STATEMENT

OF

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HEARING ON

CANNABIS POLICIES FOR THE NEW DECADE

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Chairwoman Eshoo, Ranking Member Burgess, and members of the Subcommittee, thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), to participate in this hearing. I am pleased to address the state of the science on cannabis and its constituent compounds and the process for conducting research with cannabis and other Schedule I drugs.

Background

In 2018, 43.5 million people reported using cannabis in the past year, making it the most commonly-used illicit drug in the United States. Cannabis contains hundreds of constituent compounds, including the cannabinoids delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Cannabinoids exert their effects on the body mainly by interacting with two types of receptors: CB1 and CB2 receptors. CB1 receptors are located mainly on neurons and glial cells in the brain and in several other organs in the body. CB2 receptors are found mainly on immune cells and are less common in the brain than CB1 receptors.[1] Whereas the euphoric effects of cannabis are caused by THC's activation of CB1 receptors, CBD has a very low affinity for these receptors (100-fold less than THC), and when it binds to them it produces little to no effect. Consequently, CBD, unlike THC, does not appear to produce euphoria, intoxication, or addiction. CBD acts on other brain signaling systems and on the immune system, and it is these actions that are thought to be important to its potential therapeutic effects.[2]

Cannabis products with varying concentrations of THC, CBD, and other chemicals have proliferated. The cannabis available today is much more potent than what was available in the past. The THC concentration in commonly cultivated cannabis plants increased three-fold between 1995 and 2014 (an increase from 4 to 12 percent in that period),[3] and cannabis available in dispensaries in some states has average concentrations of THC between 17.7 percent and 23.2 percent.[4] Concentrated products, commonly known as dabs or waxes, are widely available in some states and may contain between 23.7 percent and 75.9 percent THC.[5] CBD is ubiquitous, and it is possible to purchase CBD extracts as well as food, drinks, cosmetics, and other CBD-containing products, which are sometimes marketed with health and wellness claims that are not backed by science. Given the widespread availability of cannabis, its increasing potency, and the fact that many Americans are using cannabis products for medical and/or other purposes, there is a pressing need for research on the health consequences of

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[2] Borgelt LM, Franson KL, Nussbaum AM, Wang GS. The Pharmacologic and Clinical Effects of Medical Cannabis. *Pharmacother J Hum Pharmacol Drug Ther*. 2013;33(2):195-209. doi:10.1002/phar.1187.

[3] Elsohly, M. A., Mehmedic, Z., Foster, S. (2016). Changes in Cannabis Potency Over the Last 2 Decades (1995-2014): Analysis of Current Data in the United States. Biological Psychiatry, 79(7), 613-619. doi:10.1016/j.biopsych.2016.01.004.

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[5] Alzghari, S. K., Fung, V., Rickner, S. S., Chacko, L., & Fleming, S. W. (2017). To Dab or Not to Dab: Rising Concerns Regarding the Toxicity of Cannabis Concentrates. Cureus, 9(9), e1676. doi:10.7759/cureus.1676.

cannabis and its constituent compounds, including CBD.

Adverse Health Effect of Cannabis

Prenatal and Adolescent Development

Cannabis is not a benign substance, and cannabis exposure carries particular risk early in life. The body's endocannabinoid system—on which cannabis acts—appears relatively early during fetal development. As the fetal brain grows, this system influences how brain cells develop and connect with one another, and it plays a major role in the formation of brain circuits including those important for decision making, mood, and responding to stress.[6] THC freely crosses the placenta resulting in fetal exposure.[7] Animal studies have shown that *in utero* exposure to cannabis can interfere with the proper development and regulation of brain circuitry.[8] In humans, fetal exposure is associated with significant negative outcomes including fetal growth restriction,[9,10] lower birth weight,[11] and preterm delivery.[10]

Adolescents, whose brains are also undergoing major developmental changes, are also particularly vulnerable to the negative effects of cannabis. Preclinical studies have found that THC exposure during adolescence increases subsequent sensitivity to the rewarding effects of other drugs,[12] which could be one reason why those who use cannabis at a young age are more vulnerable to cannabis and other drug addiction later in life. Epidemiological studies have found that youth who regularly use cannabis have lower academic achievements and a higher risk of dropping out of school.[13] Frequent cannabis use during adolescence is associated with changes in areas of the brain involved in attention, memory, emotions, and motivation.[14] These changes may account for the adverse cognitive and behavioral effects associated with youth cannabis use, although there is likely also a role for peer and family influences, among others.

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Cannabis Use Disorder

Cannabis use can lead to cannabis use disorder and, in severe cases, addiction. Data suggest that nearly 10 percent of people who use cannabis will become dependent on it.[15] People who begin using cannabis before the age of 18 are four to seven times more likely to develop cannabis use disorder than adults.[16] The risks of physical dependence, addiction, and other negative consequences increase with frequent use and exposure to high concentrations of THC.[17]

Mental Illness

The association between cannabis use and mental illness is another major concern, particularly in light of the higher content of THC in today's cannabis. Serious mental illnesses and suicides are on the rise in our country,[18] and while multiple factors very likely contribute to this rise, it is imperative to understand if exposure to cannabis in adolescence is one of them. High doses of THC can trigger acute psychotic episodes, which is one of the main causes for emergency department visits associated with cannabis use.[19] Most of these episodes are short lasting, but some can last from days to weeks after use.[20] While overall risk of developing a lasting psychotic disorder is low, multiple studies have associated adolescent cannabis use (especially use of high potency products) with an increased overall risk for, and early onset of, chronic psychosis such as schizophrenia,[21,22] particularly in those with other risk factors.[23] Adolescent cannabis use is also associated with increased risk of suicidal behavior.[24]

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Lung Injuries

Inhalation of vaporized THC has been implicated in the outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI) that was first reported in June of 2019. EVALI results in an acute respiratory illness characterized by respiratory, gastrointestinal, and constitutional (e.g., chills, fever) symptoms, which has resulted in more than 2,500 hospitalizations and 55 deaths across the country over a 6 month period.[25] Most EVALI patients report vaping THC-containing products.[26] Vitamin E acetate, frequently found as an additive to vaped THC, is closely associated with EVALI. This substance, while safe to ingest or apply topically, may damage the lungs when heated and inhaled. Vitamin E acetate has a similar viscosity to THC, and the timing of its appearance as an additive to illicit THC-containing vaping products corresponds to the EVALI outbreak.[27]

Other Medical Complications

Different cannabis products (e.g., plant, THC concentrates) and routes of administration (e.g., inhalation, ingestion) pose unique risks. For example, eating cannabis can increase the risk of taking unintentionally high amounts due to its lengthy absorption time and delayed effect, which may prompt users to take more. This can result in aversive psychiatric and cardiac symptoms; edibles are, therefore, responsible for a disproportionate number of cannabis-related emergency department visits.[28] Edibles are often in the form of desserts or snacks and have increasingly been a cause of accidental ingestion by children[29] and adolescents.[30]

An additional medical complication that can result from chronic use of cannabis is known as cannabinoid hyperemesis syndrome, which is marked by severe cycles of nausea and vomiting.[31] The increase in the THC content of cannabis has led to a worrisome upward trend in the rate of calls to poison control centers and emergency department visits, especially in States that have

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[25] https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease/need-to-know/index.html

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legalized the drug.[32,33]

Impaired Driving

Cannabis significantly impairs judgment, motor coordination, and reaction time, and studies have found a direct relationship between blood THC concentration and impaired driving ability.[34,35,36] Several meta-analyses found that the risk of being involved in a crash significantly increased after cannabis use.[37] However, in a large case-control study, the significance of cannabis use disappeared after controlling for drivers' age, gender, race, and the presence of alcohol.[38] A complicating factor in determining crash risk is the difficulty of assessing cannabis impairment in the field, particularly compared to assessing impairment due to alcohol. Blood alcohol concentration is easily determined in a breath sample and reliably reflects impairment level.[39] Cannabis, however, is rapidly absorbed by fat cells; this means that blood levels drop rapidly after smoking and that cannabis may be detected in frequent users long after its impairing effects have subsided.[40]

Therapeutic Potential of Cannabis and Its Constituent Cannabinoids

While cannabis has been legalized for medical use in many states, it remains a Schedule I substance under the Federal Controlled Substances Act (CSA), and it does not have FDA approval for any indication. Some synthetic forms of THC are FDA approved (i.e., Marinol and Syndros) for the treatment of anorexia and weight loss in AIDS patients and for nausea and vomiting associated with cancer treatment. The FDA also approved Cesamet, which contains the active ingredient nabilone, a synthetic chemical similar to THC, for treating nausea and vomiting related to cancer chemotherapy.

Epidiolex is the first cannabis-derived medication and contains a highly purified form of CBD. It has been approved by the FDA for the treatment of seizures associated with Lennox-Gastaut and Dravet syndromes in patients two years of age and older. Research is underway to assess the

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[40] Hartman RL, Brown TL, Milavetz G, et al. Effect of blood collection time on measured Δ9-tetrahydrocannabinol concentrations: implications for driving interpretation and drug policy. Clin Chem2016;62:367–77.

therapeutic potential of CBD to treat multiple health conditions including, pain, inflammation, posttraumatic stress disorder, HIV, digestive disorders, and substance use disorders.[41] Outside of standard drug development there has been a proliferation of purported dietary supplements and food products that contain CBD.

A recent report published by the National Academies of Sciences, Engineering, and Medicine, which was sponsored by the Centers for Disease Control and Prevention, NIDA, the National Cancer Institute (NCI), FDA, and other stakeholders, concluded that there is substantial evidence that cannabis or cannabinoids are effective for treating chronic pain and improving patient-reported spasticity symptoms in multiple sclerosis. However, in general, adequate and well-controlled studies are lacking, which means that individuals across the country are using cannabis strains and extracts that have not undergone the rigorous clinical trials required to show they are safe and effective for medical use, and are not regulated for consistency or quality.

Research Supported by the National Institutes of Health's (NIH) National Institute on Drug Abuse (NIDA)

Research supported by NIH is helping to close the gaps in our understanding of the risks and potential benefits associated with cannabis product use. In fiscal year 2018, NIH Institutes and Centers supported $147 million in cannabinoid research, broadly, including $38 million on therapeutic cannabinoid research and $19 million on studies involving CBD.[42] Although most of this research is supported by NIDA, several other NIH Institutes and Centers fund cannabinoid research relevant to their respective missions. NIDA's portfolio includes research on the pharmacology of THC and other cannabinoids; the changes in the brain at the molecular, cellular, and systems levels associated with cannabis addiction and other adverse effects; the potentially beneficial effects of cannabis and its constituent compounds; preventing and treating cannabis misuse and addiction; and research to elucidate the prevalence and patterns of cannabis use and how cannabis policies affect public health.

Several important areas of interest across NIH include evaluating the endocannabinoid system as a new target for pain and addiction therapies,[43] disentangling the distinct therapeutic benefits and potential health risks of different component compounds within cannabis as they relate to pain,[44,45] and evaluating the effects of cannabis and exposures to other substances during vulnerable periods of development. The Adolescent Brain Cognitive Development (ABCD) study has great potential to advance knowledge on the developmental effects of cannabis exposure during adolescence. The largest long-term study of brain development and child health, the ABCD study will follow more than 11,000 children ages 9-10 into young adulthood. Researchers will assess their development, including how it may be affected by cannabis and other drug use, through brain imaging, genetic and other biological markers, and psychological, behavioral, and other health assessments. Complementing ABCD is the HEALthy Brain and Child Development (HBCD)

[41] https://projectreporter.nih.gov/Reporter_Viewsh.cfm?sl=15E1C90E468AC7D17598B8961CAA4A01A2FFCEB861BF
[42] https://report.nih.gov/categorical_spending.aspx
[43] https://grants.nih.gov/grants/guide/pa-files/pa-18-465.html
[44] https://grants.nih.gov/grants/guide/rfa-files/rfa-at-19-008.html
[45] https://nccih.nih.gov/news/press/09192019

Study. Currently in its planning phase, the HBCD study will advance knowledge on prenatal exposure to cannabis and other substances.

Conducting Research with Schedule I Substances

The increasing availability and potency of cannabis along with the proliferation of new cannabis products and methods for consuming them raise serious public health concerns. We know from other drug research that potency and route of administration are important factors in understanding the consequences of drug use, yet there is a relative dearth of research on these newer products. Rigorous research is essential for understanding how the changing cannabis landscape will affect public health and, ultimately, for guiding evidence-based policy. Despite the public health urgency, legal and regulatory barriers continue to present challenges to advancing cannabis research.

Obtaining and Modifying a Registration to Conduct Research with Cannabis and Other Schedule I Drugs is Challenging

Under the CSA, cannabis and its constituent compounds, excluding hemp, are classified as Schedule I controlled substances – defined as having no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.[46] Obtaining or modifying a Schedule I registration involves significant administrative challenges, and researchers report that obtaining a new registration can take more than a year. Adding new substances to an existing registration can also be time consuming.

It would be useful to clarify aspects of the CSA that have been sources of confusion and administrative burden for the research community, including that it is permissible for one individual to hold a Schedule I registration under which colleagues from the same institution may work even if those colleagues do not work directly for the registrant (e.g., as members of their laboratory); that registered researchers may store, administer, and work with any substances for which they hold a researcher registration at multiple practice sites on a single contiguous campus; and that if a person is registered to conduct research with a controlled substance and applies to conduct research with a second controlled substance that is in the same schedule or in a schedule with a higher numerical designation, an inspection that was performed for purposes of the existing registration shall be sufficient to support the application.

Lastly, and specifically relevant to cannabis research, it would be helpful to clarify that individuals registered to conduct research with a controlled substance who need to perform limited manufacturing activities on small quantities of that substance consistent with their research protocol (for example, creating a particular dosage formulation for research purposes) are not required to obtain a separate manufacturing registration. This would be especially helpful in cases in which researchers are required to create dosage formulations in their own laboratories from cannabis products supplied through the NIDA Drug Supply Program.

[46] https://www.deadiversion.usdoj.gov/schedules/

NIDA is the Only Source of Cannabis in the United States Permitted for Research
Although the CSA permits importation of cannabis and cannabis related substances for research, the University of Mississippi is the only entity in the United States currently registered with the DEA to cultivate cannabis for research purposes, which it does under a contract with NIDA. Having only a single domestic source of research cannabis limits the diversity of products and formulations available to researchers and slows the development of cannabis-based medications. Although the University of Mississippi supplies cannabis for clinical trials, it does not have the capacity to manufacture a broad array of cannabis-derived formulations for research or to supply these cannabis products for commercial development. Moreover, it is not clear how entities seeking to develop these products for commercial purposes would demonstrate equivalency between the University of Mississippi cannabis used in clinical trials and the drug product that would ultimately be approved by the FDA for marketing and sale. NIDA was pleased that on August 26, 2019, the DEA signaled that it is moving forward with its review of additional grower applications[47] and that it would promulgate new regulations governing cannabis cultivation. NIDA looks forward to opportunities to provide input to the DEA as it develops a new regulatory framework that ensures an adequate and diverse supply of cannabis for research.

Researchers are Unable to Access Marketed Cannabis Products
Under Federal law, researchers supported by NIDA and other federal agencies are unable to access marketed cannabis products through state marijuana dispensaries. There is a significant gap in our understanding of their impact on health. The recent outbreaks of e-cigarette or vaping product use associated lung injury (EVALI), which has been linked to informally-sourced THC-containing vape products, underscores the critical importance of facilitating researcher access to different product sources

NIDA appreciates this opportunity to discuss our work to advance research on cannabis and its constituent compounds. Rigorous research is essential for understanding how the changing cannabis landscape will affect public health, for guiding evidence-based policy and to help advance therapeutics. I look forward to answering any questions the Subcommittee may have on this important issue.

[47] https://www.dea.gov/press-releases/2019/08/26/dea-announces-steps-necessary-improve-access-marijuana-research