Written Testimony for
Cannabis Policies for the New Decade
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Thank you Chairman Pallone, Ranking Member Walden, Chairwoman Eshoo, and Ranking Member Burgess for the opportunity to submit testimony on the subject of responsibly researching medicines that may be derived from the marijuana plant. I represent Smart Approaches to Marijuana (SAM), the leading non-partisan national non-profit organization offering a science-based approach to marijuana policy. SAM was founded by former Congressman Patrick Kennedy, senior editor of *The Atlantic* David Frum, and myself, a former White House advisor to the Obama Administration as well as two other U.S. Administrations. SAM is advised by a Science Advisory Board with researchers and physicians from top university research institutions, including Harvard, Yale, and Johns Hopkins.

The Committee is considering legislation that would reduce barriers to researching marijuana (H.R 3797, H.R. 601), and several pieces of legislation that would bypass the research process entirely to legalize recreational marijuana at the federal level without any scientific studies prior to that action (the MORE Act, H.R. 3884, and the Marijuana Freedom and Opportunity Act, H.R. 2843). While the proponents of these legalization bills characterize them as "decriminalization," these bills go far beyond that to completely remove marijuana from the Controlled Substances Act, which would create a pathway for Big Tobacco to take over the marijuana industry as Former Speaker John Boehner has indicated they are poised to do.[i]

Just as there is often confusion over the terms "decriminalization" and "legalization," there is often a lot of confusion concerning the scheduling system within the Controlled Substances Act. Contrary to popular belief, the scheduling system is not a harm index in which marijuana is considered as dangerous as heroin. Rather, the scheduling system is a mechanism for controlling prescription drugs according to their potential for abuse. Because raw plant marijuana has not been proven safe and effective through clinical trials, it cannot be prescribed by doctors and remains in Schedule 1.

In sum, my beliefs after over 25 years of experience can be summed up as such:

- Legalization would usher in a new industry similar to Big Tobacco, and would be detrimental to public health and safety.
- There is a false dichotomy between legalization and criminalization. In fact, removing criminal penalties for low-level use can be done without unleashing commercial legalization.

- There has been extensive research on marijuana by the National Academy of Sciences, and other eminent scientific bodies, but the federal government should reduce barriers to research, especially given the escalating potency of marijuana.
- Current medical literature and statistical surveys are clear: marijuana is a drug of abuse, is addictive, and causes clear negative effects in both individuals and society.

It may be helpful to begin with a clarification of terms:

What is marijuana?
Marijuana is a complex plant with hundreds of components. Some of those components are called cannabinoids, and affect the brain in different ways. CBD (cannabidiol) and THC (tetrahydrocannabinol) are the two most researched cannabinoids produced by the cannabis (marijuana) plant. Unlike THC, CBD does not produce a state of intoxication and is not addictive. However, CBD has all but been bred out of modern recreational marijuana because it counteracts the intoxication from THC.

Is marijuana medicine?
Unfortunately, the issue of marijuana as medicine has become highly politicized rather than adhering to the ordinary scientific process for researching and approving medications. In the mid-1980s, THC was synthesized into a pill form – called Marinol – with a capsule containing THC in sesame oil and approved by the FDA in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy, supported primarily by the National Cancer Institute (NCI), whose research support goes back to the 1970s. In 1999, the Institute of Medicine (now called the National Academy of Medicine) undertook the most exhaustive review of marijuana's medical potential to date, concluding that smoked marijuana was unlikely the way of the future regarding medical potential, and "should generally not be recommended for long-term medical use…" but that components of marijuana indeed held promise. Since then, there has been interest in how different cannabinoids work together, not only in isolation.

In 2017, the National Academy of Medicine (as a part of the National Academies of Sciences, Engineering, and Medicine) issued an updated report[ii] on the current state of knowledge surrounding marijuana by reviewing over 10,000 peer reviewed studies in the international scientific literature that had been conducted since the 1999 report. It is interesting to note that the vast majority of studies showing benefits were conducted with isolated cannabinoids rather than whole-plant marijuana. The report also contained specific guidelines for reducing barriers to researching marijuana.[iii]

There are currently four FDA-approved medications based on marijuana (Marinol, Syndros, Cesamet, and Epidiolex). The first three are made from synthesized forms of THC, while the fourth is a purified whole-plant extract CBD. Other potential medications, based on complex plant extracts or isolated cannabinoids, are currently undergoing FDA-approved investigation.

What is the definition of a medicine?
For a drug to be legally considered a medicine, per 57 Fed. Reg. 10499, 10504-10506 (1992), it must pass five common-sense tests:

1. **The Drug's Chemistry Must Be Known and Reproducible**. Doctors must know how much and what they are giving their patients. If the researchers don't know what they are giving test subjects, they cannot record meaningful observations.
2. **There Must Be Adequate Safety Studies**. Measured doses must be tested for safety, usually in animal studies and pre-clinical human trials, to ascertain the pharmacological and toxicological effects of the drug.
3. **There Must Be Adequate and Well-Controlled Studies Proving Efficacy**. Measured doses must be tested and provide evidence of efficacy in treating the intended condition. Double-blind, placebo-controlled clinical trials are the gold standard for ascertaining medicinal safety and effectiveness.
4. **Acceptance by Qualified Experts**. The Food, Drug, and Cosmetics Act requires those with scientific training in pharmacology and toxicology to evaluate the safety and effectiveness of drugs before they can be sold to the general public.
5. **The Scientific Evidence Must Be Widely Available**. The supporting scientific evidence must be published in scientific and medical journals so that other experts may evaluate and test the assumptions made in the clinical trials.

Raw marijuana does not pass the five tests to be considered a medicine. Why not?

- **The chemistry of marijuana has not been dosed or standardized.** Approved medicines are the same wherever you buy them. The penicillin tablet bought in a Boston pharmacy is the same as one purchased in San Diego. Not so with the marijuana sold in dispensaries. The marijuana plant grown in Seattle is different from the one grown in Denver. No two are the same—and unlike a pharmacist, the "budtender" selling the product couldn't tell you all the chemicals each plant contained.
- **Raw marijuana contains hundreds of compounds in unknown quantities.** Even if some compounds, if extracted, purified, and standardized, have been proven to treat certain conditions like childhood seizures, raw marijuana contains so many unknown compounds that we do not yet understand their overall effect on humans. That's why even the most basic over-the-counter drugs have a more complex label than pot.
- **Lack of rigorous clinical trials.** As late as 2016, raw marijuana failed the FDA's scientific review to be considered a medicine. Looking at the scientific literature, it's not hard to understand why. Aside from a handful of anecdotal studies, all successful, large-scale clinical trials have been with isolated compounds from the marijuana plant, not raw marijuana itself. The science on raw marijuana just isn't there.

What about the terminally ill and those who say marijuana helps them?

No one suggests that the government should arrest or imprison the intractably or terminally ill for trying a substance they think may help them. But decriminalizing small amounts of marijuana for use by cancer patients is very different from legalizing "medical marijuana" for the treatment of everything from headaches to insomnia. These legalization efforts have led to the creation of a new industry that lobbies to expand the use of raw marijuana as a miracle drug that treats all symptoms, with the eventual goal of legalizing recreational marijuana without any restrictions on THC content or form. At that point, the ruse is dropped and many of the businesses who were selling medical marijuana convert to recreational stores.

Moreover, patients with side effects from unapproved, untested marijuana products have no recourse against the fly-by-night companies that produce them. This is the reason why we have an FDA process, and why the results can be so heartbreaking when it is circumvented. The good news is that, as noted above, a number of FDA-approved products derived from the marijuana plant already exist, and more are in the process of clinical trials.

How can we chart a path forward?
Research and compassion should guide us as we seek to help those who are suffering. Regulations on marijuana research can be streamlined and improved to speed research and development of new, FDA-approved drugs. Additionally, we should increase federal funding for legitimate research into the medicinal constituents of cannabis and fast-track those medicines so that voters will not seek to bypass the FDA.

Unfortunately, bypassing these controls opens the door to a dangerous form of unregulated "medicine" that exposes Americans to unsafe and unscrupulous practices.

How do state medical marijuana programs work?
In the absence of medication development, legalization advocates have waged political campaigns to deem marijuana as medicine in various states. Some states have small, highly regulated regimes for a limited number of very sick individuals. But the vast majority of medical marijuana users in the US are not seriously ill. Many studies have found that fewer than 5% of people with medical marijuana recommendation cards have cancer, AIDS, MS, or other serious illnesses.[iv]

Why not just reschedule marijuana or get it out of the Food, Drug, and Cosmetic Act?
Neither of those proposed solutions would solve the problem of the need for more research, and instead would likely encourage illegal operators to continue to manufacture harmful products. Rescheduling is a red herring in this discussion since many better options exist to expedite research. Rescheduling would not have any effect on specific marijuana penalties and would not permit doctors to prescribe it.[v]

In the case of marijuana, rescheduling the drug to Schedule II or lower would immediately trigger requirements that the FDA regulate the safety and efficacy of the drug. Because the marijuana industry has realized that whole plant marijuana is unlikely to ever pass through FDA trials since they have not dosed or standardized their products, they now vociferously argue against rescheduling the drug. Rescheduling would also not effectively reduce barriers to research, as researchers for Schedule II drugs face nearly all of the same requirements and restrictions as those who research Schedule I drugs.

Current science argues against removing marijuana from CSA
Current medical literature and statistical surveys are clear: marijuana is a drug of abuse, is physiologically and psychologically addictive, and causes clear negative effects in both individuals and society. Regular use of marijuana can cause permanent changes in the brain, increasing the mass of the *nucleus accumbens* (reward center),[vi] similar to the effect of other addictive drugs. Cessation of use may result in physical withdrawal symptoms, including cravings, decreased appetite, sleep difficulty, and irritability.[vii] Surveys show that regular

marijuana users report more severe consequences than alcohol in most categories, including serious problems at work or school, taking time away from work or school, causing problems with family or friends, or spending a lot of time getting/using drugs.[viii] Drugged driving fatalities have markedly increased in states which have legalized marijuana, posing a hazard to the general public.[ix] The current body of evidence strongly reinforces current classification of marijuana as a controlled substance under the Controlled Substances Act, particularly with respect to modern, high-potency marijuana and extracts.

In addition, emerging research demonstrates a link between heavy use of high potency marijuana and the development of serious mental illness. A European study from 2019 showed these factors contributing to a five times greater likelihood of having an episode of cannabis induced psychosis.[x] And a recent meta-analysis of peer-reviewed research demonstrated that over one-third of patients experiencing cannabis induced psychosis transitioned to schizophrenia, higher than any other drug.[xi]

What can be done to facilitate research on marijuana's medical potential?

RECOMMENDATION: ALLOW DEA/NIDA TO ISSUE MULTIPLE AUTHORIZATIONS FOR GROWING MARIJUANA FOR RESEARCH PURPOSES

Under international agreements, the US NIDA– the National Institute on Drug Abuse is the sole source for research marijuana, which NIDA procures by contract from the University of Mississippi. According to NIDA, demand for marijuana for research purposes is generally low at this time. Still, multiple states have set up their own marijuana grow operations because of a purported need for marijuana rich in certain components, like CBD. Though the University of Mississippi is now growing marijuana rich in CBD, it is not unreasonable for other NIDA-approved sites to be able to grow different strains of marijuana. Therefore, SAM endorses the idea of NIDA (or other NIH-entities) to be able to grant multiple contracts for research purposes under strict supervision, in coordination with DEA. This is a key part of H.R. 3797, the Medical Marijuana Research Act and H.R. 601.

RECOMMENDATION: WAIVE DEA REGISTRATION REQUIREMENTS FOR NON-INTOXICATING CANNABINOID RESEARCH

Under the CSA, the DEA has the authority to issue a regulation **waiving the registration requirement** for certain manufacturers, distributors or dispensers, if the DEA determines that it is "consistent with the public health and safety." 21 USC Sec. 822(d). In theory, DEA could waive the Schedule I research registration requirement for physician researchers working under FDA-approved INDs and using products that have met FDA quality standards. Currently, Epidiolex® (a botanically-derived CBD drug) has been approved by the FDA for treatment of children with epilepsy that is resistant to other medications. Each of the physicians with such a program had to go through a burdensome and time-consuming process to secure a Schedule I research registration. As researchers seek to research other cannabinoids to better understand their potential as new drugs or how they interact with other medications, DOJ/DEA could issue a statement that DEA would issue Schedule I research registrations to all teaching hospitals and clinics with the appropriate field of researchers, allowing them to possess and dispense cannabinoid formulations that have passed some FDA standards. Such registrations could be

time-limited, e.g., one year, with a possibility of renewal. If the FDA approves a drug made from those cannabinoids, it then has a medical use and must be moved out of Schedule I. At that point, there would no longer be a need for such special registrations for that product.

RECOMMENDATION: MAKE PERMANENT THE ELIMINATION OF THE PUBLIC HEALTH SERVICE (PHS) REVIEW FOR MARIJUANA RESEARCH APPLICATIONS

In 1999, the Department of Health and Human Services (HHS) announced that it intended to establish new procedures "to make available a sufficient amount of research-grade marijuana to support those studies that are the most likely to yield usable, essential data." Marijuana is the only drug that had this new procedure attached to it. HHS explained that "the scientific merits of each protocol will be evaluated through a Public Health Service (PHS) interdisciplinary review process [which] will take into consideration a number of factors, including the scientific quality of the proposed study, the quality of the organization's peer-review process, and the objective of the proposed research."[xii] The intention was to streamline and increase research, but the general consensus is that it has had the unintended consequence of stalling research. Since research proposals still have to go through FDA and individual Institutional Review Board (IRB) protocols, many have questioned the wisdom of the PHS process, since it seemingly adds an extra step for no reason. Given that research protocols would still need to go through the FDA and other entities, NIH administratively eliminated the PHS review process for marijuana research applications in 2015. SAM supports making this elimination permanent as Section 5 of H.R. 3797, the Medical Marijuana Research Act, proposes.

RECOMMENDATION: DOJ AND HHS SHOULD ESTABLISH SPECIAL FEDERAL RESEARCH PROGRAMS FOR SERIOUSLY ILL INDIVIDUALS THAT DO NOT RESPOND TO OTHER MEDICATIONS

The CSA authorizes the DOJ/DEA to carry out educational and research programs "directly related to enforcement of the laws...concerning drugs, which may include... (2) studies or special projects to compare the deterrent effects of various enforcement strategies on drug use and abuse; ...and (5) studies or special projects to develop more effective methods to prevent diversion of controlled substances into illegal channels....." 21 USC sec. 872 (a).
DOJ/DEA could collaborate with the National Institute for Neurological Diseases and Stroke (NINDS) on a program similar to NCI's Group C program for Marinol. In that program, **over 20,000 patients received the drug over a period of four years under a "Group C" program**. The Group C program was closed when Marinol was approved. Here's how such a program was described in the 1980s:

> *"The National Cancer Institute (NCI) is initiating a national THC distribution program by applying to the FDA for its classification as a Group C investigational agent. Since THC is also a Schedule I drug, the distribution system requires strict adherence to Drug Enforcement Agency (DEA) security and safety regulations. Contrary to the usual distribution of Group C drugs, THC will not be available directly to physicians. THC will be made available to hospital pharmacies which are: (1) an NCI recognized Cancer Center (P-30 grant supported), (2) an NCI designated New Drug Study Group, (3) a member of the Council of Teaching Hospitals. Hospital pharmacies that are located in inadequately represented geographic areas when certain criteria are met*

> *by them will also be considered. Physicians desiring to prescribe THC need not have Schedule I registration, but should (1) have experience in cancer chemotherapy, (2) have a current DEA registration number, (3) agree to abide by the Guidelines for Use of THC, and (4) be registered with a participating pharmacy. A registered physician may prescribe THC by writing a Research Order for Medication on a usual prescription blank, including, in addition to normal required information, confirmation that patient consent has been obtained and the name of the hospital at which the physician is registered to prescribe THC."*

RECOMMENDATION DOJ/DEA COULD ENTER INTO AGREEMENTS WITH INTERESTED STATE AND LOCAL AGENCIES TO ALLOW FOR RESEARCH OF CANNABINOIDS

The federal government could (**without the need for changing the CSA**) enter into a cooperative agreement with the states. The CSA, 21 USC sec. 873(a), provides:

> "*The Attorney General **shall cooperate** with local, State, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, he is **authorized** to....**notwithstanding any other provision of law,** enter into contractual agreements with State and local law enforcement agencies to provide for cooperative enforcement and regulatory activities under this chapter."*

Under this section, the Attorney General is mandated to cooperate and permitted to enter into contractual cooperation agreements "notwithstanding any other provision of law."

DOJ could in theory enter into such agreements with state and local agencies in order to expand current research protocols. The argument would be that, by making CBD or other cannabinoids of research interest (that meet FDA quality standards) more available, patients would not have to resort to federally-unlawful channels, such as dispensaries and other purveyors, where they might purchase cannabis with significant amounts of THC; such agreements would thereby "suppress the abuse of controlled substances."

RECOMMENDATION: CRACK DOWN ON ILLEGAL OPERATORS

Currently, illegal purveyors of cannabis products are making rich profits from wild health claims, which they falsely promote to patients and other consumers as "legal dietary supplements," resulting in public health hazards. DOJ and FDA should work together to take these products off the online "shelf."

While the FDA has sent warning letters to some companies manufacturing CBD products illegally, FDA has traditionally resisted taking enforcement action in the area of medical marijuana, claiming that since marijuana is a Schedule I drug, jurisdiction is left solely to DEA.

However, medical marijuana companies **routinely and blatantly violate the Food, Drug and Cosmetic Act by selling foods and/or "medicines" that are *dangerous, contain illegal components, and have not been reviewed by FDA.*** Virtually none of these purveyors is complying with FDA requirements for proper manufacturing (GMP, registration with FDA), labeling and advertising/promotion. Manufacturers and other purveyors of marijuana products

make many therapeutic claims that bring those products within the scope of the Food, Drug, and Cosmetic Act (FDCA).

Conclusions

The legalization of marijuana has far outpaced what a sober survey of the scientific literature would indicate. It is time to hit the pause button on further recreational and medical legalization initiatives until we can collect meaningful data from state experiments that are bypassing currently accepted medical practices (see Appendix A for the positions of major medical societies on marijuana legalization). It is also time for the FDA to assert its authority in regulating medications to stop the marketing of marijuana as a cure-all for any and all conditions.

Recently, the Surgeon General issued an advisory that pregnant women should refrain from marijuana use during pregnancy because of the effect of THC on the developing brain.[xiii] This was tragically necessary because 70% of marijuana stores in Denver were recommending marijuana to pregnant women for morning sickness.[xiv]

There is still much we do not understand about the hundreds of chemical compounds within the marijuana plant, some of which may hold great promise to treat medical conditions. But there is a right way and a wrong way to go about meaningful and responsible research. We do not need to legalize recreational marijuana in order to study it. We should reduce barriers and make marijuana easier to research within the scheduling system.

Thank you for your consideration.

APPENDIX A: MEDICAL ASSOCIATION POSITIONS ON MARIJUANA[xv]

American Society of Addiction Medicine: "ASAM does not support the legalization of marijuana and recommends that jurisdictions that have not acted to legalize marijuana be most cautious and not adopt a policy of legalization until more can be learned from the 'natural experiments' now underway in jurisdictions that have legalized marijuana."

American Cancer Society:
"The ACS is supportive of more research into the benefits of cannabinoids. Better and more effective treatments are needed to overcome the side effects of cancer and its treatment. The ACS does not advocate the use of inhaled marijuana or the legalization of marijuana."

American Glaucoma Society:
"Marijuana, or its components administered systemically, cannot be recommended without a long term trial which evaluates the health of the optic nerve… Although marijuana can lower IOP, its side effects and short duration of action, coupled with a lack of evidence that its use alters the course of glaucoma, preclude recommending this drug in any form for the treatment of glaucoma at the present time."

The American Academy of Pediatrics (AAP) opposes "medical marijuana" outside the regulatory process of the US Food and Drug Administration. Notwithstanding this opposition to use, the AAP recognizes that marijuana may currently be an option for cannabinoid administration for children with life-limiting or severely debilitating conditions and for whom current therapies are inadequate. The AAP strongly supports research and development of pharmaceutical cannabinoids and supports a review of policies promoting research on the medical use of these compounds.

The American Medical Association (AMA) "has urged legislatures to delay legalizing cannabis until further research is completed on the public health, medical, economic, and social consequences of its use. In states that have already legalized cannabis, the AMA has urged jurisdictions to take steps to regulate the product effectively to protect the health and safety of high risk populations and the public."

The American Psychiatric Association (APA) states:
"There is no current scientific evidence that cannabis is in any way beneficial for the treatment of any psychiatric disorder. In contrast, current evidence supports, at minimum, a strong association of cannabis use with the onset of psychiatric disorders. Adolescents are particularly vulnerable to harm, given the effects of cannabis on neurological development. Further research on the use of cannabis-derived substances as medicine should be encouraged and facilitated by the federal government."

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[ii] National Academy of Medicine. The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research. (2017)

[iii] *Ibid*. https://www.nap.edu/read/24625/chapter/18

[iv] See for example Nunberg H, et al. "An Analysis of Applicants Presenting to a Medical Marijuana Specialty Practice in California." *Journal of Drug Policy Analysis*, 4(1); (2011). http://www.bepress.com/jdpa/vol4/iss1/art1.

[v] See Sabet, K. Should Marijuana Be Rescheduled? *HuffingtonPost.* (2014). http://www.huffingtonpost.com/kevin-a-sabet-phd/should-marijuana-be- resch_b_3745354.html

[vi] Gilman, et al., Cannabis Use Is Quantitatively Associated with Nucleus Accumbens and Amygdala Abnormalities in Young Adult Recreational Users**,** *Journal of Neuroscience.* 16 April 2014, 34 (16):5529-5538.

[vii] Gorelick DA, Levin KH, Copersino ML, et al. Diagnostic Criteria for Cannabis Withdrawal Syndrome. *Drug Alcohol Depend*. 2012;123(1-3):141-147.

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[ix] AAA Foundation for Traffic Safety. Prevalence of Marijuana Involvement in Fatal Crashes: Washington, 2010-2014. May 2016. Web. 23 Oct. 2016.

[x] Di Forti, et al. The contribution of cannabis use to variation in the incidence of psychotic disorder across Europe (EU-GEI): a multicentre case-control study. *Lancet Psychiatry*. Vol. 6, Iss. 5. May 1, 2019. https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(19)30048-3/fulltext

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[xii] Health and Human Services Guidance. See: http://grants.nih.gov/grants/guide/notice- files/not99-091.html

[xiii] https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html

[xiv] Dickson, et al. Recommendations from Cannabis Dispensaries About First-Trimester Cannabis Use. *Obstetrics & Gynecology*. Vol. 131, No. 6, (2018). https://www.denverhealth.org/-/media/denver-health-marijuana--pregnancy-study.pdf?la=en&hash=7CF1182B6937B9E4267378A1E5F04D8ED221DC6C

[xv] Medical Organization Statements:

American Society of Addiction Medicine. "Public Policy Statement on Marijuana, Cannabinoids, and Legalization." https://www.asam.org/docs/default-source/public-policy-statements/marijuana-cannabinoids-and-legalization-9-21-2015.pdf?sfvrsn=38e06fc2_0#search="public%20policy%20statement%20on%20medical%20marijuana" (2015).

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