

March 5, 2014

Hon. Attorney General Eric H. Holder, Jr. Hon. James M. Cole Hon. Hon. Michele Leonhart (DEA) U.S. Department of Justice

Hon. R. Gil Kerlikowske Mr. Michael P. Botticelli Office of National Drug Control Policy, Executive Office of the President

Dr. Nora Volkow (NIDA) Commissioner Peggy Hamburg (FDA) Department of Health and Human Services

RE: Marijuana Policy and Rescheduling

Dear Attorney General Holder, Deputy Attorney General Cole, Administrator Leonhart, Director Kerlikowske, Deputy Director Botticelli, Director Volkow, Commissioner Hamburg:

We represent tens of thousands of people working in drug prevention, drug treatment courts, mental health, treatment, medicine, criminal justice reform, and millions of individuals in recovery from alcohol and drug dependence. We are aware of a small chorus in the United States Congress (copied on this letter) who are calling for the rescheduling of marijuana and we write to inform you that our groups agree with the most recent Health and Human Services (HHS) determination that marijuana should remain a Schedule I drug.

We also are united in our belief, consistent with the Institute of Medicine (IOM) and current Food and Drug Administration (FDA)/Drug Enforcement Administration (DEA)/National Institute on Drug Abuse (NIDA) efforts, that marijuana's components should be vigorously studied for possible (non-smoked) medication development. However, rescheduling marijuana would be a mistake for the following reasons:

Herbal marijuana could never qualify to become anything other than a Schedule I drug because the plant material cannot itself become a medication, even if components or extracts might have therapeutic value.

Even if Congress placed the marijuana plant into the Schedule II category, <u>no doctor</u> could prescribe it because prescriptions can only be written for individual products that have each been approved by the FDA. Marijuana would never be able to secure FDA



approval of a "New Drug Application" (or even FDA approval to enter large Phase 3 clinical trials) since plant material cannot be delivered in a manner that assures a reliable and reproducible dose without creating harmful byproducts. The FDA has never approved plant material for prescription by doctors.

Rescheduling marijuana also would do very little directly to change criminal laws affecting marijuana-related offenses. Marijuana already carries lighter sentences than any other illicit drug, both federally and on the state level.

Rescheduling marijuana is not necessary to facilitate research. There are ways to speed up research without rescheduling marijuana.

Rescheduling marijuana to III-V (or de-scheduling it altogether) is scientifically dubious because of marijuana's widespread abuse and addictive potential.

Rescheduling herbal marijuana would violate our international treaty obligations.

Rescheduling marijuana would mainly serve as a symbolic victory for marijuana advocates - since it would do nothing to change marijuana's non-placement in the pharmacopeia or even decrease marijuana-specific penalties for use or trafficking.

We do strongly support efforts to research the components of marijuana. We should break down the barriers of such research by making it easier for researchers to access, store, and administer such components. That can be done in the context of keeping marijuana in Schedule I. For example, DEA could relax storage requirements for components of marijuana used in the context of an FDA Investigational New Drug (IND) program. DEA could instruct all field offices to process applications for research licenses without delay once FDA has agreed to an IND. We are encouraged by, and fully support, the current INDs that are studying components of marijuana in the context of childhood epilepsy, as well as in cancer pain.

But we remain troubled with the normalization of marijuana that continues unabated. Cable service providers are openly flaunting and violating federal statutes (21 USC 843(c)) barring the advertising of Schedule I drugs. The Drug Enforcement Administration has testified that foreign criminal groups have already exposed new banking guidelines. Daily marijuana use has tripled among 12th graders over the past 20 years. Kids today are getting the idea that marijuana is safe because of mixed messages surrounding marijuana legalization, despite the fact that the American Medical Association and other scientific groups oppose such efforts and are concerned with the drug's public health impact.

Finally, we remain extremely troubled by the misstatements made by Members of Congress who are determined to legalize marijuana. These misstatements include



declarations that marijuana use doesn't "kill" (despite marijuana-related car crashes, suicide links, and other negative consequences) or that marijuana doesn't lead to emergency-room admissions (despite HHS/DAWN reports showing more than 400,000 such episodes last year).

As we begin to track the numerous DOJ violations occurring in Colorado and Washington in the context of the most recent guidance to U.S. Attorneys (website: www.legalizationviolations.org), we remain gravely worried about the societal impacts of today's sophisticated, commercialized, multi-million dollar marijuana industry.

Director, Project SAM (Smart Approaches to Marijuana)

Sam Ball, PhD

Sincerely,

President and Chief Executive Officer, CASAColumbia Professor of Psychiatry, Yale School of Medicine

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Center for education Dependency Addiction and Rehabilitation (CeDAR)

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| CC: Members, U.S. Representatives Committee on Oversight & Government Reform Rep. Steve Cohen Rep. Earl Blumenauer Jenny Durkan, United States Attorney (Western Washington) Thomas Freiden, Director, Centers for Disease Control and Prevention |
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