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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

October 23, 2020

Mr. Timothy Shea
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. Shea:

We write to request information related to the Drug Enforcement Administration's (DEA) oversight of the U.S. opioid supply. Our questions arise from the DEA's 2019 Drug Threat Assessment (DTA) released on January 31, 2020.[1]

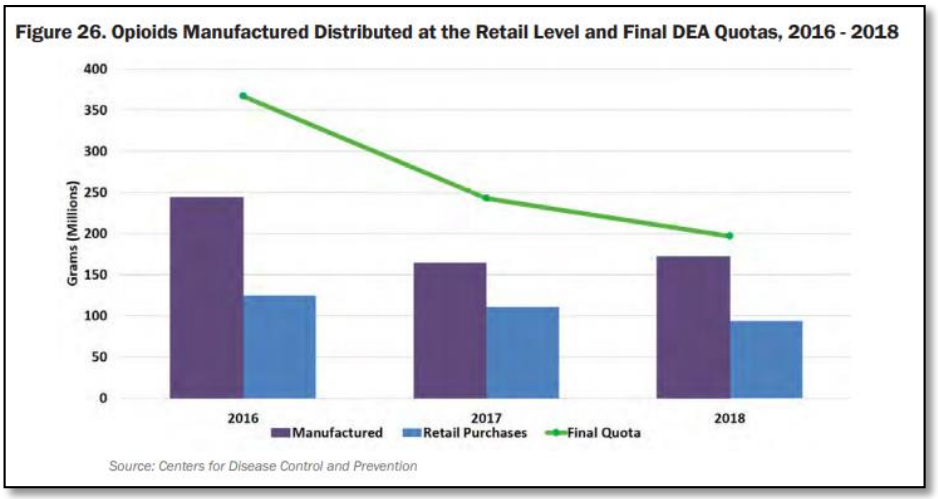
This request is in support of a reactivated investigation from Committee Republicans, started by the House Energy and Commerce Committee on August 2, 2018, that examined potential breakdowns in the controlled substances supply chain, which may have contributed to the nation's opioid epidemic, and the role of certain opioid manufacturers in such potential breakdowns.

Each calendar year, the DEA sets the aggregate production quota (APQ) of controlled substances, including opioids, to ensure that patients have the medicines they need while also reducing excess production of controlled prescription drugs that can be diverted and misused.[2] According to the DEA, the APQ reflects the total amount of substances needed to meet the country's legitimate medical, scientific, research, industrial, and export needs for the year and for the maintenance of reserve stocks. In setting the APQ, DEA considers data from many sources, including estimates of the legitimate medical need from the Food and Drug Administration's (FDA) estimates of retail consumption based on prescriptions dispensed; manufacturers' disposition history and forecasts; data from DEA's internal system for tracking controlled

[1] U.S. Drug Enforcement Adminstration, *National Drug Threat Assessment*, (Dec. 2019) *available at* https://www.dea.gov/sites/default/files/2020-01/2019-NDTA-final-01-14-2020_Low_Web-DIR-007-20_2019.pdf.
[2] U.S. Drug Enforcement Agency, *DEA proposes to reduce the amount of five opioids manufactured in 2020, marijuana quota for research increases by almost a third*, (Sept. 11, 2019) *available at* https://www.dea.gov/press-releases/2019/09/11/dea-proposes-reduce-amount-five-opioids-manufactured-2020-marijuana-quota.

substance transactions; and past quota histories. In July 2018, the DEA published a final rule related to the quota system.[3] The final rule made two additions to the list of factors that must regularly be considered in setting the APQ because of their importance.[4] First, the rule added to the list the extent of any diversion of the controlled substance in the class, to ensure that the allowed APQ is limited to that needed to provide adequate supplies for the United States' legitimate needs.[5] Second, the final rule amended the list of factors to be considered in establishing these quotas to include relevant information from the Department of Health and Human Services (HHS) and its components, including the FDA,[6] In addition, the SUPPORT Act requires DEA to "estimate the amount of diversion that took place" in the United States for each of five opioid substances and "make appropriate quota reductions."[7]

The DEA's 2019 DTA raises questions about how DEA manages the APQ for opioids. According to Figure 26 of the 2019 DTA, over 2016, 2017, and 2018 periods, the DEA approved a combined total quota of about 800 million grams of opioids, and drug companies manufactured about 560 million grams of drug and sold, through retail purchases, about 235 million grams.[8] This would indicate that during this 3-year period, drug companies over-manufactured 325 million grams of drug, and had about 235 million grams of finished product in inventory, more than they sold in any year. The DEA quota was 565 million grams over retail purchased, and 475 million grams over manufactured product. In sum, although retail purchases declined, industry increased its manufacturing and inventory year-end levels.



Source: DEA 2019 Drug Threat Assessment[9]

[3]U.S. Department of Justice, U.S. Drug Enforcement Administration, Controlled Substances Quotas, 83 Federal Register 32,784 (July 16, 2018).
[4]*Id.*
[5]*Id.*
[6]*Id.*
[7] Public Law No: 115-271.
[8] Drug Enforcement Administration, *2019 National Drug Threat Assessment*, (Dec. 2019) *available at* https://www.dea.gov/sites/default/files/2020-01/2019-NDTA-final-01-14-2020_Low_Web-DIR-007-20_2019.pdf
[9] *Id.*

To assist our understanding of DEA's management of opioid quotas, please have DEA provide a briefing for Minority Committee staff to address the following questions by November 23, 2020:

1. Figure 26 references retail sales, however, retail sales are commonly understood to exclude hospital sales. How many grams of opioids were sold to hospitals? How did the DEA take this amount from hospital sales into account in determining the quota?

2. Given the year-end inventories, which are also reported to the DEA's Year-End Reporting System (YERS), how does the DEA justify the following year quotas since year-end inventories are greater than next year's sales?

3. How does the DEA justify quotas that are twice the amount of the prior year sales, while sales are declining?

4. Even assuming the drug industry had zero inventory in December 2015,[10] Figure 26 shows the industry had 2.8 years of finished product inventory in December 2018. How did the DEA make the determination of the 2019 quota given this inventory?

5. In the September 12, 2019 Federal Register Notice, the DEA declared it could not meet the SUPPORT Act requirements to include diversion and mortality and abuse rates when calculating APQ because the data on overdose deaths was imprecise.[11] What changes are needed for the DEA to obtain overdose death data for calculating APQ?

6. Looking forward to calendar year 2021, the FDA's predicted estimate of legitimate medical need for U.S. consumption was expected to decline on average 36.52 percent, which differed from the DEA's higher assessment of the legitimate medical needs of the U.S.[12] Why was the DEA's assessment higher than the FDA's estimate? Why should the DEA differ from the FDA on such an important determination?

Your assistance is appreciated. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff at (202) 225-3641.

[10] In 2013, a 25% buffer was added to the APQ annually to guard against shortages. The APQ reduction in 2017 was primarily due to the elimination of the 25% buffer. U.S. Drug Enforcement Agency, *DEA Reduces Amount of Opioid Controlled Substances To Be Manufactured In 2017*, (Oct. 4, 2017) *available at* https://www.dea.gov/press-releases/2016/10/04/dea-reduces-amount-opioid-controlled-substances-be-manufactured-2017

[11] 84 FR 48170

[12] Larry Cote, Russel Day, *DEA Submits Proposed Quotas for 2021*, Cote Law PLLC (Sept. 2, 2020) *available at* https://www.deachronicles.com/2020/09/deas-submits-proposed-quotas-for-2021/#more-2634

Sincerely,

Greg Walden
Republican Leader
Committee on Energy and Commerce

Michael C. Burgess, M.D.
Republican Leader
Subcommittee on Health

Brett Guthrie
Republican Leader
Subcommittee on Oversight and Investigations

H. Morgan Griffith
Member of Congress