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DOJ OIG Releases Report on the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids

U.S. Department of Justice (DOJ) Inspector General Michael E. Horowitz announced today the release of a report examining the Drug Enforcement Administration's (DEA) regulatory and enforcement efforts to control the diversion of opioids to unauthorized users. The DOJ Office of the Inspector General (OIG) found that while the Department and DEA have taken recent steps to address the opioid epidemic as a national crisis, DEA was slow to respond to the significant rise in the use and diversion of opioids since the early 2000s. We also found that DEA policies and regulations did not adequately hold registrants accountable or prevent the diversion of pharmaceutical opioids.

The specific findings in today's report include:

- **DEA Increased Annual Opioid Production Quotas, Despite the Rise of Opioid Overdose Deaths.** The rate of opioid overdose deaths in the United States grew, on average, by 8% per year from 1999 through 2013 and by 71% per year from 2013 through 2017. Yet, from 2003 through 2013 DEA authorized manufacturers to produce substantially larger amounts of opioids. For example, DEA authorized a 400% increase in oxycodone production between 2002 and 2013, and it was not until 2017 that DEA significantly reduced oxycodone production quota, by 25%.*
- **Weaknesses Exist in DEA's Registration Process.** DEA is responsible for vetting and registering all those who wish to handle controlled substances, including manufacturers, distributors, and health care practitioners. We identified weaknesses in DEA's registration process, including that registrants may reapply for registration the day after their registration is revoked or surrendered for cause.
- **DEA Did Not Fully Utilize its Regulatory Authorities and Enforcement Resources to Detect and Combat the Diversion of Controlled Substances.** We found that from 2013 to 2017, as the number of opioid-related deaths drastically increased, DEA significantly reduced its use of its strongest enforcement tool, the Immediate Suspension Order, to stop registrants from diverting prescription drugs. In fact, DEA used more Immediate Suspension Orders in 2012 (45) than from 2013 – 2017 combined (43). We also found that DEA regulations do not require all prescribers to submit prescriptions electronically,

*On December 16, 2019, page 13 of the report was updated to clarify information relating to production quotas.

and that Diversion Control work plans left little room for targeting registrants suspected of diversion.

- **DEA Does Not Collect the Data Necessary to Promptly Detect the Diversion of Opioids.** DEA does not adequately collect, maintain, or analyze data in order to identify trends in use of controlled substances. Specifically, DEA does not track ordering patterns for all pharmaceuticals, including some Schedule III and all Schedule IV and V opioids and other controlled substances, which could enable the diversion of these prescription drugs and compromise public safety. Further, we found that DEA’s system to collect suspicious orders was incomplete – it contained reports from only 8 of the approximately 1,400 registered manufacturers and distributors that are required by federal law to send such reports to DEA.
- **DEA Has Recently Taken Steps to Address the Opioid Epidemic.** We found that DOJ and DEA have recently taken steps to address the opioid epidemic, including increasing enforcement staffing and enforcement actions, and working more closely with federal and state partners. However, as we outline in today’s report, more work remains.

The report makes 9 recommendations to help DEA enhance its ability to detect the diversion of controlled substances like opioids, which hopefully will assist DEA in its efforts to prevent a similar health care crisis from occurring in the future. The Department and DEA agreed with all of the recommendations.

Report: Today’s report is available under “Recent Reports” on the OIG’s website and at the following link: <https://oig.justice.gov/reports/2019/e1905.pdf>.

Video: To accompany today’s report, the OIG has released a 2-minute video featuring the Inspector General summarizing the report’s findings. The video and a downloadable transcript are available at the following link: <https://oig.justice.gov/multimedia/video-10-01-19.htm>.

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