Questions for the Record

House Committee on Energy and Commerce, Subcommittee on Health

Hearing entitled, "An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America"
April 14, 2021

Regina LaBelle, Acting Director, Office of National Drug Control Policy

The Honorable Frank Pallone, Jr.

1. There is a potential for drug identification laws like H.R. 2355 to prevent high-risk individuals, such as a homeless person without an ID, from having access to needed prescriptions. Has ONDCP itself, or in partnership with other federal agencies, done any research on the effectiveness of prescription drug identification policies in deterring opioid shopping or misuse?

   Response
   The Centers for Disease Control and Prevention (CDC) conducted a review of state prescription drug identification laws in 2013. At the time, CDC found that 25 states either explicitly required or allowed pharmacists to request identification at the time of dispensing.[1] A National Association of Model State Drug Laws review conducted under a contract with the Office of National Drug Control Policy (ONDCP) found that, as of March 2016, the majority of states and the District of Columbia had some form of controlled substance prescription ID requirement;[2] however, an assessment of the effectiveness of these laws in reducing opioid prescribing was beyond the scope of the effort. ONDCP has not itself, nor in partnership with other federal agencies, conducted research on the effectiveness of prescription drug identification policies in deterring opioid shopping or misuse.

2. Does ONDCP have insight on whether prescription drug identification laws should remain at the state level or if a national strategy is needed?

   Response
   With the exception of controlled substances, dispensing of prescription drugs and

[1] Centers for Disease Control and Prevention. Menu of State Prescription Drug Identification Laws. Public Health Law. Office for State, Local, and Territorial Support. 2013. Retrieved July 14, 2021 at https://www.cdc.gov/phlp/docs/menu-pdil.pdf

[2] National Association for Model State Drug Laws. States that Require ID Prior to Dispensing Controlled Substances or Non-Controlled Prescription Drugs. 2016. Retrieved July 14, 2021 at https://namsdl.org/wp-content/uploads/States-that-Require-ID-Prior-to-Dispensin.pdf

prescription drug monitoring programs are generally areas of state oversight and regulation, as is the operation of prescription drug monitoring programs. At this time, given the lack of research on the impact of various prescription drug identification requirement laws, the likelihood that a single approach would likely not be equally effective across states, and given the long history of state regulation in this area, ONDCP does not believe there is a basis for recommending a transfer of such authorities to the federal government.

The Honorable Richard Hudson (R-NC)

1. There remain concerns around the reporting requirements included in Section 202 of H.R. 2366, Support, Treatment, and Overdose Prevention of Fentanyl Act of 2021. Section 202 requires a high level of reporting of highly sensitive information. This is further compounded by the directive for CMS to publish the information, with a sole exemption for "proprietary information." It would seem that most information required to be reported may be considered proprietary information. From a policy perspective, I am concerned this could dissuade entrance into the naloxone space particularly, given the highly burdensome reporting requirements. Would you provide policy rationale and reasoning for the scope of the data requested? In addition, please provide any clarification around what information may be considered "proprietary information," as used in Section 202.

Response:

The Office of National Drug Control Policy (ONDCP) is focused on increasing access to and expanding distribution of the opioid overdose reversal drug naloxone. In the midst of an overdose epidemic in which the estimated total number overdose deaths for 2020 surpassed 93,000—an all-time high that is nearly 30 percent above the 2019 figure[3]—increased access to naloxone is critical.

Naloxone should be affordable and easily accessible to anyone who needs it; to anyone who might encounter a person who could overdose, whether they are first responders, families, or friends of people who use drugs; and to those who are in treatment or receiving care through harm reduction services like syringe services programs.

As Section 202 of the "Support, Treatment, and Overdose Prevention of Fentanyl Act of 2021 was crafted by Congress, we are not aware of the specific rationale for its formulation.

[3] Centers for Disease Control and Prevention. Vital Statistics Rapid Release: Provisional Overdose Death Counts. National Center for Health Statistics. Retrieved July 14, 2021 at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

The Honorable Earl L. "Buddy" Carter

1. Generic injectable overdose agents have been available for several years, and FDA is doing all it can to encourage additional entrants to the market, yet the FTC has previously said "too much transparency can harm competition in the market." The FTC has expressed concern "when information disclosure allows competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price." Wouldn't requiring a whole host of new reporting requirements, particularly of sensitive business information that would impact competitive dynamics, impede companies from wanting to enter the market?

   Response
   Questions of market dynamics and associated regulatory incentives or disincentives are beyond the scope of the Office of National Drug Control Policy's mission. We defer to Federal agencies that deal more directly with the market for pharmaceuticals on these questions.