Regarding Request for Comment on Potential Role for Abuse-Deterrent Formulations of Central Nervous System Stimulants Docket No. FDA-2019-N-3403

My name is Jeffrey A. Singer, MD. I am a Senior Fellow at the Cato Institute in Washington, DC, where I work in the Department of Health Policy studies. The Cato Institute is a 501(c)(3) educational foundation dedicated to the principles of individual liberty, limited government, free markets, and peace. Its scholars conduct independent, nonpartisan research on a wide range of policy issues. To maintain its independence, the Cato Institute accepts no government funding. Cato receives approximately 80 percent of its funding through tax-deductible contributions from individuals. The remainder of its support comes from foundations, corporations, and the sale of books and publications.

My focus of public policy research is the overdose crisis plaguing the US and much of the developed world, as well as the harmful effects resulting from non-medical use of licit and illicit drugs in an underground market fueled by drug prohibition, seeking best approaches to mitigate those harms. My work at the Cato Institute is also informed and bolstered by the fact that I am a general surgeon in private clinical practice in Phoenix, Arizona for over 35 years, and have directly treated acute and chronic surgical patients, many of whom had used or use prescription stimulants. I received my BA in Biology at Brooklyn College (City University of New York), my MD at New York Medical College, and completed my specialty residency in general surgery at the Maricopa Medical Center in Phoenix, AZ, after which I became certified by the American Board of Surgery. I am a Fellow of the American College of Surgeons. My work has appeared in the peer-reviewed medical and scientific literature, as well as in national and regional periodicals and journals read by the general public.

The Cato Institute recently published my public policy analysis (attached) which evaluated the effect of abuse-deterrent opioids on the non-medical use of prescription opioids. According to the National Survey on Drug Use and Health (NSDUH), less than 25 percent of non-medical users of prescription opioids ever obtain them from a doctor. The majority get them from a friend, relative, or drug dealer. As my policy analysis makes clear, the evidence is strong that abuse-deterrent opioids drive non-medical users from prescription opioids to cheaper, more readily available, and more dangerous opioids such as heroin and fentanyl provided in the black market. At the same time, the reformulated prescription opioids add to the health care costs of medical users.

The above is relevant to the question of the potential role for abuse-deterrent formulations of central nervous stimulants. Compton et al, using NSDUH data, reported in 2018 that only 11.9 percent of non-medical users of prescription stimulants obtained them from one or more doctor, approximately 57 percent obtained them free from a friend or relative, approximately 22 percent bought or stole them from a friend or a relative, and roughly 4 percent obtained them from a dealer or stranger. Wang, et al found "use of other's stimulants" to be the most frequently report form of non-medical use among youths aged 10 to 18.

The pattern of non-medical use of prescription stimulants closely follows that of non-medical use of prescription opioids. It is therefore reasonable to expect that were the Food and Drug Administration to encourage the development of abuse-deterrent formulations of prescription stimulants it would have the same or similar effect as seen with the abuse-deterrent opioid example: drive non-medical users to more dangerous bootleg or illegally manufactured stimulants, while driving up costs for medical users of prescription stimulants. As with all drugs obtained in an underground market, the risk of harm and possibly death from their use is increased.

I therefore strongly recommend against a policy encouraging the development of abuse-deterrent stimulants.

Respectfully submitted,

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