with legitimate need is a dangerous practice that the DEA rightly recognized, in promulgating the Quotas Rule, must come to an immediate end. The final 2020 quotas accordingly must reflect results of the DEA's research and consideration of this important issue. Considering best practices guidelines—including most effective dosage levels for specific surgical procedures—is one tool that is currently available to help provide needed context when developing "across-the-board" quotas.

* * *

The opioid crisis is one of the preeminent tragedies facing our country today, and these quotas are an essential tool in our continued fight against senseless deaths from opioid abuse and overdoses. We appreciate the opportunity to provide input as the DEA considers how best to fulfill its responsibilities to ensure that the 2020 aggregate production quotas are consistent with governing laws and regulations, and the needs of the American people. We look forward to the DEA's continued 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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