

## Marijuana: Another Human Clinical Trial but With No Consent Form

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The United States is on the threshold of a national experiment, a human experiment that tests the health and safety of marijuana. The first experiments with psychoactive drugs began in the late 19<sup>th</sup> century, following the extraction and proliferation of active compounds from opium and coca plants. An exponential and unacceptable rise in human *behavioral and biological* calamities followed and elicited an aggressive response from the medical, legal and legislative communities. Over-the-counter use of heroin, smoked opium, morphine and cocaine died within a few decades in the early 20<sup>th</sup> century. The “War on Opium” led to a greater than 90% reduction in opium use internationally starting in the early 20<sup>th</sup> century. Since then, the popularity of illegally obtained heroin and cocaine has risen and fallen with public perception and access, but these heroin excursions affect much smaller populations than at the turn of the 20<sup>th</sup> century. We will never have an accurate tally of the human, legal and economic anguish that arose from the legal promotion and proliferation of heroin or cocaine in the few decades that these drugs were legally and widely available. Populations currently addicted are relatively small, but the grim consequences persist and are visible.

The second experiment with another chemical class of psychoactive drugs, amphetamines, emerged in the 1930’s. This wave petered out by the late 1960’s, as data on its hazardous effects (e.g. addiction, psychosis) shifted public perception and led to legal constraints, especially with over-the-counter pills. Use of amphetamines (e.g. methamphetamine and ecstasy) rose once again in the 2000’s and then declined to current relatively low levels, partly because of supply reduction strategies (e.g. tightening of precursor availability, international cooperation) and increased perception of harm (addiction, brain toxicity). The third experimental wave, hallucinogen use (e.g. LSD) in the 60’s, waned within two decades, conceivably as a result of “bad trip” publicity, enduring psychoactive effects, and restrictive legislation. The 1960’s also witnessed a surge in marijuana use in tandem with other drugs. Its use has fluctuated since then, rising and waning as perception of harm and cultural norms change.

From my perspective, the underlying value that drives our national response is to protect human brain function, the repository of our humanity. Drugs that compromise brain function, cognition and behavior compel a unique form of vigilance. The federal government finally assembled these behavioral, psychiatric and biological outcomes of naturalistic human experiments into the Controlled Substances Act (CSA) of 1970. The CSA regulated the manufacture, importation, possession, use and

distribution of psychoactive substances and ranked them in five categories or Schedules, on the basis of their potential for abuse and medical use. Marijuana was placed in the most restrictive Schedule I category, as a substance with high abuse potential and no medical use.

Current Federal law prohibits the sale, distribution and possession of the hallucinogen-intoxicant-sedative marijuana, a decision driven by unacceptably high biological, medical and behavioral risks (e.g. intoxication, cognitive impairment, sensory, auditory and temporal distortions/hallucinations, vehicular or workplace accidents, others). The status of marijuana has now entered a new, decentralized phase in American and international culture. Billionaire-funded, disingenuous, and proliferating state ballot initiatives are swelling legal access of very high potency marijuana through the guise of medical marijuana laws, or decriminalization and outright legalization. This accelerating access by the ballot box is associated with a tandem decline in public perception of harm and a rise in marijuana use and use disorders. The financially well-endowed legalization movement has catalyzed yet another naturalistic, uncontrolled, human experiment with a drug. This experiment requires no informed consent, no signatures approving human experimentation, no oversight from a professional Institutional Review Board, no protections based on the Nuremberg Code, the Helsinki Declaration, the Belmont Report, the federal Office of Human Research Protection or the Food and Drug Administration and no recourse for adverse outcomes. No effective prevention strategy is in place for our most vulnerable population - youth. The experiment may last a few decades and the laws conceivably will be reversed, as even more data on human consequences pour in and society deems them too costly to bear. In the meanwhile, a generation of *susceptible* youth will be transformed and derailed by the drug's consequences: addiction, IQ reduction, psychosis, cognitive impairment, educational underachievement. In a valid clinical trial, the sponsors are held responsible for health and financial consequences for adverse events. No such recourse exists against the unethical perpetrators of this human marijuana experiment.

#### **About The Author:**

**Dr. Bertha K. Madras** is Professor of Psychobiology, Department of Psychiatry at Harvard Medical School (HMS), and is cross-appointed at the Massachusetts General Hospital. She served as Deputy Director for Demand Reduction (prevention, intervention, treatment) in the White House Office of National Drug Control Policy (ONDCP), a Presidential appointment confirmed unanimously by the US Senate. At Harvard, her multidisciplinary research focuses on neuropsychiatric diseases and addiction biology, documented in over 150 manuscripts and as co-editor of books “The Cell Biology of Addiction” (2006), “The Effects of Drug Abuse on the Human Nervous System” (2012), “Imaging of the Human Brain in Health and Disease” (2012). At ONDCP, she incorporated Screening, Brief Intervention, Referral to Treatment (SBIRT) into the national drug control strategy and into health care systems. In service to the public, she directed creation of a Museum exhibit, a CD (licensed by Disney Corp), “Changing Your Mind: Drugs in the Brain” with the Boston Museum of Science. She has given

hundreds of presentations worldwide, on how drugs affect the brain and consults to government, organizations and industry. She holds 19 patents, is a recipient of a number of awards, and a citation by The Better World Report, 2006, for developing a brain imaging agent as one of “25 technology transfer innovations that changed the world”. Her experiences in translational neurobiology, government and public service afford her a unique perspective on science and public policy.