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Before the House Committee on Appropriations
Subcommittee on District of Columbia Appropriations
"Medical Marijuana" and National Drug Control

All of us in the Office of National Drug Control Policy thank the Committee for the opportunity to testify today about "medical marijuana" and national drug control policy. The Administration has actively and consistently opposed marijuana legalization initiatives in all jurisdictions throughout the nation. Our steadfast opposition is based on the fact that: such electoral procedures undermine the medical-scientific process for establishing what is a safe and effective medicine; contradict federal regulations and laws; and in the Office of National Drug Control Policy's (ONDCP) view, may be vehicles for the legalization of marijuana for recreational use.

Marijuana and Medicine

The Administration is adamantly opposed to the use of marijuana outside of authorized research.(1) However, legitimate medications containing synthetic equivalents of marijuana components have proven effective in some medical conditions. Dronabinol, a synthetic form of a psychoactive component of marijuana, tetrahydrocannabinol (THC), has been approved by the Food and Drug Administration (FDA) to control nausea in cancer patients receiving chemotherapy and stimulate appetite in AIDS patients. This pill form of THC has been approved and available for 15 years and sold under the trade name Marinol (r). Recently, dronabinol was rescheduled from Schedule II to Schedule III of the Controlled Substances Act (CSA).

In determining the relative risks and benefits of a given drug, it is important that research-based evidence be the foundation of any analysis. This is the case with all drugs under consideration for approval by the Food and Drug Administration. The purpose of this type of analysis is to protect and promote public health by ensuring that medical products are both safe and effective. Research-based standards must provide a rational basis for concluding that the benefits of a medical product outweigh its risks.

Marijuana is a botanical product. The IOM study points out that botanical products "are complex mixtures of active and inactive ingredients."(2) Concerns about product consistency, potency of active ingredients, contamination, and stability of both active and inactive ingredients would have to be overcome by sponsors to meet the requirements for an NDA, especially those related to safety, manufacturing, and control."(3) The risks of medicines that are not scientifically tested were outlined in a New England Journal of Medicine editorial last September by Editor-in-Chief Jerome P. Kassirer, M.D. and Marcia Angell, M.D.(4) The authors wrote:

"Until the 20th century, most remedies were botanical, a few of which were found through trial and error to be helpful."

"All that began to change in the 20th century as a result of rapid advances in medical

science."

"In particular, the evolution of the randomized, controlled clinical trial enabled researchers to study with precision the safety, efficacy, and dose effects of proposed treatments and the indications for them. No longer do we have to rely on trial and error and anecdotes. We have learned to ask and expect statistically reliable evidence before accepting conclusions about remedies."

The IOM study points out that today, a "handful of botanical preparations are on the market, but none received formal approval as a new drug by today's standards of safety and efficacy ..." The three marketed botanical preparations are older drugs that came to market years before safety and efficacy studies were required by legislative amendments in 1938 and 1962, respectively.(5)

The Institute of Medicine Study
Marijuana and Medicine: Assessing the Science Base

In light of this need for research-based evidence, ONDCP asked the Institute of Medicine (IOM) in January 1997, to conduct a review of the scientific evidence concerning the potential health benefits and risks of the medical use of marijuana and its constituent cannabinoids. ONDCP believed that an objective and independent evaluation of research regarding the use of marijuana for medical purposes was appropriate given the ongoing debate about cannabis and its health effects. This approach also was consistent with the principles of science-based medicine on which our national drug approval process is anchored.

The IOM began its review in November of 1997 and after eighteen months of rigorous research published the results. This IOM study is the most comprehensive summary and analysis of what is known about the medical use of marijuana. It emphasizes evidence-based medicine (derived from knowledge and experience informed by rigorous medical-scientific analysis), as opposed to belief-based medicine (derived from judgment, intuition, and beliefs untested by rigorous science). We believe that the discussion of medical efficacy and safety of cannabinoids can now take place within the context of science. The two principal researchers (Dr. John A. Benson, Jr., Dean Emeritus and Professor of Medicine at the Oregon Health Sciences University School of Medicine and President Emeritus of the American Board of Internal Medicine & Dr. Stanley J. Watson, Jr. Co-Director and Senior Research Scientist at the Mental Health Research Institute, University of Michigan, Ann Arbor) have provided us the basis for informed public discussion of the potential medical uses of marijuana's constituent cannabinoids.

1. The study concludes that there is little future in smoked marijuana as a medically approved medication

Although marijuana smoke delivers THC and other cannabinoids to the body, it also delivers harmful substances, including most of those found in tobacco smoke. The

long-term harms from smoking make it a poor drug delivery system, particularly for patients with chronic diseases and pregnant women.

In addition, cannabis plants contain a variable mixture of biologically active compounds. Even in cases where marijuana can provide relief of symptoms, the crude plant mixture does not meet the modern expectation that medicines be of known composition and quality. Nor can marijuana guarantee precise, controlled doses.

If there is any future in cannabinoid drugs, it lies with agents of more certain, not less certain composition, and controlled delivery of doses. The future of medical marijuana lies on classical pharmacological drug development that results from clinical research.

2. The study does not deny the correlation between adolescent marijuana use and subsequent use of other illegal drugs.

The study notes strikingly regular patterns in the progression of drug use from adolescence to adulthood. The study notes that because it is the most widely used illicit drug, marijuana is predictably the first illicit drug most people encounter. Not surprisingly, most users of other illicit drugs have used marijuana first. In fact, most drug users do not begin their drug use with marijuana; they begin with alcohol and nicotine -- and usually when they are too young to do so legally.

In a discussion of the progression from marijuana to other drugs, the IOM study concludes that while there is no evidence that marijuana serves as a stepping stone on the basis of its particular drug effect, there is evidence that marijuana serves as a gateway to the world of illegal drugs in which youth have greater opportunity and are under greater social pressure to try other illegal drugs. The study asserts that the factors that best predict illicit drug use other than marijuana are likely the following: age of first alcohol or nicotine use, heavy marijuana use, and psychiatric disorders.

The study concludes that "in the sense that marijuana use typically precedes rather than follows initiation into the use of other illicit drugs, it is indeed a gateway drug."(6) This correlation between initial marijuana use and subsequent use of other illicit drugs is also noted in the 1999 National Drug Control Strategy.(7)

The Federal Government supports research into cannabinoid-based drugs

We ought to go where science and medicine lead us. The IOM study suggests that cannabinoid-based drugs might be modestly effective for a variety of indications, particularly for antiemesis, appetite stimulation, and pain relief. The study recommends further research, studies, and pre-clinical and clinical trials so that safe and effective cannabinoids might be added to the pharmacopoeia of drugs that treat these symptoms. Formulations that can rapidly and directly deliver THC to the circulation include deep lung aerosols, nasal sprays, nasal gels, sublingual preparations, and suppositories. Phase I clinical studies are underway for deep lung aerosols, nasal sprays, nasal gels, and

sublingual formulations of Marinol (r).

In response to the IOM report's conclusion about the need for more research, the Department of Health and Human Services (HHS), which provides marijuana for medical research, revised its guidance on May 21, 1999 on the provision of marijuana by making research-grade marijuana more accessible to peer-reviewed research programs that are not federally funded. Through this revision, HHS intends to facilitate additional research into the question of whether marijuana and its constituent cannabinoids are useful as a medicine. ONDCP fully endorsed this decision by HHS. Such research will allow us to better understand what benefits might actually exist for the use of cannabinoid-based drugs, and what risks such use entails.

CONCLUSION

The federal government is committed to ensuring that the analysis of the medical efficacy and safety of cannabinoids takes place within the context of medicine and science. It is imperative that "medical marijuana" ballot initiatives do not remove the discussion from this context and, more importantly, circumvent the drug approval process, potentially endangering public health.

Continued strict regulation of cannabis as a Schedule I drug is essential. Until we fully understand the health ramifications of allowing cannabinoid-based medicines, such uses should only be part of clinical studies to expand the body of scientific understanding. In short, we need to be sure that as we examine cannabinoid-based drugs for possible medical benefit that we do not contribute to reckless use and increased abuse of this psychoactive substance.

Medical considerations, not drug-control concerns, should determine whether cannabinoid-based drugs should be prescribed as medicines. The federal government has already demonstrated its support for these drugs. NIH research was key to the development of the one cannabinoid -- dronabinol -- that is commercially available.(8) Cocaine and opiates can be used medically. Decisions over what constitute safe and effective medications will be made by appropriate medical authorities, not ONDCP.

Chairman Istook, Ranking Minority Member Moran, all of us at the Office of National Drug Control Policy have appreciated the committee's bipartisan support of our efforts to reduce drug abuse and its consequences in America. Thank you for the opportunity to explain the Administration's opposition to ballot initiatives that seek to legalize the use, possession, and cultivation of marijuana for certain persons.

1 As "medical use" may be defined in different ways, it is important to underscore that "medical use" is not the equivalent of "recreational use."

2 Marijuana and Medicine: Assessing the Science Base, Institute of Medicine, Janet E.

Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Editors, National Academy Press, Washington, D.C., 1998, p. 215.

3 Ibid. NOTE: The FDA encourages the submittal of NDAs for botanical products.

4 "Alternative Medicine -- The Risks of Untested and Unregulated Remedies," The New England Journal of Medicine, September 17, 1998, Vol. 339, No, 12.

5 Marijuana and Medicine: Assessing the Science Base, p. 215-216. The three botanical preparations are digitalis (it came to market before 1938 and was "grandfathered" under the law), psyllium, and senna (both were evaluated by the FDA under an over-the-counter drug review.

6 Marijuana and Medicine: Assessing the Science Base, p. 100.

7 The 1994 report Cigarettes, Alcohol, Marijuana: Gateways to Illicit Drug Use prepared by the Center on Addiction and Substance Abuse (CASA) at Columbia University found that smoking, drinking and using marijuana lead a large number of children and adults to experimentation, regular use and addiction involving substances like cocaine. Some of the key findings of the report include: Children who have used marijuana are more than 85 times likelier to use cocaine than children who have never used marijuana. The younger an individual uses any gateway drug, the more often an individual uses any gateway drug, the more gateway drugs an individual uses, the likelier that individual is to experiment with cocaine, heroin, and other illicit drugs and the likelier that individual is to become a regular adult drug user and addict. Sixty percent of children who smoke marijuana before age 15 move on to cocaine; only one-fifth of those who smoke marijuana after age 17 use cocaine.

8 Marijuana and Medicine: Assessing the Science Base, p. 207.