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 Quota System from 2010-2016

Attorney General Patrick Morrisey
June 4, 2020

PLAINTIFFS TRIAL EXHIBIT
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June 4, 2020

To the Reader:

I am pleased to provide this report to the citizens of West Virginia, showing the failures of the Drug Enforcement Administration to account for diversion when managing its drug quota system. These failures significantly contributed to increasing opioid abuse and senseless death, in our State and across the nation.

The multi-year, multi-faceted investigation described in this report would not have been possible without the work of many dedicated public servants, including Robert Cheren, Michael Greibrok, Thomas Lampman, Anthony Martin, Tera McCown, and Lindsay See. Each of them contributed a great deal in shining a light on the federal government's epic failure to manage the national opioid supply, and to our ongoing fight for solutions. I commend each of them for their work on behalf of our State.

Sincerely,

Patrick Morrisey
Attorney General of West Virginia

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EXECUTIVE SUMMARY

Tackling the opioid crisis has been a top priority for the Office of the West Virginia Attorney General ("Office") under Attorney General Patrick Morrisey's leadership. As part of this effort, the Office conducted a multi-year investigation into federal regulators' role in allowing excessive over-production of the prescription opioids that helped fuel this crisis. An excessive supply of these *legal* opioids makes it easy for drugs initially obtained through a valid prescription to be diverted from legitimate medical and scientific users into the hands of abusers—through theft, secondhand sales, and even gifts from well-meaning family or friends. The significant role diversion plays in rampant opioid abuse was well-documented as early as 2010, which raised the question what the United States Drug Enforcement Administration ("DEA")—the federal agency tasked with setting annual production limits for opioids—was doing to stem the tide. By law, the DEA must set "annual production quotas" ("APQs") at a level that reflects legitimate medical and scientific need in the United States. Yet from 2010 to 2016, the DEA routinely increased production quotas for opioids by substantial amounts.

The investigation that led to this report reflects the Office's multi-year efforts to find an explanation for this concerning trend. This report catalogues the results of two Freedom of Information Act ("FOIA") requests that sought information from the DEA regarding the inputs the DEA received when setting annual production quotas from 2010 to 2016, and the information and methodology it used—if any—to account for diversion. The DEA's public statements regarding APQs summarized the factors and data sources that it claimed to use when calculating APQs, but publicly available documents made it difficult to assess what the agency actually did, and in any event before 2018 none of these factors expressly included diversion. We do know, however, how many people died as a consequence of the DEA's refusal to lower the permissible amount of pain pills that could be introduced into the marketplace. The Agency's failures were deadly.

The first FOIA request sought information regarding the data flowing into the process of setting APQs. This request sought all communications from outside sources to the DEA requesting increases or decreases in the APQs for the most commonly abused opioids, including communications from drug manufacturers and from other government agencies. The documents produced in response to this request[1] reveal several overall trends:

[1] Referred to herein as "Vol. I," available on the Office's website at https://bit.ly/2AxjiJc.

- *First*, the vast majority of comments the DEA received were requests for production increases based on growing sales. These requests did not, however, justify the requested increases based on more than mere assertions of consumer demand or increased sales—and critically, did not demonstrate that projected increases in demand were not tied to the well-documented diversion and abuse of opioids that were occurring at this time.

Example manufacturer request for quota increase:

RE: Docket No.DEA-343R (b)(4) **Comment**

Dear Sirs:

(b)(4);(b)(7)(E) and (b)(4);(b)(7)(E) have previously submitted quota correspondence as set forth in the table below for the following manufacturing categories. (b)(4) requests that the correspondence provided to the Quota Unit, which constitutes "CONFIDENTIAL BUSINESS INFORMATION", be considered during the 2011 Aggregate Production Quota review.

Quota Category	Quota Application Ref. #	Material Name	Date of Correspondence	Action Needed
Manufacturing	109184 (b)(4) 109532 (b)(4)	Hydrocodone for Sale – 9193	July 25, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	**109722**	**Oxycodone for Sale – 9143**	**October 12, 2011**	**An aggregate increase based on (b)(4) customer demand**
Manufacturing	109524	Oxymorphone for Sale – 9652	September 26, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109138	Amphetamine – 1100	August 3, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	92075	Methylphenidate – 1724	August 15, 2011	An aggregate increase based on (b)(4) customer demand

- *Second*, in contrast to these minimally supported requests, the Food and Drug Administration ("FDA") provided the DEA with a comprehensive set of data and mathematical models to project opioid sales for a given year. These projections also did not account for diversion, but even so they were frequently lower—substantially—than the APQs that the DEA ultimately set.

- *Third*, the DEA appears to have broadly accepted manufacturers' projections over the FDA's. Although the produced documents show instances where the DEA referred favorably to both types of projections, the DEA often departed from the FDA's recommendations while frequently granting increases based on manufacturers' proffers.

The second FOIA request summarized in this report asked the DEA for "all documents . . . showing how and when the Office of Diversion Control accounted for diversion of prescription opioids in setting annual drug quotas" for quota years 2010-2016. This request also asked for communications between leadership and staff at the DEA's Office of Diversion Control showing how the quota management system related to the scope and magnitude of the opioid crisis. The documents produced in response to this request,[2] viewed alongside those previously described, lead to three additional conclusions:

- *First*, during this period the DEA was aware of the growing scope of diversion and its role as one of the key drivers of the opioid crisis, yet it failed to act.

- *Second*, the DEA does not appear to have had a concrete methodology to account for diversion when setting APQs. Nothing in the DEA's documents reflects a level of data-driven mathematical modeling like the FDA's, for instance, much less one that specifically questioned the premise that all market demand equates to legitimate medical need. Indeed, the DEA's documents did not even show that the agency substantively accounted for its own data sources related to diversion in *any* way.

- *Third*, the DEA's process of reviewing individual quota applicants for "adverse information" was limited in scope and rigor. Moreover, it does not appear that the agency incorporated even this information into its process for setting APQs.

There is hope at the end of this investigation. Over the past three years—and due in part to this investigation and the Office's related federal lawsuit—the DEA has begun improving its management of drug quotas. The DEA has made substantial cuts to overall opioid quotas several times since 2017. In 2018, the DEA adopted a new rule that affirmatively requires the agency to account for the diversion of controlled substances from legitimate uses when calculating APQs. The new rule also requires the DEA to solicit input on proposed APQs from the federal Department of Health and Human Services and the States, and to consider any data from these entities that bear upon the magnitude of diversion. The rule even gives States the opportunity to challenge an APQ before it is finalized if they believe the process has not adequately accounted for diversion. Parts of this rule were also codified in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act") as part of a broader series of reforms.

As promising as these efforts are, it is only the beginning of the work yet to be done. Based on the context from years of massive agency failure that the produced documents reveal, the report ends with several recommended steps that the DEA could—and should—take to continue making progress in this critical area:

- **Demand higher standards of data from manufacturers**. Manufacturers who claim that APQs should be increased because of increased sales should bear the burden of justifying their requests, including by demonstrating that increased demand is not attributable to diversion.

[2] Referred to herein as "Vol. II," available on the Office's website at https://bit.ly/2AxjiJc.

- **Improve the collection and maintenance of the DEA's internal data sets**. Institutional and technical limitations prevent the DEA from making better use of existing data sets, and the agency should take steps to improve and build on these sources to increase the accuracy of inputs and outputs for future years.

- **Aggressively review APQs of past years to quantify the degree of inflation**. APQs were clearly excessive from 2010-2016. The DEA should conduct a thorough review of how much the APQs exceeded actual consumption and legitimate need in prior years to ensure that it is operating from an accurate baseline going forward.

- **Develop a concrete, data-driven methodology to account for diversion**. The DEA should use and expand on existing resources like the FDA's demand-projection model and information from the States and private organizations to account for diversion in a nuanced and accurate way when setting annual quotas.

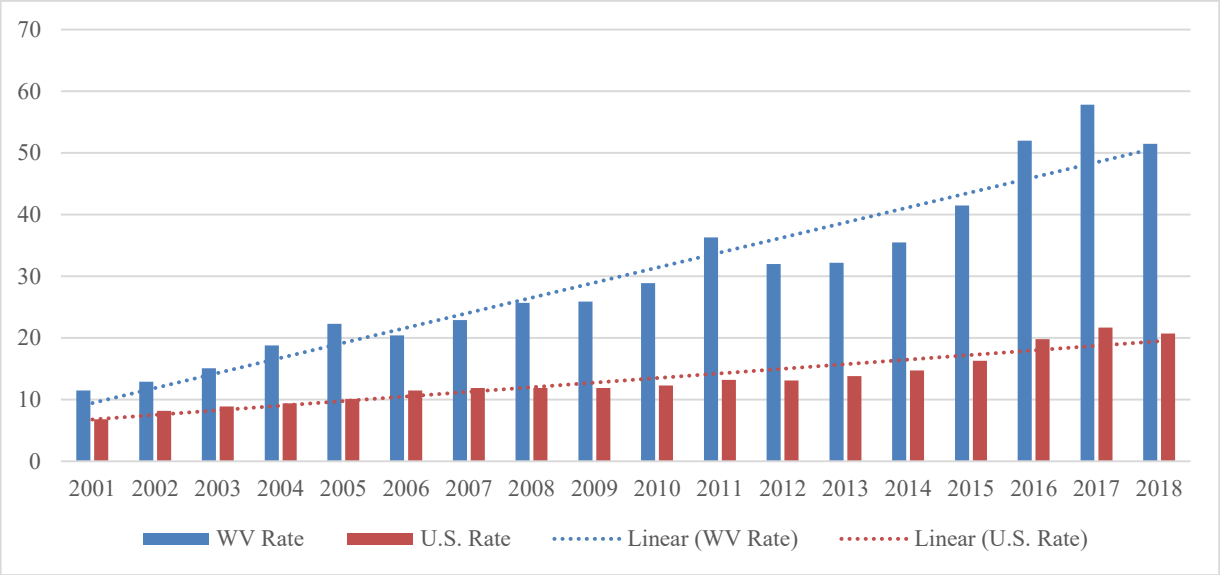
BACKGROUND

I. The Opioid Crisis in West Virginia

Over the past twenty years, opioid abuse has skyrocketed in West Virginia and around the country. From 1999-2015, the number of prescriptions tripled for powerful opioids like oxycodone and hydrocodone.[1] Predictably, this increase in supply paralleled a dramatic rise in opioid-related overdose deaths, emergency room visits, and admissions for substance abuse treatment.[2] In 2017, drug overdose became the leading cause of death for Americans under the age of 50.[3]

West Virginia has been one of the hardest hit States in this crisis, frequently suffering from overdose death rates more than double the national average:[4]

Figure 1: Drug Overdose Deaths Per 100,000 Residents, West Virginia and U.S. (2001-2018)[5]



Indeed, West Virginians feel the toll opioids have taken in every county, and it cannot be measured simply through loss of life. Opioid abuse and its attendant harms also reverberate across the

[1] *See* Haffajee, *et al*., *States with Overall Robust Prescription Drug Monitoring Programs Experienced Reductions in Opioids Prescribed to Commercially-Insured Individuals*, HEALTH AFFAIRS 37:6:964-974 (2018), https://bit.ly/2TXkTie.

[2] *Id*.

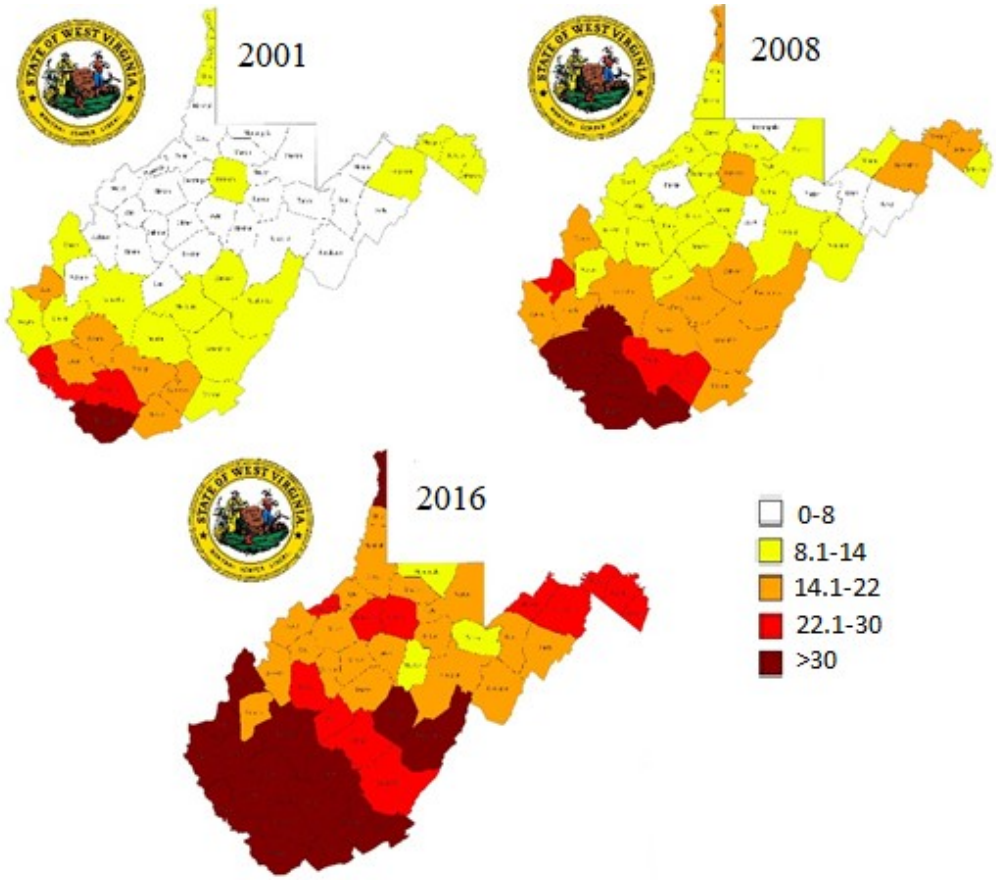
[3] NPR, *Report: Americans Are Now More Likely To Die Of An Opioid Overdose Than On The Road* (Jan. 14, 2019), https://n.pr/2LOoHh9.

[4] Data source: W.Va. Dept. of Health & Human Resources, *West Virginia Drug Overdose Deaths Historical Overview 2001 – 2015*, at 5 (Aug. 17, 2017), https://bit.ly/3eO7SzF.

[5] Data Source: U.S. Ctr. Disease Control, *Multiple Causes of Death, 1999-2018*, https://bit.ly/3cfRc21.

healthcare system, the criminal justice system, and society as a whole.[6] One often invisible example is the consequences for the foster care system. As more and more West Virginians are killed or incarcerated as a result of opioid addiction, West Virginia's foster care system has been overwhelmed with the children who are left behind. As of January 2020, more than 7,000 children in West Virginia are in state care—a 71% increase over the past decade.[7]

Figure 2: County-level Trends in Overdose Deaths: 2001-2016[8]



Although the crisis did not stem from any one drug—from 2001 to 2015, overdose deaths associated with many prescription opioids increased exponentially—three deserve special mention: hydrocodone, oxycodone, and oxymorphone. Each of these drugs were uncommon in 2001, yet a decade later each killed hundreds of West Virginians annually. This explosion of prescription opioid abuse was also a driving force behind a broader increase in abuse of synthetic

[6] U.S. Govt. Accountability Office, *Drug Misuse: Sustained National Efforts Are Necessary for Prevention, Response, and Recovery* 19, (Mar. 2020) https://bit.ly/3e5RBWm.

[7] Hannah Rappleye and Brenda Breslauer, '*Love, over everything': As West Virginia struggles with foster care crisis, families step up*, (Jan. 21, 2020), https://nbcnews.to/2zY3DlS.

[8] Data Source: U.S. Ctr. Disease Control, *Multiple Causes of Death, 1999-2018*, https://bit.ly/3cfRc21.

opioids like fentanyl, as well as heroin and other illicit drugs. But critically, it was prescription opioids that took root first. For example, heroin was associated with fewer than 70 overdose deaths a year until 2013, but (as shown in Table 1), hydrocodone and oxycodone crossed that threshold by 2007. And fully 80% of heroin users reported that they used prescription opioids first.[9]

Table 1: Opioid Abuse Recorded On West Virginia Death Certificates (2001-2015)[10]

Opioid	2001	2003	2005	2007	2009	2011	2013	2015	2001-2015 Total
Buprenorphine	0	0	0	0	5	15	30	31	164
Codeine	6	8	11	9	9	11	5	17	158
Fentanyl	9	36	54	60	49	51	40	180	769
Heroin	9	5	14	22	38	41	157	201	819
Hydrocodone	31	53	61	72	97	171	138	113	1399
Hydromorphone	1	0	2	6	11	14	12	8	97
Morphine	11	26	50	68	43	45	48	76	696
Methadone	39	71	120	109	78	61	55	32	1187
Oxycodone	39	45	58	112	141	224	200	182	1924
Oxymorphone	0	0	0	6	17	182	32	54	505
Propoxyphene	26	19	27	36	19	2	0	0	255
Tapentadol	0	0	0	0	0	0	0	0	1
Tramadol	2	1	11	17	16	35	37	22	283
At least 1 Opioid	148	214	314	412	399	579	500	638	6001

II. The Role of Diversion in Fueling the Crisis

One reason prescription opioids are often the gateway to opioid addiction is that, unlike illicit opioids such as heroin, prescription opioids are sold directly to the public to meet legitimate medical and scientific needs. In addition to the problem of addiction from legitimate medical use, it has become common for abusers to "divert" prescription opioids from legitimate uses. The concept of "diversion" thus refers to processes through which controlled substances are diverted away from legitimate uses—for example, abusers buying or stealing pills from patients with a legitimate prescription. Diversion is a critically important driver of the opioid crisis, because it is now the most common way opioids get in abusers' hands: Of the 5 million Americans who reported

[9] *See* CM Jones, *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers*, *United States 2002 – 2004 and 2008*, 2010 DRUG ALCOHOL DEPENDENCE 132(1-2), at 95 (2013), https://bit.ly/2XKj3Cw.

[10] Data source: W.Va. Dept. of Health & Human Resources*, West Virginia Drug Overdose Deaths Historical Overview 2001-2015*, at 8 (Aug. 17, 2017), https://bit.ly/2zNjeF4. (NOTE: Annual totals are less than the sum of each column, as an overdose event can be associated with more than one drug.)

having recently abused opioids, 71% obtained those drugs through diversion, not prescriptions.[11] Diverted drugs factored in roughly one-third of all fatal drug overdoses in 2016 that involved West Virginia residents.[12] And rural and impoverished areas are particularly fertile grounds for diversion, as prescription-holders can earn a 1,200% profit from reselling a single pill.[13]

These and other statistics reveal the hard truth: The type of opioid abuse that fosters dependency and eventual addiction too often has roots in a legitimate prescription,[14] not synthetic opioids or other street drugs. Reducing the demand for opioids thus requires tackling the problem of diversion head on.

III. The West Virginia Attorney General's Office Response to the Crisis

When Attorney General Morrisey took office in January 2013, he immediately began implementing measures to confront this crisis. Through a holistic approach with both short- and long-term goals, the Office's response approached the issue from the perspective of supply, demand, and education.

First, the most direct response involves identifying and cutting off the sources of abusable opioids before they reach their victims: prosecuting drug dealers, shutting down "pill mill" pharmacies, and suing the manufacturers and wholesalers responsible for flooding West Virginia with opioid pills. Unfortunately, the Office does not possess the ability to assist in the local criminal prosecution of those responsible for opioid abuse (except when appointed by the Governor, when serving as a Special Assistant U.S. Attorney, or when prosecuting cases of fraud against the State's Medicaid system). That fact has intensified the Office's focus on the civil liability side of the opioid epidemic, which led to the Office filing more opioid-related civil lawsuits than virtually any other State in the nation.

To date, civil litigation against 13 pharmaceutical distributors that contributed to the crisis of overdose deaths resulted in more than $84 million in settlements for West Virginians. Moreover, the settlement amounts received from these same wholesalers will likely increase substantially as the Office explicitly separated county and local governments from the State-based settlement. The Office's decision has positioned the State of West Virginia and her political subdivisions to proportionally receive far more in settlement and treatment dollars than practically any place in the country. The Office recently filed an *amicus* brief in the multi-district litigation which discusses the critical decision the Office made to exclude local governments from the State-based settlement, and strongly supports the localities' public nuisance claims.

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[11] *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).

[12] W. Va. Dept. of Health & Human Resources, *2016 West Virginia Overdose Fatality Analysis* 4 (Dec. 20, 2017), https://bit.ly/2TnZGOf.

[13] U.S. Govt. Accountability Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110, at 37 (Dec. 2003), https://bit.ly/2BcDUqe.

[14] CM Jones, *supra* note 9.

Further down the supply chain, the Office has also pursued pharmacists and pharmacies who were complicit with these manufacturers and distributors. Portions of proceeds from these settlements have been distributed to the West Virginia State Police and to many treatment centers to combat this crisis.[15] These lawsuits have also been a helpful vector for correcting the behaviors that allowed the crisis to become so widespread. The Office's February 2016 settlement with Miami-Luken, for example, was one of several settlements that required companies to report suspicious orders to the West Virginia State Police and the Office.[16]

Second, beginning in December 2015 the Office has worked with healthcare providers to develop best practices in opioid prescribing. Patterns in unnecessary and excessive opioid prescribing can be traced, in part, to (1) aggressive promotion of opioids as a no- or low-risk way to eliminate a patient's pain without fear of addiction;[17] and (2) changes in the healthcare industry (including through regulations imposed under the Affordable Care Act) that evaluate hospitals and practitioners on how they assess and treat patients' pain.[18] The Office's "Best Practices Toolkit" works to reverse these misconceptions and strongly encourage safe and appropriate opioid dosages when treating patients. The final version of the Toolkit was adopted as part of the West Virginia School of Osteopathic Medicine's curriculum and was implemented at the school's Robert C. Byrd Clinic. Similarly, the Office worked with the state Board of Pharmacy to develop a "morphine milligram equivalents" calculator, which determines the total strength of opioids a patient has been prescribed and displays it on the Board's Controlled Substances Monitoring Program. The Toolkit, increased monitoring through this program, and many other policy initiatives have led to an 85% reduction in doctor-shopping between 2014 and 2017.[19] And in order to protect doctors from retaliation stemming from responsible prescribing practices, the Office drafted a statute establishing that health care providers cannot be subject to negative employment consequences for not prescribing or dispensing opioids. The bill was passed by the West Virginia Legislature and signed into law during the 2018 legislative session.[20]

Third, the Office has placed significant focus on educating citizens and community groups on how to counter and prevent drug misuse and abuse. All of the Office's consumer field representatives are equipped with substance abuse materials to distribute to consumers whenever needed. The field staff are trained on substance abuse issues and have given hundreds of presentations across the State. Similarly, the Office partners with the Division of Protective

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[15] The Office, in conjunction with many from around the State and country, is currently developing a statewide abatement plan to ensure that any future monies are utilized to attack the root causes of the problem and address the harms imposed on West Virginians.

[16] W.Va. Dept. of Military Affairs & Public Safety, *W.Va. Public Safety, Public Health Departments Welcome $2.5 Million Drug Settlement News*, (Feb. 3, 2016), https://bit.ly/3eEvqGK.

[17] *See* Same Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* 99, 127 (2015).

[18] Sean Gregory, *How Obamacare is Fueling America's Opioid Epidemic*, TIME MAGAZINE (Apr. 13, 2016), https://bit.ly/3bSTNyK.

[19] W. Va. Bd. Pharmacy, *Controlled Substance Monitoring Program: 2018 Annual Report* 1 (2018), https://bit.ly/2XlgTu8.

[20] S.B. 273, 2018 Reg. Sess. Ch. 46.

Services in the DEA National Prescription Drug Take-Back Day. Since 2013, this event achieved two goals: it broadened public awareness of the importance of drug disposal, and highlighted the concrete effects of disposal programs by collecting hundreds of pounds of medication—thus removing the chance for any of it to be available for diversion. This event repeats annually, and in 2018 the Office further expanded its efforts by partnering with law enforcement and substance abuse groups at six sites across West Virginia.

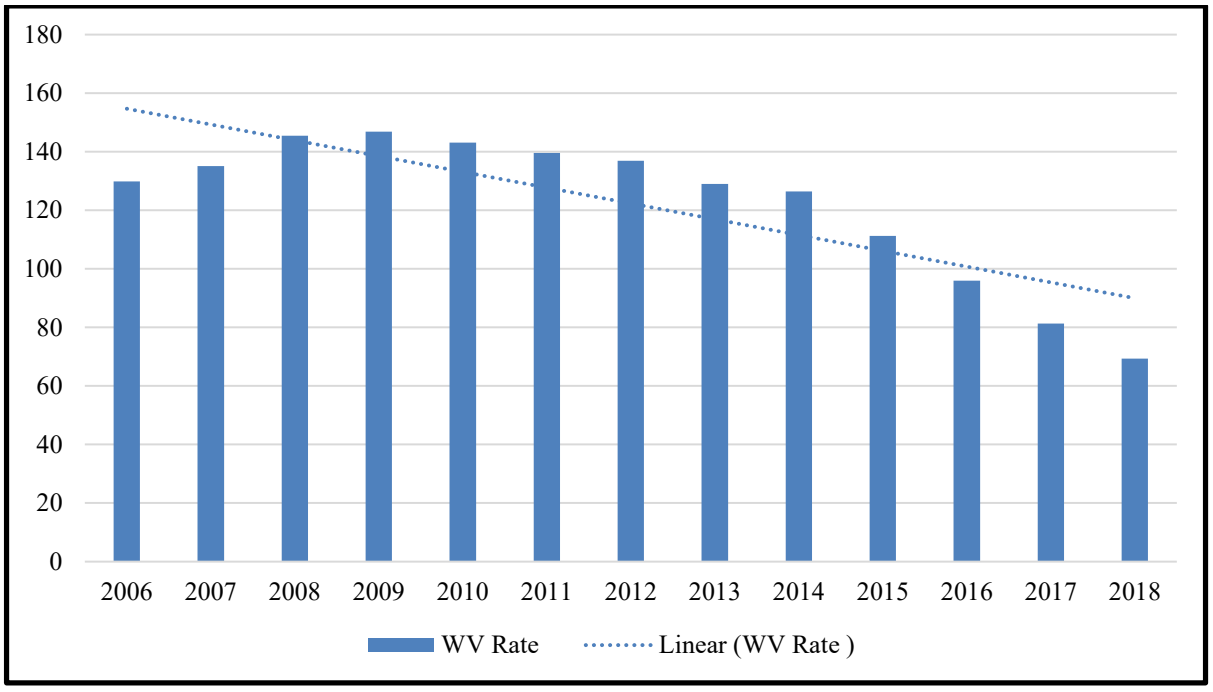
Educating children and young adults about the dangers of drug abuse is also a critical piece of the learning effort. High school athletes, particularly football players, face higher risks of injury than their peers, and thus higher risks of being prescribed opioids. Beginning in July 2016, the Office announced a partnership with groups including the West Virginia Secondary School Activities Commission ("WVSSAC"), the West Virginia Board of Medicine, and the West Virginia Physical Therapy Association to raise awareness and battle opioid use in high school athletics. The Office also created the "Opioid Abuse Prevention Game of the Week" program, through which Office staff engage with student athletes, coaches, school officials and communities across West Virginia. Representatives from the Office inform the respective coaches as to the dangers of opioid use and provide educational material for display and distribution in the schools to foster more discussion of the issue. The week culminates with the Office staffing an information booth at each of the select sporting events to distribute opioid abuse awareness materials. Since this program began four years ago, Office staff have attended and educated athletes and citizens at 212 games. Similarly, the Office launched an annual youth opioid PSA contest, "Kids Kick Opioids," in 2016. Through this program, students around the State create their own public service announcements to illustrate the dangers of opioid abuse, with the winning PSAs published in state and local newspapers. For instance, in 2020 there were 3,366 entries in this contest from 3,521 children, representing 90 schools. And more generally, the Office drafted legislation to require that students in grades 6-12 receive 60 minutes of instruction on the dangers of opioid use.[21]

All of these actions—taken by an Office with little authority to assist local prosecutors with criminal opioid matters—have contributed to a significant decrease in the amount of opioids prescribed in West Virginia. The number of hydrocodone pills dispensed in the State dropped from nearly 100 million in 2011 to just under 38 million in 2018, for example, and oxycodone dropped from nearly 44 million to under 25 million.[22]

[21] HB 2195, 2017 Reg. Sess. Ch. 69.

[22] Office of the West Virginia Att'y Gen., *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*, at 4 (Oct. 15, 2019), https://bit.ly/3eDN79x.

Figure 3: West Virginia Opioid Prescriptions Per 100 Residents (2006-2018)[23]



IV. Investigation and Lawsuit Against the DEA

As these efforts made headway, it became plain that although aggressive state action is vital, so is reform on the federal level. On that score, a disconnect between the words and actions of the DEA on these issues became increasingly clear. For example, in 2013, the DEA acknowledged that prescription opioids were being diverted for abuse on an unprecedented scale, and requested a $38 million increase in its fiscal year 2014 budget to address this issue.[24] The it emphasized that it "focuses on preventing diversion from all levels of the closed distribution system," and "us[es] all criminal and regulatory tools possible to identify and determine who is most likely involved in the illicit distribution of controlled substances."[25] Nevertheless, just over a year earlier, the DEA had rejected calls to limit the production of opioids in response to the ongoing crisis.[26] And in the year following that budget request, the DEA *increased* the production limits on opioids, including hydromorphone, oxycodone, and oxymorphone, by 21,781 kg.[27]

[23] U.S. Ctr. for Disease Control, *U.S. Opioid Prescribing Rate Map*, https://bit.ly/3eCR0f4.

[24] U.S. Dept. of Justice, Drug Enforcement Admin., *FY 2014 Performance Budget Congressional Submission* 75, 76 (Apr. 9, 2013), https://bit.ly/2XckTvw.

[25] *Id*. at 10, 76.

[26] 76 Fed. Reg. 78,044, 78,044 (Dec. 15, 2011).

[27] *See* Appendix I.

> *"DEA focuses on preventing diversion from all levels of the closed distribution system."*
>
> *-DEA's April 2013 budget request*

Faced with this sharp contradiction, the Office began an investigation into the DEA's methods of controlling the supply of prescription opioids. The Office submitted multiple requests to the DEA under the Freedom of Information Act ("FOIA") seeking to better understand the policies and procedures at play. The first request, submitted in 2015, was met with a response to narrow the request's focus without providing any of the requested materials. The Office submitted a second request in early 2017, but still the DEA refused to provide any information. That time, however, Department of Justice officials were willing to work with members of the Office to address the DEA's concerns, and the Office's third FOIA request, submitted June 2017, incorporated these suggestions. But even so, the DEA still did not provide a response.

In the face of these roadblocks, the Office filed a lawsuit in 2017 against the DEA to reform the process of setting controlled substance quotas.[28] As a result of the Office's lawsuit, the DEA conducted a regulatory review designed to correct past practices and set a better framework for future years: On April 19, 2018, the DEA proposed adding new factors to the quota-setting calculation.[29] Under the new rule secured by this lawsuit, the DEA no longer has discretion to consider diversion—or to disregard diversion—when formulating aggregate production quotas. Moreover, the DEA must seek out and incorporate input from States and federal agencies on whether the proposed quotas are "excessive."[30] These requirements became effective August 15, 2018.[31] A federal statute enacted later that year addressed similar concerns: As part of a broader set of reforms, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act") codified the Quotas Rule in federal law.[32]

> *DEA allowed increased opioid production by 21,781 kilograms in 2013.*

With this important step forward in regulatory reform, the Office agreed to dismiss its lawsuit against the DEA—but on the condition that the DEA finally allow the Office's FOIA investigation into past practices to move forward. This report details the results of that investigation.

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[28] *See West Virginia v. DEA*, No. 17-1256 (D.C. Cir. filed Dec. 8, 2017).
[29] 83 Fed. Reg. 17,329 (Apr. 19, 2018).
[30] *Id.* at 32,793.
[31] 83 Fed. Reg. 32,784 (July 16, 2018).
[32] *See* Pub. L. No. 115-271, 132 Stat. 3893, 3954-56 (Oct. 24, 2018); *see also* U.S. Dept. of Justice, Office of the Inspector General, *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids* 43 (Sept. 2019), https://bit.ly/2AogOg0 ("the SUPPORT Act codifies the new quota regulation").

RESULTS OF INVESTIGATION

As the name suggests, the federal Controlled Substances Act ("CSA") places the production and distribution of narcotic substances under the control of the federal government. The Attorney General of the United States—through the Office of Diversion Control within the DEA—sets annual production limits for the most dangerous and potentially addictive controlled substances. In recent years, concerns have emerged that the DEA was not living up to its obligation to adequately control the supply of prescription opioids. Indeed, one commentator suggested that the DEA's process entailed "nothing more than a survey of drug companies regarding how much of any given drug they'd like to produce."[33]

After persistently seeking access to documents from the DEA explaining how it set quotas for the time period of 2010 to 2016, the Office finally received information responsive to these requests. These responses spanned two separate FOIA requests. The first request, sent in June of 2017, pertained to *external influences* on the quota setting process. Specifically, the Office requested communications that the DEA had with interested parties before setting annual quotas. Part of the materials the DEA provided the Office include many requests from drug manufacturers seeking quota increases, few of which offered explanation or justification beyond a general plea to "market demand." Also noteworthy were annual quota recommendations that the FDA sent to the DEA criticizing large quota increases, which the DEA appears to have largely disregarded.

The second FOIA request, sent in March of 2019, focused on *internal influences* within the DEA itself, including any information about how the DEA accounted for drug diversion when setting opioid quotas, as well as internal discussions about the efficacy of the quota system in fighting the opioid crisis. The documents the Office received in response underscore that the DEA was aware of diversion and its serious effects, but did nothing of substance to account for it when setting production quotas during this time. For example, the DEA provided extensive documentation of communications within the Office of Diversion Control recommending that the DEA deny individual companies' requests for increased quotas, yet none of the information provided supports that these recommendations were incorporated in the final quotas that year. These and other internal communications surrounding diversion and its role in driving the opioid crisis drive home that the DEA failed to take action in this critical area.

I. Overview of the Production Quota System

In the United States, the CSA creates a closed regulatory system that governs the manufacture, distribution, dispensing, and possession of certain controlled substances, including prescription opioids.[34] Pursuant to this authority, the U.S. 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.[35] These "aggregate production quotas" ("APQs") are designed to prevent unjustified increases in the national supply of potentially dangerous drugs,

[33] *See* Kathleen Drydl, *My President's Worst Failure: Barack Obama & the Opioid Crisis* (Oct. 17, 2017), https://bit.ly/2XoPOpW.

[34] 21 U.S.C. § 821.

[35] 21 C.F.R. § 1303.11.

including highly addictive and frequently abused opioids like oxycodone and hydrocodone. To that end, the DEA has a duty to limit production of controlled substances to levels sufficient for—but 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."[36] This means that when APQs are set correctly, they are high enough to allow for legitimate medical and other purposes, but low enough that excess supply that becomes vulnerable to misuse or diversion is not produced in the first place.

Consistent with this mandate, each year the Office of Diversion Control establishes three types of quotas for Schedule II substances: APQs limiting the total amount of a substance all manufacturers can produce nationwide; individual bulk manufacturing quotas limiting the amount each registered manufacturer can produce; and procurement quotas. As relevant to the Office's investigation, the process of establishing APQs for each class of controlled substance begins with the DEA Administrator publishing a notice of the "Proposed Aggregate Production Quotas" for the coming year in the Federal Register.[37] A copy of this notice is also mailed to each person registered with the DEA as a bulk manufacturer of the basic class.

Registrants, along with other interested parties, then have a brief window of time during which they may comment on the proposed APQs. Comments received become part of the public record. Prior to 2018, the Administrator had discretion to consider the comments received or to hold a public hearing.[38] After considering the comments and information received at any hearing, the Administrator makes any revisions to the proposal and publishes the final order determining APQs for the basic classes of controlled substances.

Until the DEA modified its regulations following the Office's lawsuit,[39] the DEA was required to consider five factors throughout this process before ultimately finalizing the annual APQs:

> (1) total net disposal of each class or chemical by all manufacturers and chemical importers during the current and two preceding years;
>
> (2) trends in the national rate of net disposal of the class or chemical;
>
> (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation;

[36] *Id.* § 1303.11(a).

[37] U.S. Govt. Accountability Office, *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should be Improved* 10, GAO-15-202 (Dec. 2003), https://bit.ly/2ZVVk4H.

[38] 21 C.F.R. § 1303.12 (2017).

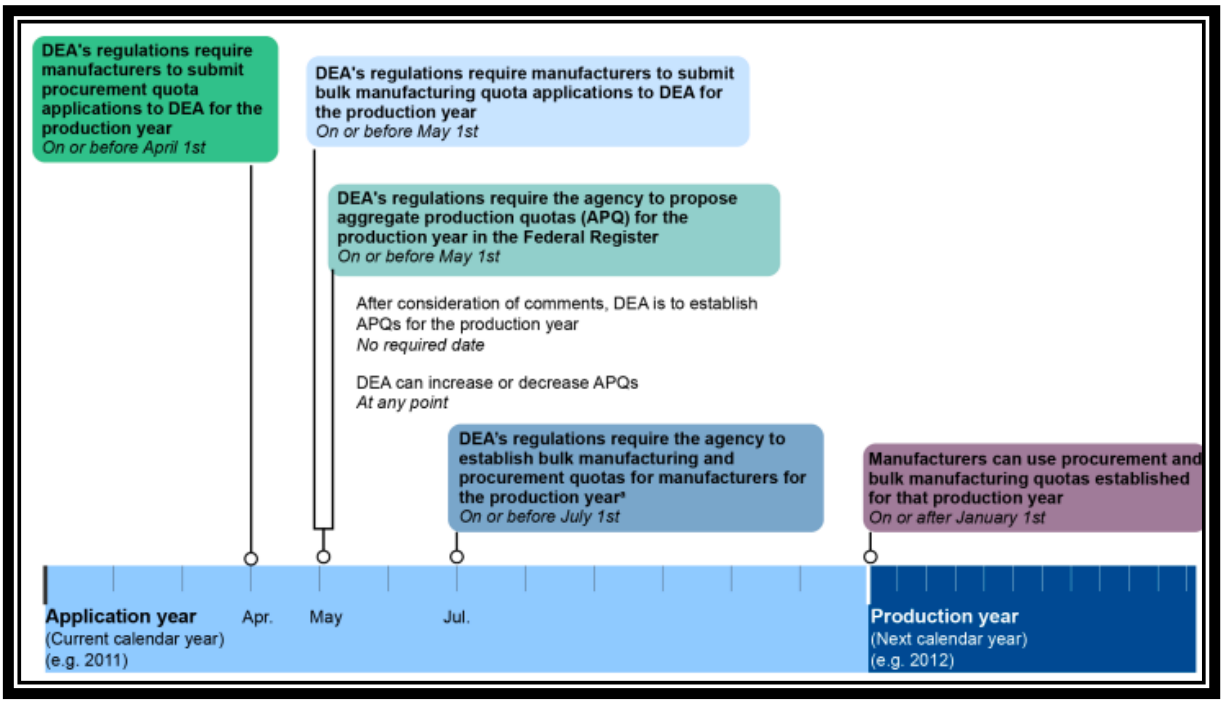
[39] *See* 83 Fed. Reg. 32,784 (July 16, 2018).

(4) projected demand for each class or chemical as indicated by procurement and import quotas requested in accordance with 21 CFR 1303.12, 1315.32, and 1315.34; and

(5) other factors affecting medical scientific, research and industrial needs of the United States and lawful export requirements, as the [] Administrator finds relevant.[40]

The DEA could consider "other factors . . . as the Director consider[ed] relevant," but was not required to do so.[41]

Figure 4: Timeline of the Quota Process[42]



II. Flaws in the Quota Process

The DEA has historically made very little information available to the public about the process it uses to set APQs. The annual notices of proposed and finalized quotas contained little information, if any, about how the DEA derives each quota. In a typical year, the notice would simply recite the five factors that the DEA was required to consider, state that they had been considered with no further explanation, and then set forth the new quotas.[43] In the rare event that

[40] 21 C.F.R. § 1303.13(b) (2017).
[41] *Id*. at § 303.11(b)(5).
[42] *Drug Shortages*, *supra* note 37.
[43] *See*, *e.g.*, 77 Fed. Reg. 55,500 (Sept. 10, 2012).

someone other than a representative of the pharmaceutical industry had provided comments on a proposed quota, these comments appeared to be minimized.[44]

This "black box" approach was concerning to the Office—especially because the information that *was* available raised serious questions about the quota-setting process.

A. APQs were repeatedly increased in 2010-2016 despite the ongoing opioid crisis

As early as 2010 it was clear that the nation was trapped in a prescription drug crisis. Yet this issue appeared largely ignored in the APQs set from 2010 through 2016, as they generally rose sharply, with no identifiable, fixed methodology to account for increasing opioid abuse. Indeed, the DEA *increased* the supply of many opioids just as the crisis was reaching its peak. Using *oxycodone (for sale)* as an example, Table 2 illustrates the various quantities recommended in each stage of the quota-setting process for 2010-2015, including the percent change within each cycle:

Table 2: Proposed and Final APQs, "Oxycodone (for sale)," (2010-2015)[45]

2010	**Citation**	**Amount (kg)**
Proposed Initial	74 Fed. Reg. 23,881 (May 21, 2009)	77,560
Established Initial	74 Fed. Reg. 54,080 (Oct. 21, 2009)	88,000
Proposed Revised	75 Fed. Reg. 35,838 (June 23, 2010)	88,000
Final Revised	75 Fed. Reg. 55,828 (Sept. 14, 2010)	105,500
Change from Prior Year Final Revised APQ = 12.2% Increase		

2011	**Citation**	**Amount (kg)**
Proposed Initial	75 Fed. Reg. 56,137 (Sept. 15, 2010)	105,500
Established Initial	75 Fed. Reg. 79,404 (Dec. 20, 2010)	105,500
Proposed Revised	76 Fed. Reg. 56,810 (Sept. 14, 2011)	98,000
Final Revised	76 Fed. Reg. 77,016 (Dec. 9, 2011)	98,000
Change from Prior Year Final Revised APQ = (7.1%) Decrease		

2012	**Citation**	**Amount (kg)**
Proposed Initial	76 Fed. Reg. 65,537 (Oct. 21, 2011)	98,000
Established Initial	76 Fed. Reg. 78,044 (Dec. 15, 2011)	98,000
Proposed Revised	77 Fed. Reg. 39,737 (July 5, 2012)	98,700
Final Revised	77 Fed. Reg. 55,500 (Sept. 10, 2012)	105,200
Change from Prior Year Final Revised APQ = 7.3% Increase		

[44] *See*, *e.g.*, 76 Fed. Reg. 78,044, 78,044 (Dec. 15, 2011).
[45] *See* Appendix I.

2013	Citation	Amount (kg)
Proposed Initial	77 Fed. Reg. 46,519 (Aug. 3, 2012)	123,375
Established Initial	77 Fed. Reg. 59,980 (Oct. 1, 2012)	131,500
Proposed Revised	78 Fed. Reg. 37,237 (June 20, 2013)	153,750
Final Revised	78 Fed. Reg. 48,193 (Aug. 7, 2013)	153,750
Change from Prior Year Final Revised APQ = 46.2% Increase		

2014	Citation	Amount (kg)
Proposed Initial	78 Fed. Reg. 40,186 (July 3, 2013)	149,375
Established Initial	78 Fed. Reg. 55,099 (Sept. 9, 2013)	149,375
Proposed Revised	79 Fed. Reg. 33,780 (June 12, 2014)	149,375
Final Revised	79 Fed. Reg. 50,700 (Aug. 25, 2014)	149,375
Change from Prior Year Final Revised APQ = 2.8% Decrease		

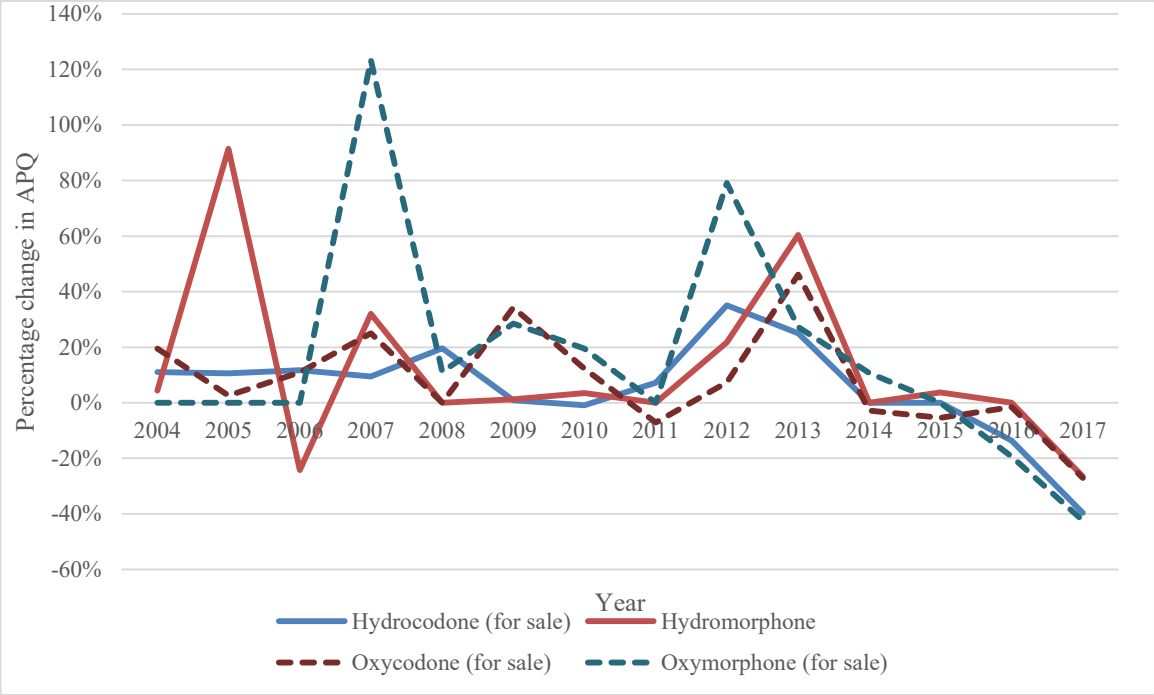
2015	Citation	Amount (kg)
Proposed Initial	79 Fed. Reg. 37,772 (July 2, 2014)	137,500
Established Initial	79 Fed. Reg. 53,216 (Sept. 8, 2014)	137,500
Proposed Revised	80 Fed. Reg. 39,156 (July 8, 2015)	139,150
Final Revised	80 Fed. Reg. 55,642 (Sept. 16, 2015)	141,375
Change from Prior Year Final Revised APQ = 5.4% Decrease		

The largest spike—in the 2013 APQs—is partially attributable to a specific DEA policy to allow for reserve drug stock: "DEA [] specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. § 826(a), as intended. This would be of concern if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need."[46] This explanation, however, accounted for only "an additional 25% of the estimated medical, scientific, and research needs" to the APQ for all Schedule II substances.[47] Setting aside the question whether this buffer was wise in an era of increased opioid abuse, it does not explain why the oxycodone APQ in 2013 was increased 46.2%. And oxycodone is not an isolated example. From 2004 to 2017, most opioid APQs were frequently unchanged or increased. To be sure, there were some years with actual decreases—contrasted to decreases in the rate of increase—but not enough to arrest the persistent momentum upwards. Real and substantial cuts to most opioid APQs were not seen until 2017.

When one focuses on the massive increases of APQs approved by the DEA, it is hard to see how local, state, and federal officials ever had a fighting chance to stem the growing tide of opioid prescriptions and subsequent deaths. Industry want and agency incompetence substituted for patients' actual medical needs.

[46] 78 Fed. Reg. 48,193, 48,194 (Aug. 7, 2013) (finalizing 2013 adjusted APQ).
[47] *Id.*

Figure 5: Percentage Increase or Decrease in Adjusted APQs for Select Opioids (2004-2017)



B. Nothing indicated that the DEA accounted for diversion

As explained above, until 2018 the DEA was required to consider only five specific factors when setting APQs, and diversion was not one of them. Although the DEA had discretion to consider other relevant factors, notices and final rules during this time do not reference—never mind quantify—diversion as a relevant factor in the analysis. It is axiomatic that opioids diverted for abuse are not being used to meet legitimate "medical or scientific" needs, so the DEA's silence on this issue when setting annual quotas raised red flags. Indeed, the express mission of the DEA's Office of Diversion Control is to prevent, detect and investigate the diversion of controlled substances from legitimate sources while ensuring an adequate and uninterrupted supply remains available for legitimate medical, commercial, and scientific needs.[48]

C. The DEA appeared to rely on incomplete or flawed data

While most of the factors that the DEA did consider in setting the APQ appear straightforward, on closer examination, they are not. The data the DEA used from 2010-2016 is purportedly derived from several sources, including:

- Manufacturers' production history and anticipated needs;
- Estimates from IMS Health on retail consumption based on prescriptions dispensed;

[48] U.S. Govt. Accountability Office, *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders* 7, GAO-20-118 (Jan. 2020), https://bit.ly/36PaASI.

- Data from DEA's internal system for tracking controlled substances transactions, known as the Automation of Reports and Consolidated Orders System ("ARCOS");

- Past histories of quota granted for each substance from YERS/QMS;

- Estimates of the projected medical, scientific, and reserve stock needs provided by the FDA's Controlled Substances Staff;

- Information regarding new and discontinued drug products containing schedule substances from FDA; and

- Data on the diversion of controlled substances, such as information from case seizures and national databases of drug evidence.[49]

Of these data sources, only a few are directly overseen by the DEA. For example, ARCOS allows the DEA to monitor the flow of controlled substances from their point of manufacture through commercial distribution channels, to point of sale or distribution at the dispensing/retail level.[50] Aggregating these reports, in theory, captures the full universe of controlled substance transactions. Nevertheless, the regularity with which manufacturers and distributors report this information varies, with some reporting monthly and others quarterly. This lack of consistency forces the DEA to wait a full year before ARCOS contains all of the ordering data needed to fully analyze the data, and significantly undermines its accuracy and value when setting APQs.[51]

Similarly, the Suspicious Order Reporting System ("SORS") is intended to provide a mechanism for wholesalers to report orders of unusual size or that deviate substantially from normal patterns. Yet it too is plagued by gaps in coverage and time delays. Case in point, this is the system that should have caught the dumping of pills in Williamson, West Virginia, by two regional drug wholesalers, Miami-Luken and H.D. Smith, but did not. Moreover, the DEA acknowledges that its field offices do not upload SORS reports in a comprehensive or timely way, so the database also has limited value.[52]

III. Results of 2017 FOIA Request – External Influences on the Quota Process

The goal of the Office's FOIA investigation was to get answers for these and other serious flaws evident on the face of the DEA's annual notices and final APQs. The first FOIA inquiries the DEA responded to focused on identifying the sources of information that flowed into the DEA

[49] U.S. Govt. Accountability Office, *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should be Improved* 10, GAO-15-202 (Feb. 2015), https://bit.ly/2ZVnhK0.

[50] U.S. Govt. Accountability Office, *Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results* 9, GAO-11-744 (Aug. 2011), https://bit.ly/2BwqCVV.

[51] Dept. of Justice, *supra* note 32, at 28.

[52] Dept. of Justice, *supra* note 32, at 30-32.

regarding the APQ process. Specifically, the request that was ultimately granted focused on 2010 through 2016, and sought all communications to the DEA from "persons or entities requesting an upward or downward adjustment of the [APQ, bulk manufacturing, or procurement quota] of any opioid," as well as all communications between the DEA and other government agencies regarding the quota process.

In total, the DEA produced 1,566 pages of responsive documents, and indicated that a further 40 would not be produced pursuant to various FOIA exemptions. The DEA objected to the request to the extent it related to bulk manufacturing and procurement quotas on the basis that there were too many communications to make a response feasible, and the Office agreed to focus the investigation on communications related to APQs.

A. Input from the public: victims' calls for reductions not acknowledged

One aspect of the APQ process that became readily apparent when reviewing the documents DEA produced in response to the first FOIA request is that there were only a small number of letters requesting decreased APQs. Nevertheless, the information contained in them should have made a significant impression on the quota management office.

One letter commenting on the proposed initial APQs for 2012 was from a mother whose only child overdosed on prescription pills.[53] She chided the DEA on the "overproduction and saturation of the market which has contributed to this epidemic of legally prescribed Heroin-like drugs." Another letter commenting on the same proposal was from the President of the Advocates for the Reform of Prescription Opioids, Inc., who lost his 18-year-old daughter to an OxyContin overdose.[54] He quoted DEA Administrator Leonhart's statement that "DEA establishes manufacturing and procurement quotas each year for schedule I and II controlled substances . . . for the purpose of reducing the risk of diversion to illicit traffic. Accordingly the quota system serves the vital purpose of reducing the risk of diversion."[55] He continues his argument for decreasing APQs by presenting evidence that suggests a strong correlation between increasing APQs and overdose deaths, and argues that increasing quotas make the DEA "directly responsible for enabling the American drug production system to mass produce huge quantities of narcotics that are killing people and destroying lives."[56] He continues, stating that, "[w]ith all of the problems brought on by the mass production of oxycodone in this country, a 2012 proposal to allow the production of 103,600,00 kg (114 tons), a 1,747% increase over the amount produced in 1996, the year OxyContin first came on the market, is unconscionable and reflects a complete disregard for the loss of life that this drug has caused."[57]

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[53] Vol. I, p. 462.

[54] Vol. I, p. 464.

[55] *Id*., citing DEA Administrator Michelle Leonhart, speaking before the United States Department of Justice Subcommittee on Commerce, Manufacturing and Trade, United States House of Representatives on April 14, 2011.

[56] *Id.*

[57] *Id.*

The records provided to our Office contain no indication that the DEA did anything in response to these comments. The public notice that the DEA filed to establish the 2012 APQs, for example, refers to these comments only in passing, dismissing their concerns by noting that "[a]ddressing prescription drug abuse requires a multi-faceted approach which includes education, treatment, and enforcement."[58] The notice gave the same recitation of the regulatory factors, and claimed without analysis that "[a]ll aspects of the closed system of distribution must work together to reduce or eliminate the diversion of controlled substances."[59]

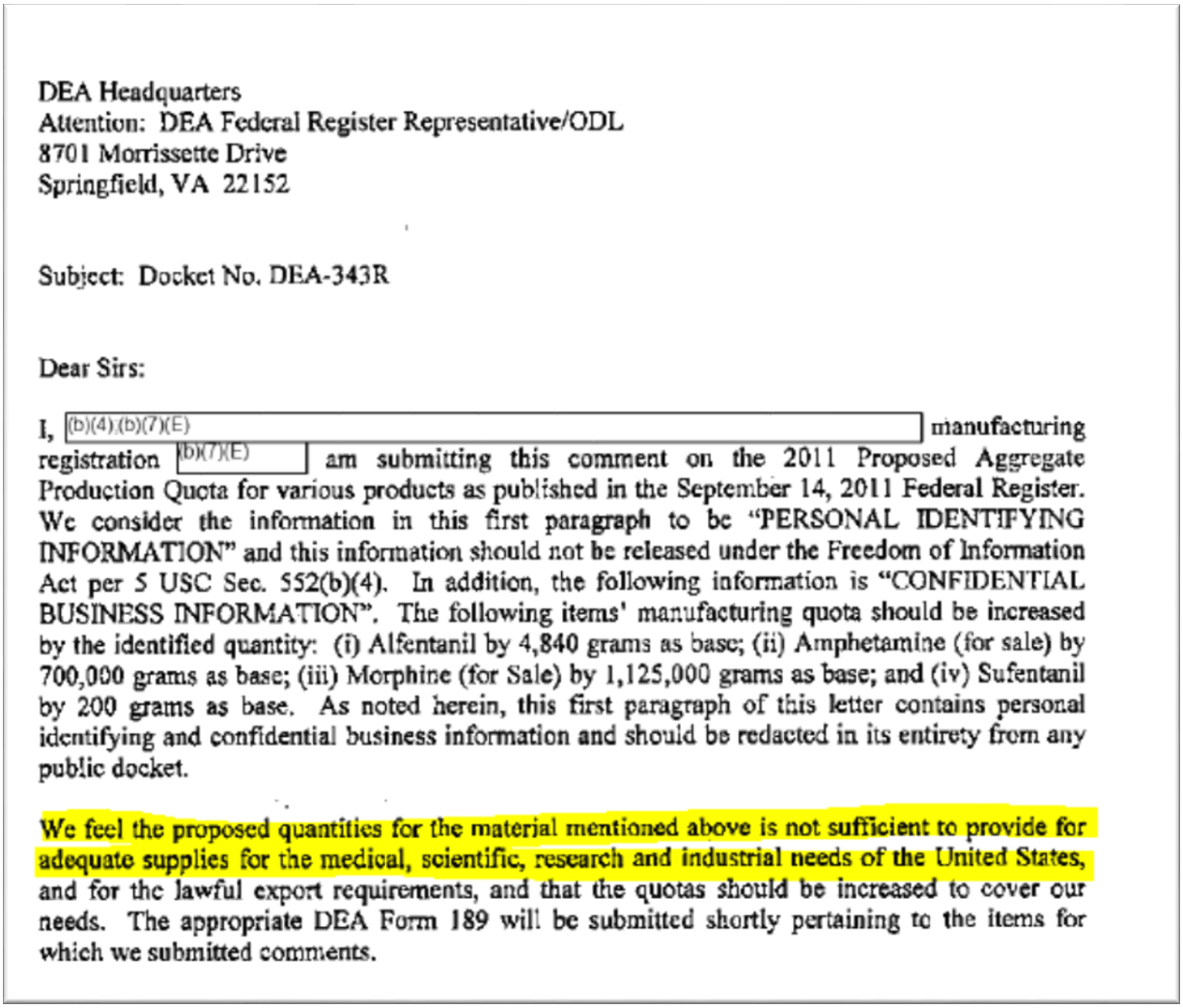
B. Input from the public: industry calls for quota increases unquestioningly accepted

In contrast to the lack of meaningful engagement with the (admittedly small) number of comments from those directly affected by the effects of opioid abuse, a different pattern quickly becomes available with respect to the DEA's response to industry participants. Even a cursory review of the produced documents reveals that the overwhelming majority of comments the DEA received were from manufacturers requesting increases in APQs for opioids that they sell (names of individual manufacturers were redacted in the DEA's production).

Many of the commenters frame their requests as coming from a place of concern with being able to "provide for adequate supplies for the medical, scientific, research and industrial needs of the United States."[60] This is an understandable approach, as it mirrors the CSA's standard for quota-setting. What is missing from these requests, however, is data quantifying this need or even, in most cases, any explanation at all. Figure 6 contains a representative example of this type of minimally supported request:

[58] 76 Fed. Reg. at 78,044.
[59] *Id*.
[60] *See*, *e.g.*, Vol. I, p. 701.

Figure 6: Sample Communication Requesting APQ Increase[61]



DEA Headquarters
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Subject: Docket No. DEA-343R

Dear Sirs:

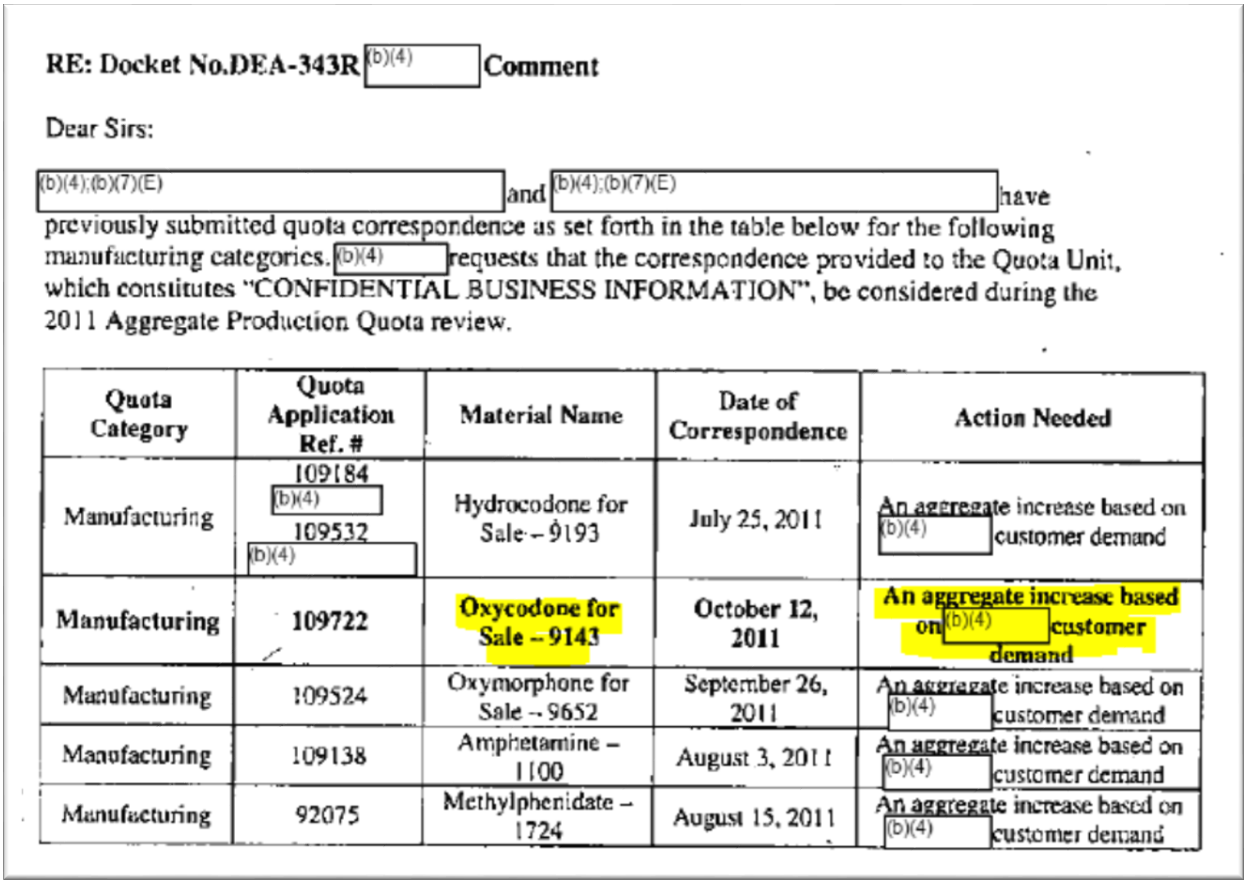
I, (b)(4),(b)(7)(E) manufacturing registration (b)(7)(E) am submitting this comment on the 2011 Proposed Aggregate Production Quota for various products as published in the September 14, 2011 Federal Register. We consider the information in this first paragraph to be "PERSONAL IDENTIFYING INFORMATION" and this information should not be released under the Freedom of Information Act per 5 USC Sec. 552(b)(4). In addition, the following information is "CONFIDENTIAL BUSINESS INFORMATION". The following items' manufacturing quota should be increased by the identified quantity: (i) Alfentanil by 4,840 grams as base; (ii) Amphetamine (for sale) by 700,000 grams as base; (iii) Morphine (for Sale) by 1,125,000 grams as base; and (iv) Sufentanil by 200 grams as base. As noted herein, this first paragraph of this letter contains personal identifying and confidential business information and should be redacted in its entirety from any public docket.

We feel the proposed quantities for the material mentioned above is not sufficient to provide for adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements, and that the quotas should be increased to cover our needs. The appropriate DEA Form 189 will be submitted shortly pertaining to the items for which we submitted comments.

Indeed, as the example in Figure 7 shows, the most common justification given for increased quotas was simply "customer demand":

[61] Vol. I, p. 701.

Figure 7: Sample Request Attributing APQ Increase to Increased Customer Demand[62]



RE: Docket No.DEA-343R (b)(4) Comment

Dear Sirs:

(b)(4);(b)(7)(E) and (b)(4);(b)(7)(E) have previously submitted quota correspondence as set forth in the table below for the following manufacturing categories. (b)(4) requests that the correspondence provided to the Quota Unit, which constitutes "CONFIDENTIAL BUSINESS INFORMATION", be considered during the 2011 Aggregate Production Quota review.

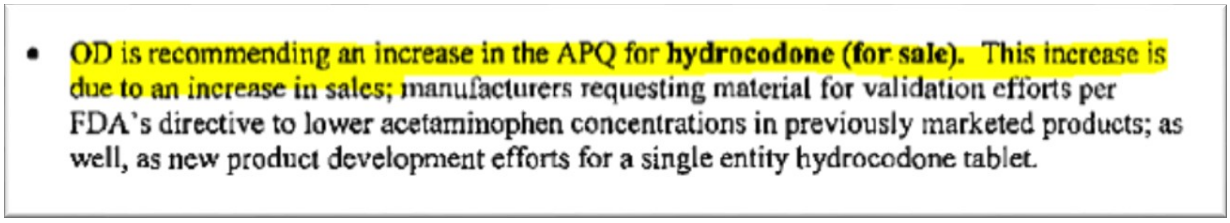
Quota Category	Quota Application Ref. #	Material Name	Date of Correspondence	Action Needed
Manufacturing	109184 (b)(4) 109532 (b)(4)	Hydrocodone for Sale – 9193	July 25, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109722	Oxycodone for Sale – 9143	October 12, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109524	Oxymorphone for Sale – 9652	September 26, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	109138	Amphetamine – 1100	August 3, 2011	An aggregate increase based on (b)(4) customer demand
Manufacturing	92075	Methylphenidate – 1724	August 15, 2011	An aggregate increase based on (b)(4) customer demand

Critically, these and the many comments like them do not acknowledge diversion or the concept of illicit use. This is an important omission, because diversion starts from a *legitimate* prescription, so "an increase in sales" or "market demand" is not enough on its own to establish genuine need for increased quotas. In other words, nothing in these comments demonstrated that projected increases in sales would be related to the legitimate medical and scientific needs of the United States, rather than contributing to a cycle of diversion and abuse. Indeed, this trend is particularly troubling because while opioid production expanded dramatically between 2009 and 2013 in response to increased quotas, the proportion of Americans with opioid prescriptions actually decreased during the same period.[63]

The produced documents also show that the DEA's staff accepted these projections of increased demand largely at face value. To be sure, the DEA rarely attributed its conclusion that sales were increasing directly to industry comments. Summary documents would often refer to "an increase in sales," for instance, without further explanation. Yet there are no sources supporting this conclusion *other* than manufacturers' bare assertions of increased need in the documents the DEA produced.

[62] Vol. I, p. 702.
[63] U.S. Ctr. Disease Control, *supra* note 23.

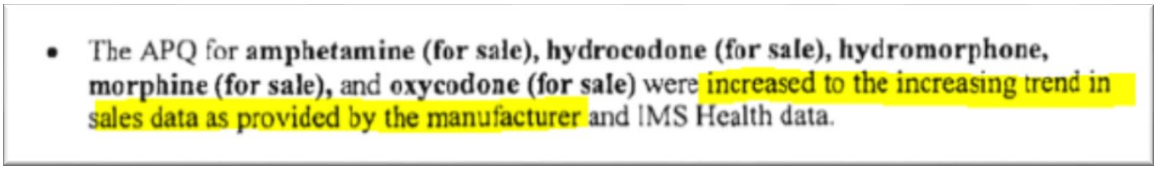
Figure 8: Excerpt From DEA Adjusted APQ Summary (2012)[64]



- OD is recommending an increase in the APQ for **hydrocodone (for sale).** This increase is due to an increase in sales; manufacturers requesting material for validation efforts per FDA's directive to lower acetaminophen concentrations in previously marketed products; as well, as new product development efforts for a single entity hydrocodone tablet.

2013 is a notable exception that underscores this likely pattern of acceding to industry claims without additional justification. In a year where all APQs were already increased by 25%, as explained above, the DEA explained that "sales data as provided by the manufacturer" warranted an even larger increase:

Figure 9: Excerpt From DEA Established APQ Summary (2013)[65]



- The APQ for **amphetamine (for sale), hydrocodone (for sale), hydromorphone, morphine (for sale),** and **oxycodone (for sale)** were increased to the increasing trend in sales data as provided by the manufacturer and IMS Health data.

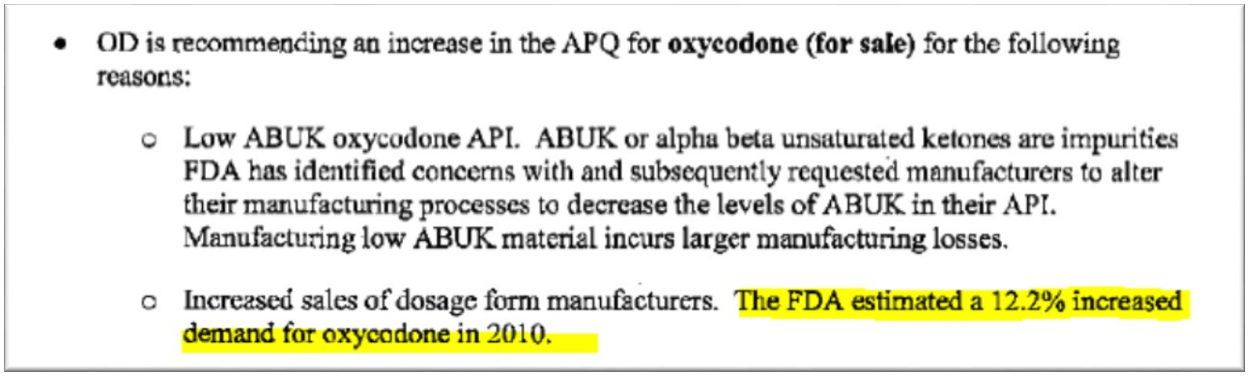
In short, the materials the DEA produced to our Office reveal a pattern of manufacturer requests for increased quotas that are strikingly thin on analysis or justification, with no indication that the DEA had better data to support these claims before finalizing each year's quotas.

C. Input from within the federal government: FDA's calls for decreases or only moderate increases disregarded

In some cases, the produced documents indicate that the DEA attributed reliance on rising sales to the FDA, and not manufacturers. For example, a summary of the 2010 Final Revised Aggregate APQ recommended increasing the APQ for oxycodone for sale because of "increased sales," and noted that "[t]he FDA estimated a 12.2% increased demand for oxycodone in 2010."[66]

[64] Vol. I, p. 587.
[65] Vol. I, p. 102.
[66] Vol. I, p. 1345.

Figure 10: Excerpt From DEA Revised APQ Summary (2010)[67]



- OD is recommending an increase in the APQ for **oxycodone (for sale)** for the following reasons:
  - Low ABUK oxycodone API. ABUK or alpha beta unsaturated ketones are impurities FDA has identified concerns with and subsequently requested manufacturers to alter their manufacturing processes to decrease the levels of ABUK in their API. Manufacturing low ABUK material incurs larger manufacturing losses.
  - Increased sales of dosage form manufacturers. The FDA estimated a 12.2% increased demand for oxycodone in 2010.

Again, setting aside whether increased demand—without more—should be enough to show an increase in legitimate medical or scientific need, looking closer at the FDA's pattern of recommendations reveals that the DEA was quick to follow those recommendations only when they supported *increased* quotas.

Both the DEA and the FDA have a role in regulating controlled substances in the United States. While the DEA is ultimately responsible for setting quotas, the FDA is the regulatory agency responsible for promoting and protecting the public health by ensuring drug safety. Among its responsibilities, the FDA approves new drug applications, conducts inspections of manufacturing facilities, and monitors post-marketing data to evaluate adverse events and mitigate and help prevent drug shortages. The FDA also has responsibilities that specifically relate to controlled substances and require collaboration with the DEA such as evaluating Schedule I research protocols for scientific merit, and providing scientific and medical evaluations and scheduling recommendations for drugs under consideration for control. Most relevant here, those responsibilities also include providing information for the DEA to use when calculating estimates of U.S. medical and scientific stock needs for Schedule I and Schedule II substances.[68]

The produced documents therefore include communications from the FDA responding to the DEA's requests for estimates of medical, scientific and reserve stock needs for calendar years 2010 through 2016. The stated purpose of these materials is to provide data "useful to the Drug Enforcement Administration in making quota determinations."[69] Specifically, the FDA provided the DEA with forecasts of the usage of Schedule II controlled substances for these years. The FDA generated these forecasts using a database of sales statistics from chain drug stores, independent pharmacies, and mass merchandisers, as well as clinics, federal and non-federal hospitals, HMOs, and long-term care facilities. As this process repeated year after year, past years' projections could be compared to the observed sales data that was eventually collected in that year.

The relevant documents indicate that the FDA has a robust and objective mathematical model for forecasting future sales based off past observations.[70] This model assumes that the

[67] Vol. I, p. 1345.
[68] Vol. I, pp. 1595-1604.
[69] Vol. I, pp. 1256-1268.
[70] Vol. I, pp. 589-590.

current trends shaping demand for a specific substance will continue into the future, and therefore it will not be able to capture changes caused by, for example, a new medication entering the market. Conversely, the model can also become more accurate over time, as the database that powers it is updated with actual observed sales data for a given year. All told, the FDA's model appears to provide a research-backed method to predict future demand.

It is important to emphasize, however, that the model was designed to forecast past demand into the future, not to assess how much of that demand reflects legitimate need. And because past demand for opioids has been inflated by diversion, there is even more reason to be skeptical that projections of increased sales are an adequate way to approximate increased medical and scientific need. Nevertheless, even with this caveat, there is a stark—and concerning—contrast between the FDA's recommendations for APQs and those that the DEA ultimately adopted.

For example, the DEA consistently set APQs for oxycodone at levels significantly higher than what the FDA recommended, sometimes by as much as 247%. Hydrocodone APQs were slightly below the FDA's recommended level in 2010 and 2011, but by 2013 the DEA increased it to nearly double the recommend level. Overall, the quotas set by the DEA continued to climb during the investigation period, while the FDA's data-driven recommended amounts frequently declined. Indeed, the FDA's recommendations were also borne out in hindsight—the average FDA projection for hydrocodone or oxycodone consumption was less than 6% off from the observed data. Comparatively, the DEA's APQs missed the mark by more than 75% on average.

Table 3: DEA APQ for Hydrocodone Versus FDA Projections of Demand (kg) (2010-2015)

	DEA's Initial APQ	**FDA's Recommendation**	**DEA's Revised APQ**	**Actual demand observed after the fact**
2010	55,000	61,164.8	55,000	58,584.2
2011	55,000	62,539.47	59,000	62,341.1
2012	59,000	64,217.68	79,700	62,447.7
2013	99,625	63,496.96	99,625	60,585.3
2014	99,625	59,708.95	99,625	55,648.3
2015	99,625	51,885.61	99,625	48,488.43

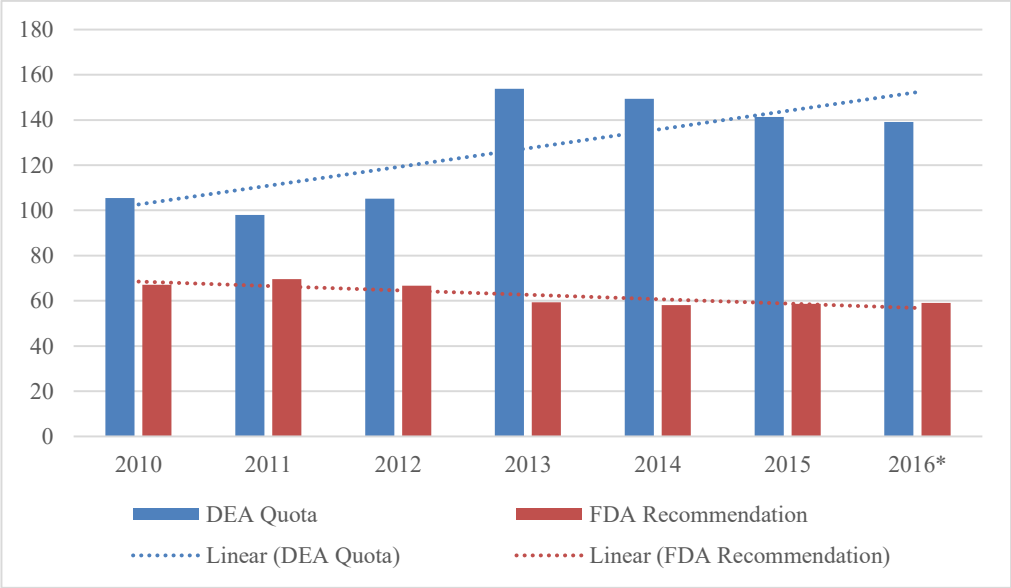
Table 4: DEA APQ for Oxycodone Versus FDA Projections of Demand (kg) (2010-2015)

	DEA's Initial APQ	**FDA's Recommendation**	**DEA's Revised APQ**	**Actual demand observed after the fact**
2010	88,000	64,346.2	105,500	67,083.2
2011	105,000	75,516.46	98,000	69,651.3
2012	98,000	74,613.9	105,200	66,728.1
2013	131,500	66,731.26	153,750	59,336.7
2014	149,375	59,336.7	149,375	58,114.8
2015	137,500	57,071.11	141,375	58,702.64

Even the FDA appears to have taken notice of this disconnect: The produced documents include a letter sent by Dr. Margaret Hamburg, former FDA Commissioner, to the Office of Diversion Control. In it, she specifically notes the discrepancies between the FDA's recommendations and the final APQs, and requests "information regarding the DEA process for establishing quotas." In particular, she requests information regarding "how the DEA Automation of Reports and Consolidated Orders System (ARCOS) or any other data sources are used to establish and distribute the APQ."[71] This request appears to have gone unanswered.

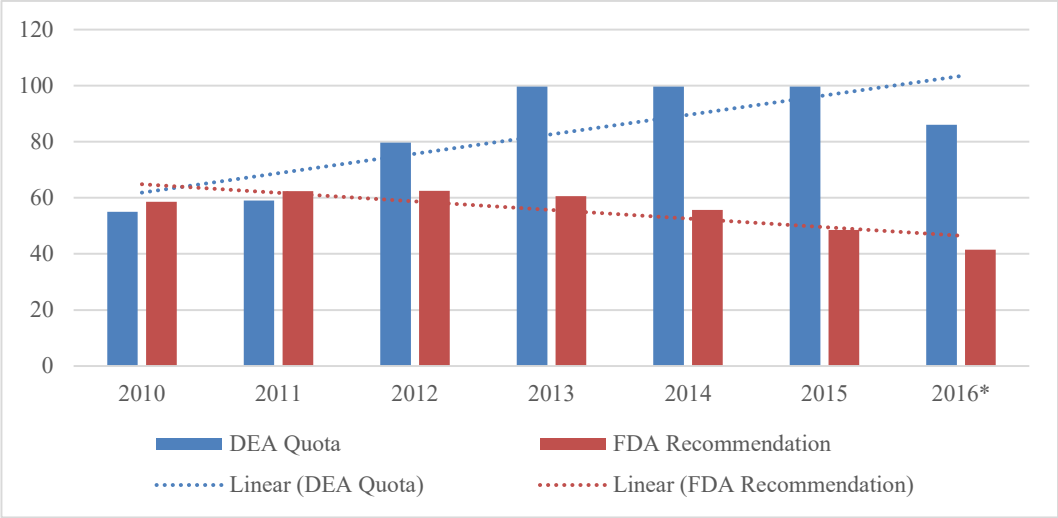
Given the inherent weaknesses in relying entirely on a demand-driven model, it would make sense for the DEA's APQs to be *more* conservative than the FDA's projections—not markedly less. This pattern underscores concern that the DEA did not seek to address diversion when setting APQs during the investigation period.

Figure 11: FDA Recommendations Versus DEA Adopted APQ For Oxycodone



[71] Vol. I, p. 857.

Figure 12: FDA Recommendations Versus DEA Adopted APQ For Hydrocodone



* * *

The results from the first FOIA request shed considerable light on the inputs that informed the DEA's process of establishing APQs. It appears clear that information related to consumer demand and projected sales was the critical factor in this process. And while it is not surprising that sales figures were growing in the midst of a worsening addiction epidemic, the DEA's apparent degree of deference to these figures *is* cause for concern—especially because many of the claims of increased need appear to rely on unsupported claims from manufacturers that were at odds with the FDA's more data-supported model.

IV. Results of 2019 FOIA Request – DEA's Internal Processes

Armed with this initial information, the Office turned next to how the DEA evaluated the information that it received—specifically, whether and how it accounted for diversion, which did not appear to be part of the DEA's calculus at all from the communications discussed above. The Office's second FOIA request accordingly asked the DEA for "all documents . . . showing how and when the Office of Diversion Control accounted for diversion of prescription opioids in setting annual drug quotas" for quota years 2010-2016. This request also asked for communications between leadership and staff at the Office of Diversion Control about the quota management system related to the scope and magnitude of the opioid crisis.

The DEA produced a total of 637 pages in response to this second request, withholding 178 as privileged or confidential. These documents included a selection of internal memoranda prepared during the quota review process, emails between DEA leadership, and submissions to Congress. The DEA made clear that these materials are not the full universe of communications responsive to the second FOIA request, but that the produced documents include all materials showing whether and how the agency accounted for diversion when setting quotas during the relevant years.

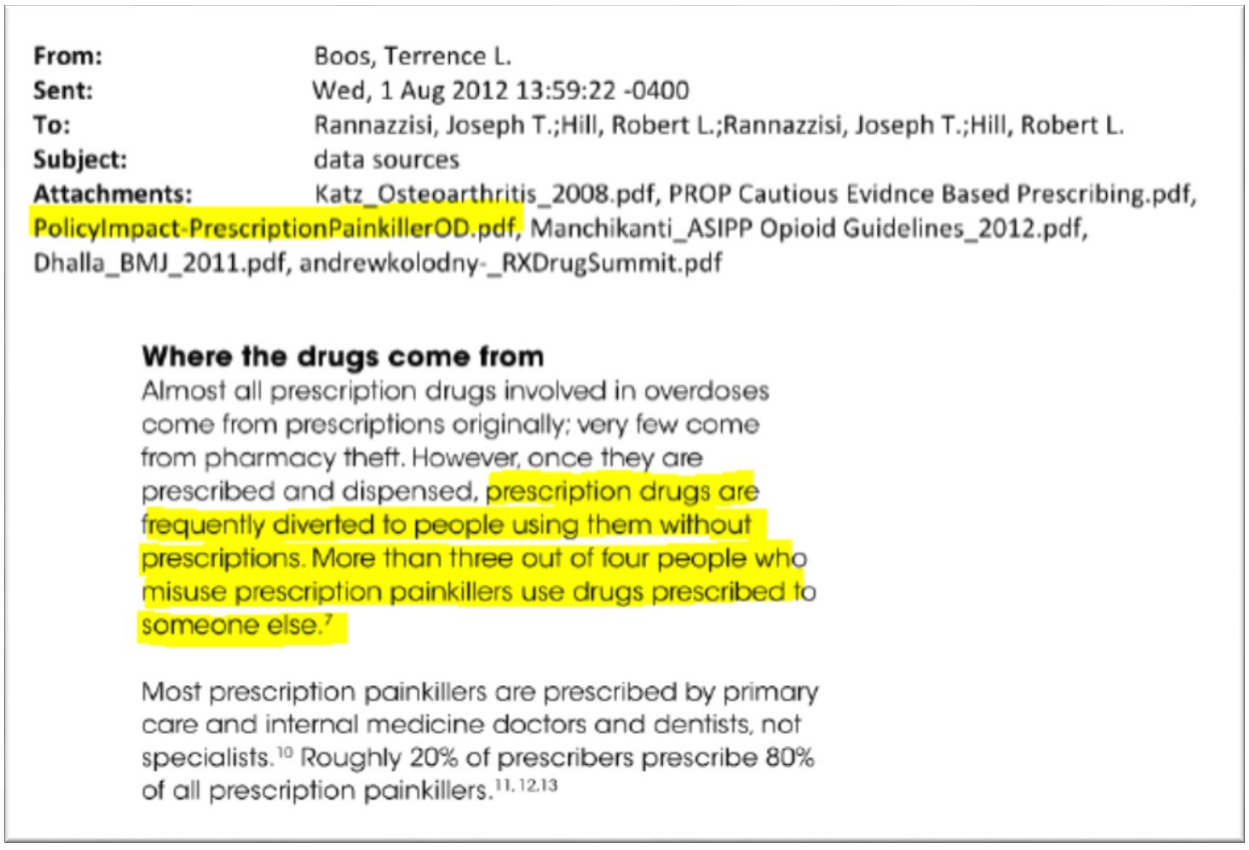
The primary conclusion from this second request confirms what the first request strongly suggested: The DEA did not account for diversion in any meaningful way when setting APQs during this period, despite its growing understanding of the scope of this issue as one of the primary drivers of the national opioid crisis.

A. The DEA understood the link between diversion and opioid abuse

The documents produced in this second set leave no doubt that the DEA was aware of diversion's role in fueling the opioid crisis and the agency's responsibility to combat diversion as part of a multi-faceted response.

The produced documents include references to policy discussions within the agency recognizing the link between diversion and opioid abuse. As one example, a study emailed to the head of the Office of Diversion Control made this link explicit as early as 2012, indicating that over 75% of prescription opioid abusers use drugs that were originally prescribed to someone else.

Figure 13: Email to Joseph Rannazzisi, Deputy Assistant Administrator of Office of Diversion Control (Aug. 1, 2012)[72]



From: Boos, Terrence L.
Sent: Wed, 1 Aug 2012 13:59:22 -0400
To: Rannazzisi, Joseph T.;Hill, Robert L.;Rannazzisi, Joseph T.;Hill, Robert L.
Subject: data sources
Attachments: Katz_Osteoarthritis_2008.pdf, PROP Cautious Evidnce Based Prescribing.pdf, PolicyImpact-PrescriptionPainkillerOD.pdf, Manchikanti_ASIPP Opioid Guidelines_2012.pdf, Dhalla_BMJ_2011.pdf, andrewkolodny-_RXDrugSummit.pdf

Where the drugs come from

Almost all prescription drugs involved in overdoses come from prescriptions originally; very few come from pharmacy theft. However, once they are prescribed and dispensed, prescription drugs are frequently diverted to people using them without prescriptions. More than three out of four people who misuse prescription painkillers use drugs prescribed to someone else.[7]

Most prescription painkillers are prescribed by primary care and internal medicine doctors and dentists, not specialists.[10] Roughly 20% of prescribers prescribe 80% of all prescription painkillers.[11,12,13]

[72] Vol. II, pp. 198, 217.

The DEA even acknowledged this link publicly, such as in requests to Congress for increased funding to Tactical Diversion Squads ("TDSs"). These TDSs provide law enforcement support to the DEA's Diversion Control Program. The DEA asked for increased funding to combat diversion based on express acknowledgment that pharmaceutical diversion is a significant problem.[73] Similarly, they emphasized that "[n]on-medical use of addictive prescription drugs has been increasing throughout the U.S. at alarming rates."[74] And in a 2012 Performance Budget Request, the DEA cites increased incidence rates for years 2001 to 2009 of state and local law enforcement in the number of pharmaceutical cases being submitted to forensic labs (oxycodone: 330%; hydrocodone: 314%) as justification for increased funding for the TDS program.[75]

Tellingly, not only does the DEA acknowledge the severity of opioid diversion in these documents, but it purports to have a detailed understanding of the issue. These TDS budget documents champion the DEA's ability to perceive diversion with precision: For example, the DEA's "Intelligence Program" is described as using "predictive intelligence" to "collect[], collat[e], analyz[e], and disseminat[e] tactical, investigative, and strategic drug intelligence" in order to determine in advance where enforcement resources should be committed.[76]

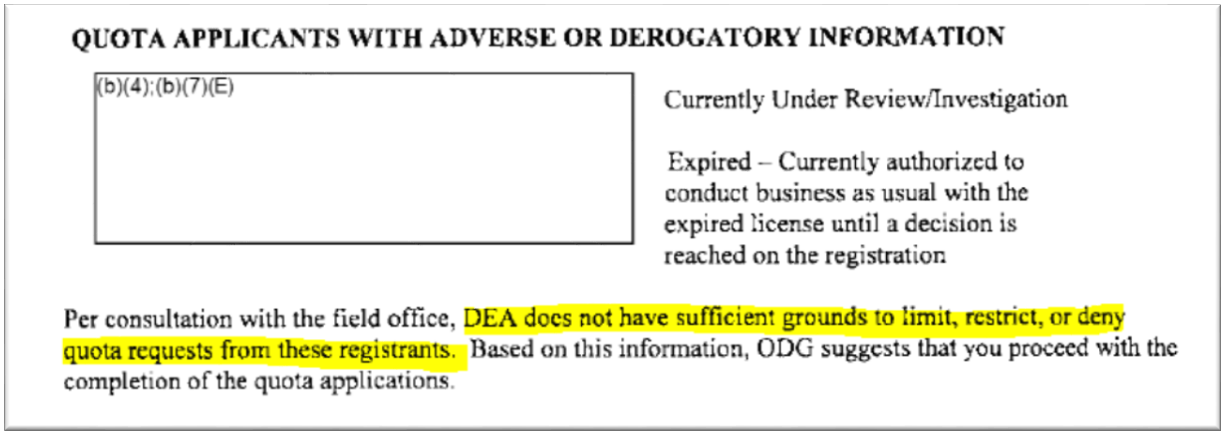
B. The DEA had no methodology to account for diversion in any way

The second takeaway from this FOIA request, however, is that none of this information was reflected when setting APQs based on forecasts of the "legitimate medical and scientific needs" of the United States. Critically, the DEA produced no documents, formulas, or accounting explaining how—if at all—it accounted for diversion when setting quotas from 2010-2016.

The only documents the DEA produced that suggest it "accounts for diversion" in setting APQs are a series of review memoranda prepared by the Drug & Chemical Evaluation Section ("ODQ") and the Regulatory Section ("ODG") regarding individual quota applicants. Even here, the DEA's individual reviews of specific quota applicants contain numerous red flags with little or no response. For example, the enforcement division reported numerous instances of "derogatory information" on an individual or customer affiliated with a quota applicant. Given the large amount of redactions in the documents the DEA produced, it is impossible to determine specifics, but frequently the phase "currently under investigation / review" is cited. The advice of the ODG is, "[p]er consultation with the field office, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications."

[73] Vol. II, p. 108.
[74] Vol. II, p. 109.
[75] Vol. II, p. 116.
[76] Vol. II, p. 130.

Figure 14: Sample ODGR Memorandum Recommending No Action (2010)[77]



QUOTA APPLICANTS WITH ADVERSE OR DEROGATORY INFORMATION

(b)(4);(b)(7)(E)

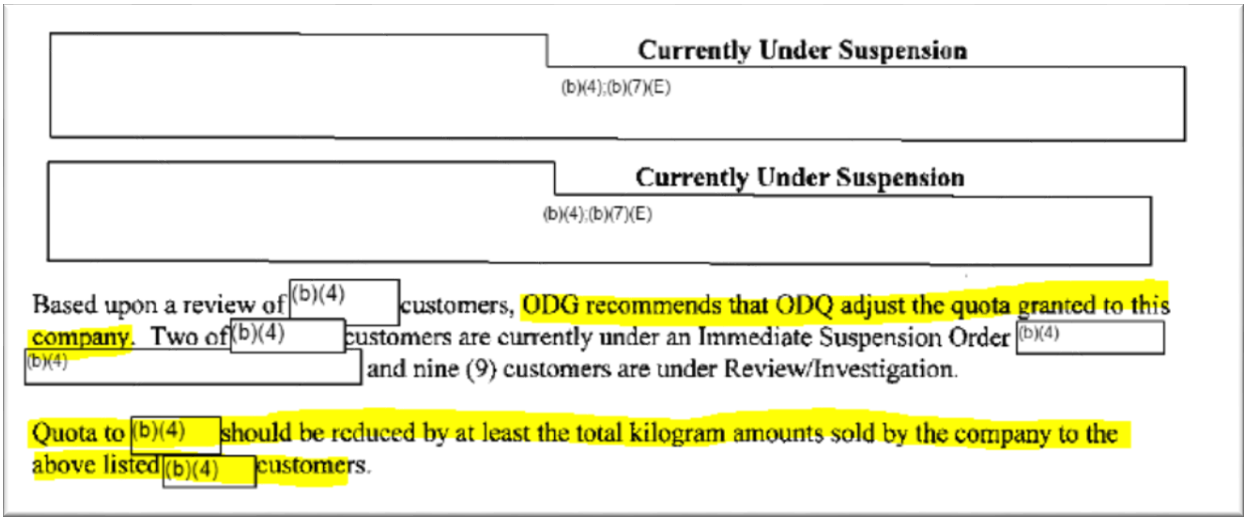
Currently Under Review/Investigation

Expired – Currently authorized to conduct business as usual with the expired license until a decision is reached on the registration

Per consultation with the field office, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from these registrants. Based on this information, ODG suggests that you proceed with the completion of the quota applications.

Although far less common, some registrants whose customers presented more serious concerns are reported back to ODQ in 2011 and 2012 with recommendations that quotas should be either reduced or denied. These typically correspond to registrants with customers that are retired or have had their own license to distribute controlled substances suspended.

Figure 15: Sample ODGR Suspension Memorandum Recommending Quota Reduction (2011)[78]



Currently Under Suspension

(b)(4);(b)(7)(E)

Currently Under Suspension

(b)(4);(b)(7)(E)

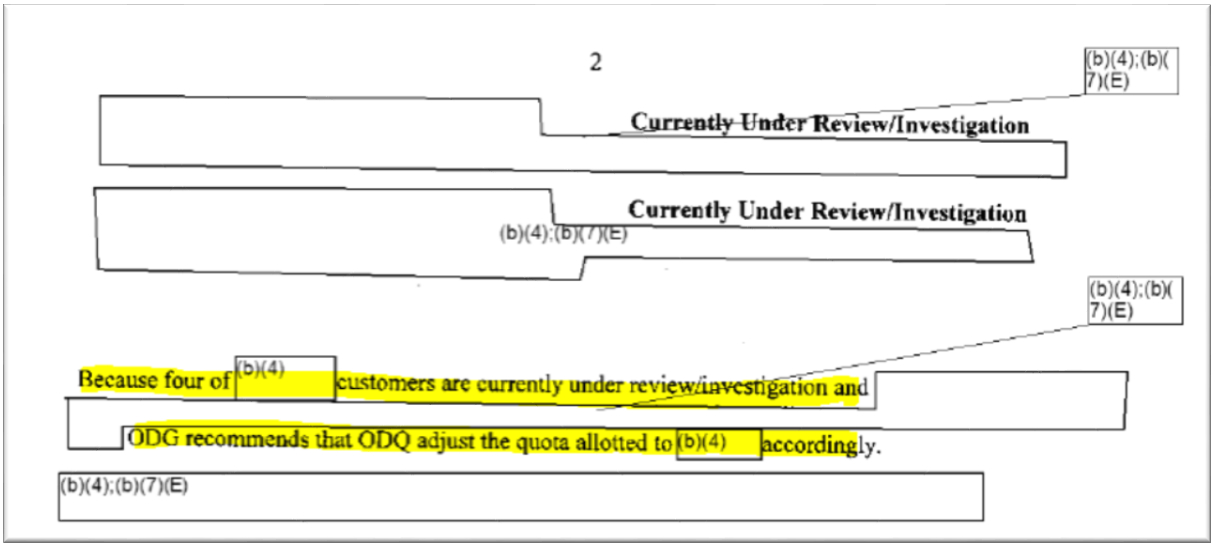
Based upon a review of (b)(4) customers, ODG recommends that ODQ adjust the quota granted to this company. Two of (b)(4) customers are currently under an Immediate Suspension Order (b)(4) (b)(4) and nine (9) customers are under Review/Investigation.

Quota to (b)(4) should be reduced by at least the total kilogram amounts sold by the company to the above listed (b)(4) customers.

Registrants with customers who are merely "under investigation" rarely have their quotas reduced as a result—consistent with the notion that an "investigation" is a preliminary step towards reaching a conclusion. But this is not always the case. Some registrants did have their quotas adjusted because ODG reported having active investigations into their customers.

[77] Vol. II, p. 6.
[78] Vol. II, p. 406.

Figure 16: Sample ODGR Investigation Memorandum Recommending Quota Reduction (2012)[79]



Again, with the large redactions it is difficult to determine the details of why some registrants are approved and others are denied. Indeed, it is not possible to determine which of these reports relate to "diversion" of opioids, much less how or in what form. However, two general takeaways can be drawn from these documents. *First*, the combined weight of the "derogatory information" ODG reported did not slow, much less reverse, the runaway growth in the quota system. Indeed, the heaviest consequence that could be imposed is a decrease *of the requested increase to the quota*. Yet it does not appear that ODG contemplated affirmatively lowering quotas in response to diversion.

Second, in an era of unprecedented drug abuse and diversion, the specific office responsible for policing diversion could not quantify it in any meaningful way. Indeed, during budget discussions, the DEA had a much more concrete and measurable sense of when and where diversion takes place, yet utterly failed to use that information when fulfilling its mandate to set quotas that protect the American people.

* * *

In sum, the documents received in response to this second request did not provide evidence that the DEA's internal review process was able to make up for the poor quality of inputs it received. It appears that the agency made minimal effort to test the validity or legitimacy of the sales data submitted by quota applicants, and frequently declined to act on damaging information. And even this limited process was initiated only in response to requests for increased quotas, and at most only amounted to moderate reductions in the amount of increase granted. The DEA appears to have had a considerable understanding of diversion's scope and dangerous role in the opioid crisis from the early stages of the investigation period, yet the documents it produced show little to no effort to bring that knowledge to bear in the quota-setting process.

[79] Vol. II, p. 453.

CONCLUSIONS

At least from 2010 through 2016, the DEA was asleep at the switch when it came to setting APQs for many of the most dangerous and addictive opioids. The documents the DEA produced in response to both of our Office's FOIA requests do not show that the agency took steps to seek out information about the scope and magnitude of diversion—despite clear recognition of this concern. Instead, the DEA routinely accepted sales figures and unsupported claims of increased demand as a proxy for the legitimate medical and scientific needs of the United States. Apart from data from the FDA, which the DEA appears to have frequently ignored or minimized when setting quotas, our investigation revealed no other significant attempt to consult with other agencies, the States, or private organizations to better substantiate its annual quotas during the same years that opioid deaths were skyrocketing nationwide.

Whether by using its own data and tools, soliciting more comprehensive public participation, or simply crediting the robust quantitative work done by the FDA, the DEA should have done something—anything—during this time to live up to its statutory duty. And although the DEA is now required by statute and regulation to account for diversion and to solicit participation by States in that process, that alone cannot be a complete solution. This investigation has strongly suggested that the DEA lacked critical information about opioid diversion, and a will to live up to its mission.

Seeking out relevant information and using it in a reliable, objective manner is not an unrealistic expectation, especially in an area with such significant consequences for our nation. The FDA model, for example, provided a data-driven approach to forecasting that, although incomplete, appears far more robust than anything the DEA provided to our Office demonstrating their methodology. Indeed, the DEA itself was in the best position to fill in the gaps in the FDA model, because it is the agency charged with monitoring and operating the "closed system" of controlled substance production and sale. With legal authority and resources to take responsibility for this issue, it did not fulfill its duty to act as a robust gatekeeper when setting APQs.

We also recognize that the DEA has taken positive steps in recent years to right the ship.[80] Drug quotas have been reduced considerably since 2017, and the new policies adopted in response to this Office's lawsuit show that the DEA is willing to improve.[81] Yet there is still considerable work to be done to fully address the shortcomings identified in this report. For example, the DEA's APQs for 2020 attempted to quantify diversion for the five opioids identified in the SUPPORT Act using the DEA's database of theft reports and seizures of controlled substances by law enforcement.[82] The DEA then made a straightforward reduction in these substances' aggregate quotas "by the corresponding quantities"[83]—the sort of common-sense analysis that should have

[80] The Office appreciates the leadership efforts of Attorneys General Jeff Sessions and Bill Barr to make improvements and work with our Office to effectuate needed reforms in this area.

[81] 83 Fed. Reg. at 32,784.

[82] 84 Fed. Reg. 48,170, 48,172-73 (Sept. 12, 2019) (proposing 2020 quotas); *see also* 84 Fed. Reg. 66,014, 66,016 (Dec. 2, 2019) (finalizing 2020 quotas).

[83] *Id.* at 48,173.

been part of the DEA's approach all along. When conducting the required analysis of diversion for other substances, however, the DEA stopped short of conducting the same division calculations even while acknowledging that these theft and seizure databases contained "usable information."[84]

There are two problems with this approach. *First*, the DEA is obligated to account for diversion in setting all controlled substance quotas—not merely those listed in the SUPPORT Act—as a result of this Office's lawsuit.[85] *Second*, even the process used for the SUPPORT Act substances is still too simplistic for such a critical piece of the analysis. Theft and law-enforcement seizure reports show only part of the picture; opioid pills that were prescribed pursuant to a legitimate but excessive prescription and reached abusers through other means—unreported theft, secondhand sales, etc.—are also a significant part of the problem and should not be counted toward the nation's "medical and scientific needs." Thus, much more work remains to be done. Based on the findings of this report, this Office offers the following recommendations:

- **Demand higher standards of data from manufacturers**. The DEA should not continue allowing manufacturers to request APQ increases simply by citing to sales projections. Manufacturers who claim that APQs should be increased because of increased sales should bear the burden of demonstrating that these sales are not contributing to diversion.

- **Improve the collection and maintenance of the DEA's internal data sets**. The DEA is not currently able to utilize data from ARCOS or SORS in a way that fully captures the scope of opioid diversion.[86] Nor does the DEA utilize other enforcement-tracking mechanisms to quantify diversion, whether prospectively or retrospectively. And the DEA does not even attempt to track the quantities of controlled substances returned through its Drug Takeback Program, all of which are self-evidently medically unnecessary and many of which would have been ripe targets for diversion if not disposed of through this program.

- **Conduct a rigorous, retrospective review of previous APQs**. The Office has recommended that the DEA expand its use of many of these existing data sources, as well as other national and state data sets, in comments on proposed APQs.[87] The DEA has, for its part, claimed that these changes are not practical or would not yield data that could be directly incorporated into a particular quota.[88] These data sources, however, do not need to be used as direct proxies for diversion in order to better account for diversion. After all, when current tools for addressing a crisis are incomplete, the solution should be to use them to the extent possible now and invest in fixing them for

[84] *Id.* at 48,172.

[85] *Compare* 84 Fed. Reg. at 48,176, *with* 83 Fed. Reg. at 67,353 (proposing 2020 production quota of amphetamine (for sale) that is identical to the quota for 2019).

[86] Dept. of Justice, *supra* note 32, at 30-32; *see also* 84 Fed. Reg. 66,016 (describing obstacles to utilizing these sources in setting 2020 quotas).

[87] Office of the West Virginia Att'y Gen., *supra* note 22, at 8-11.

[88] 84 Fed. Reg. 66,016-17.

the future, not to claim defeat and do nothing to address the problem. Further, APQs were clearly wildly excessive from 2010-2016, and the DEA should thoroughly review its over-estimation when it calculated actual consumption and legitimate need in prior years so that it can consider future APQs from an accurate—not inflated—baseline. Similarly, studies showing systematic overprescribing of opioids[89] can help identify the broader trends that existed against the backstop of prior quotas.

- **Develop a concrete, data-driven methodology of accounting for diversion**. As explained, this work has already been started by the FDA through its robust model for forecasting future demand for opioids. The DEA is best positioned to build on that model by (1) adjusting it to reflect that past demand has been inflated by over-prescribing and diversion; and (2) quantifying the factors—drug seizures, takebacks, suspicious orders, and more—that more accurately show the difference between "demand" and actual medical and scientific need.

The documents discussed in this report as well as all documents the DEA produced to the Office across both FOIA requests are available on the Office's website.[90] We are eager to see the DEA continue to implement changes in this important area to redress its significant failures, at least from 2010 through 2016, and to take responsibility for the amount of opioids legally produced in our country each year. Millions of American lives rest in the balance.

[89] *Supra* note 87, at 11-12 (collecting several examples).
[90] https://bit.ly/2AxjiJc.

APPENDIX I – APQ HISTORY FOR SELECT OPIOIDS

Oxycodone (for sale)

2010	**Citation**	**Amount (kg)**
Proposed Initial	74 Fed. Reg. 23,881 (May 21, 2009)	77,560
Established Initial	74 Fed. Reg. 54,080 (Oct. 21, 2009)	88,000
Proposed Revised	75 Fed. Reg. 35,838 (June 23, 2010)	88,000
Final Revised	75 Fed. Reg. 55,828 (Sept. 14, 2010)	105,500
Change from Prior Year Final Revised APQ = 12.2% Increase		

2011	**Citation**	**Amount (kg)**
Proposed Initial	75 Fed. Reg. 56,137 (Sept. 15, 2010)	105,500
Established Initial	75 Fed. Reg. 79,404 (Dec. 20, 2010)	105,500
Proposed Revised	76 Fed. Reg. 56,810 (Sept. 14, 2011)	98,000
Final Revised	76 Fed. Reg. 77,016 (Dec. 9, 2011)	98,000
Change from Prior Year Final Revised APQ = (7.1%) Decrease		

2012	**Citation**	**Amount (kg)**
Proposed Initial	76 Fed. Reg. 65,537 (Oct. 21, 2011)	98,000
Established Initial	76 Fed. Reg. 78,044 (Dec. 15, 2011)	98,000
Proposed Revised	77 Fed. Reg. 39,737 (July 5, 2012)	98,700
Final Revised	77 Fed. Reg. 55,500 (Sept. 10, 2012)	105,200
Change from Prior Year Final Revised APQ = 7.3% Increase		

2013	**Citation**	**Amount (kg)**
Proposed Initial	77 Fed. Reg. 46,519 (Aug. 3, 2012)	123,375
Established Initial	77 Fed. Reg. 59,980 (Oct. 1, 2012)	131,500
Proposed Revised	78 Fed. Reg. 37,237 (June 20, 2013)	153,750
Final Revised	78 Fed. Reg. 48,193 (Aug. 7, 2013)	153,750
Change from Prior Year Final Revised APQ = 46.2% Increase		

2014	**Citation**	**Amount (kg)**
Proposed Initial	78 Fed. Reg. 40,186 (July 3, 2013)	149,375
Established Initial	78 Fed. Reg. 55,099 (Sept. 9, 2013)	149,375
Proposed Revised	79 Fed. Reg. 33,780 (June 12, 2014)	149,375
Final Revised	79 Fed. Reg. 50,700 (Aug. 25, 2014)	149,375
Change from Prior Year Final Revised APQ = (2.8%) Decrease		

2015	**Citation**	**Amount (kg)**
Proposed Initial	79 Fed. Reg. 37,772 (July 2, 2014)	137,500
Established Initial	79 Fed. Reg. 53,216 (Sept. 8, 2014)	137,500
Proposed Revised	80 Fed. Reg. 39,156 (July 8, 2015)	139,150
Final Revised	80 Fed. Reg. 55,642 (Sept. 16, 2015)	141,375
Change from Prior Year Final Revised APQ = (5.4%) Decrease		

Oxymorphone (for sale)

2010	**Citation**	**Amount (kg)**
Proposed Initial	74 Fed. Reg. 23,881 (May 21, 2009)	2,000
Established Initial	74 Fed. Reg. 54,080 (Oct. 21, 2009)	2,570
Proposed Revised	75 Fed. Reg. 35,838 (June 23, 2010)	2,570
Final Revised	75 Fed. Reg. 55,828 (Sept. 14, 2010)	3,070
Change from Prior Year Final Revised APQ = 19.5% Increase		

2011	**Citation**	**Amount (kg)**
Proposed Initial	75 Fed. Reg. 56,137 (Sept. 15, 2010)	3,070
Established Initial	75 Fed. Reg. 79,404 (Dec. 20, 2010)	3,070
Proposed Revised	76 Fed. Reg. 56,810 (Sept. 14, 2011)	3,070
Final Revised	76 Fed. Reg. 77,016 (Dec. 9, 2011)	3,070
Change from Prior Year Final Revised APQ = No Change		

2012	**Citation**	**Amount (kg)**
Proposed Initial	76 Fed. Reg. 65,537 (Oct. 21, 2011)	5,500
Established Initial	76 Fed. Reg. 78,044 (Dec. 15, 2011)	5,500
Proposed Revised	77 Fed. Reg. 39,737 (July 5, 2012)	5,500
Final Revised	77 Fed. Reg. 55,500 (Sept. 10, 2012)	5,500
Change from Prior Year Final Revised APQ = 79.2% Increase		

2013	**Citation**	**Amount (kg)**
Proposed Initial	77 Fed. Reg. 46,519 (Aug. 3, 2012)	6,875
Established Initial	77 Fed. Reg. 59,980 (Oct. 1, 2012)	6,875
Proposed Revised	78 Fed. Reg. 37,237 (June 20, 2013)	6,875
Final Revised	78 Fed. Reg. 48,193 (Aug. 7, 2013)	7,000
Change from Prior Year Final Revised APQ = 27.3% Increase		

2014	**Citation**	**Amount (kg)**
Proposed Initial	78 Fed. Reg. 40,186 (July 3, 2013)	7,750
Established Initial	78 Fed. Reg. 55,099 (Sept. 9, 2013)	7,750
Proposed Revised	79 Fed. Reg. 33,780 (June 12, 2014)	7,750
Final Revised	79 Fed. Reg. 50,700 (Aug. 25, 2014)	7,750
Change from Prior Year Final Revised APQ = 10.7% Increase		

2015	**Citation**	**Amount (kg)**
Proposed Initial	79 Fed. Reg. 37,772 (July 2, 2014)	7,750
Established Initial	79 Fed. Reg. 53,216 (Sept. 8, 2014)	7,750
Proposed Revised	80 Fed. Reg. 39,156 (July 8, 2015)	7,750
Final Revised	80 Fed. Reg. 55,642 (Sept. 16, 2015)	7,750
Change from Prior Year Final Revised APQ = No Change		

Hydromorphone (for sale)

2010	**Citation**	**Amount (kg)**
Proposed Initial	74 Fed. Reg. 23,881 (May 21, 2009)	3,300
Established Initial	74 Fed. Reg. 54,080 (Oct. 21, 2009)	3,300
Proposed Revised	75 Fed. Reg. 35,838 (June 23, 2010)	3,455
Final Revised	75 Fed. Reg. 55,828 (Sept. 14, 2010)	3,455
Change from Prior Year Final Revised APQ = 3.4% Increase		

2011	**Citation**	**Amount (kg)**
Proposed Initial	75 Fed. Reg. 56,137 (Sept. 15, 2010)	3,455
Established Initial	75 Fed. Reg. 79,404 (Dec. 20, 2010)	3,455
Proposed Revised	76 Fed. Reg. 56,810 (Sept. 14, 2011)	3,455
Final Revised	76 Fed. Reg. 77,016 (Dec. 9, 2011)	3,455
Change from Prior Year Final Revised APQ = No Change		

2012	**Citation**	**Amount (kg)**
Proposed Initial	76 Fed. Reg. 65,537 (Oct. 21, 2011)	3,455
Established Initial	76 Fed. Reg. 78,044 (Dec. 15, 2011)	3,455
Proposed Revised	77 Fed. Reg. 39,737 (July 5, 2012)	3,628
Final Revised	77 Fed. Reg. 55,500 (Sept. 10, 2012)	4,207
Change from Prior Year Final Revised APQ = 21.8% Increase		

2013	**Citation**	**Amount (kg)**
Proposed Initial	77 Fed. Reg. 46,519 (Aug. 3, 2012)	4,535
Established Initial	77 Fed. Reg. 59,980 (Oct. 1, 2012)	5,968.75
Proposed Revised	78 Fed. Reg. 37,237 (June 20, 2013)	5,968.75
Final Revised	78 Fed. Reg. 48,193 (Aug. 7, 2013)	6,570
Change from Prior Year Final Revised APQ = 60.4% Increase		

2014	**Citation**	**Amount (kg)**
Proposed Initial	78 Fed. Reg. 40,186 (July 3, 2013)	5,968.75
Established Initial	78 Fed. Reg. 55,099 (Sept. 9, 2013)	6,570
Proposed Revised	79 Fed. Reg. 33,780 (June 12, 2014)	6,570
Final Revised	79 Fed. Reg. 50,700 (Aug. 25, 2014)	6,570
Change from Prior Year Final Revised APQ = No Change		

2015	**Citation**	**Amount (kg)**
Proposed Initial	79 Fed. Reg. 37,772 (July 2, 2014)	6,250
Established Initial	79 Fed. Reg. 53,216 (Sept. 8, 2014)	7,000
Proposed Revised	80 Fed. Reg. 39,156 (July 8, 2015)	7,000
Final Revised	80 Fed. Reg. 55,642 (Sept. 16, 2015)	7,000
Change from Prior Year Final Revised APQ = 3.7% Increase		

Hydrocodone (for sale)

2010	**Citation**	**Amount (kg)**
Proposed Initial	74 Fed. Reg. 23,881 (May 21, 2009)	55,000
Established Initial	74 Fed. Reg. 54,080 (Oct. 21, 2009)	55,000
Proposed Revised	75 Fed. Reg. 35,838 (June 23, 2010)	55,000
Final Revised	75 Fed. Reg. 55,828 (Sept. 14, 2010)	55,000
Change from Prior Year Final Revised APQ = (0.9%) Decrease		

2011	**Citation**	**Amount (kg)**
Proposed Initial	75 Fed. Reg. 56,137 (Sept. 15, 2010)	55,000
Established Initial	75 Fed. Reg. 79,404 (Dec. 20, 2010)	55,000
Proposed Revised	76 Fed. Reg. 56,810 (Sept. 14, 2011)	59,000
Final Revised	76 Fed. Reg. 77,016 (Dec. 9, 2011)	59,000
Change from Prior Year Final Revised APQ = 7.3% Increase		

2012	**Citation**	**Amount (kg)**
Proposed Initial	76 Fed. Reg. 65,537 (Oct. 21, 2011)	59,000
Established Initial	76 Fed. Reg. 78,044 (Dec. 15, 2011)	59,000
Proposed Revised	77 Fed. Reg. 39,737 (July 5, 2012)	63,000
Final Revised	77 Fed. Reg. 55,500 (Sept. 10, 2012)	79,700
Change from Prior Year Final Revised APQ = 35.1% Increase		

2013	**Citation**	**Amount (kg)**
Proposed Initial	77 Fed. Reg. 46,519 (Aug. 3, 2012)	78,750
Established Initial	77 Fed. Reg. 59,980 (Oct. 1, 2012)	99,625
Proposed Revised	78 Fed. Reg. 37,237 (June 20, 2013)	99,625
Final Revised	78 Fed. Reg. 48,193 (Aug. 7, 2013)	99,625
Change from Prior Year Final Revised APQ = 25.0% Increase		

2014	**Citation**	**Amount (kg)**
Proposed Initial	78 Fed. Reg. 40,186 (July 3, 2013)	99,625
Established Initial	78 Fed. Reg. 55,099 (Sept. 9, 2013)	99,625
Proposed Revised	79 Fed. Reg. 33,780 (June 12, 2014)	99,625
Final Revised	79 Fed. Reg. 50,700 (Aug. 25, 2014)	99,625
Change from Prior Year Final Revised APQ = No Change		

2015	**Citation**	**Amount (kg)**
Proposed Initial	79 Fed. Reg. 37,772 (July 2, 2014)	99,625
Established Initial	79 Fed. Reg. 53,216 (Sept. 8, 2014)	99,625
Proposed Revised	80 Fed. Reg. 39,156 (July 8, 2015)	99,625
Final Revised	80 Fed. Reg. 55,642 (Sept. 16, 2015)	99,625
Change from Prior Year Final Revised APQ = No Change		

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- Pp. 1369-1452 (February 2015 Government Accountability Office report on issues with the DEA quota process and a call for better coordination with the FDA)
- Pp. 1459-60 (2016 study on the accuracy of registrant applications in DEA's Year-End Reporting and Quota Management System)
- Pp. 1461-91 (2016 presentation from a pharmaceutical training seminar covering online quota applications)
- Pp. 1492-96 (Code sections relating to DEA's quota process)
- Pp. 1497-1536 (presentation from a pharmaceutical training seminar explaining quotas)
- Pp. 1537-62 (user manual on quotas from April 2011, covering the Years-End Reporting and Quota Management System)
- Pp. 1563-94 (user manual on quotas from January 2017, covering the Years-End Reporting and quota Management System)

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