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MARIJUANA AS MEDICINE?

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INTRODUCTION

The hoax of using a smoked weed as medicine is the Trojan Horse of the new millennium. The claim that marijuana can be used as medicine is proving to be one of the worst scams drug legalizers have perpetrated on the American people. In reality, smoked marijuana is far too complex, unstable, and harmful a substance to be approved as a medicine.

In every instance claimed by legalizers as a use for smoked marijuana, there exist far better, legitimate, scientifically approved medications. Any argument supporting a smoked material as a medicine is dubious -- ridiculous even! The purpose of proposals to use marijuana as medicine is simple: make marijuana and other illicit substances more available to individuals and communities in our country.

The tangle of consequences of state or local referenda to make marijuana available for personal use creates more difficult policy questions and greater public health concerns than the proposed laws would address. Before joining the Bush Administration as Deputy Director for Demand Reduction in the White House Office of National Drug Control Policy (ONDCP), I served as Medical Director of Interventions, a not-for-profit drug treatment system in Illinois. At Interventions, I ran the largest and oldest adolescent treatment system in that state. Children entering treatment routinely reported that they heard that "pot is medicine"

and, therefore, believed it to be good for them. Claims that marijuana is medicine reduce the efficacy of prevention efforts.

Fortunately, modern medical science is close to developing a safe delivery system for the constituent parts of marijuana. Marijuana legalizers will no longer be able to exploit the sick and dying as part of their attempts to subvert the medical system, undermine the legal system, make a laughingstock of policy, and expose our children to dangerous poisons.

SCIENCE SHOULD DETERMINE THE PRACTICE OF MEDICINE

"Medical marijuana" is a broadly used but ill-defined term. Federal law does not recognize marijuana as a medicine. Marijuana is listed in Schedule I of the Federal Controlled Substances Act (CSA), which reflects the fact that marijuana has "no currently accepted medical use in treatment in the United States." Schedule I is the most restrictive schedule in the CSA. Smoked marijuana delivers harmful and unspecified substances to the body, cannot be expected to provide a precisely defined drug effect, and has a high potential for abuse. In short, smoked marijuana is unsafe for use -- even under medical supervision.

Nevertheless, voters in several states have passed referenda making marijuana available for a variety of medical conditions. The resulting laws are in conflict with the CSA and with the Federal Food, Drug and Cosmetic Act.

Science, not public opinion, must drive the practice of medicine. Political measures aimed at endorsing marijuana as medicine undercut efforts to ensure that approved medications have

undergone rigorous scientific scrutiny and the Food and Drug Administration (FDA) approval process. Scientists are engaged in research to determine whether there are, indeed, potential medical uses for constituents of marijuana. The purpose of such research is not to develop marijuana as a licensed drug but to investigate rapid-onset delivery systems that do not require inhaling the acrid and potentially carcinogenic smoke of a burning weed.

WILLOW TREE BARK AND OTHER CRUDE REMEDIES

In the 19th century, marijuana was thought to be useful as an analgesic, muscle relaxant, anticonvulsant, and appetite stimulant. It was provided in the form of tinctures, extracts, and elixirs. "Snake oil salesmen" extolled the virtues of marijuana for asthma, bronchitis, migraine headaches, depression, gonorrhea, uterine hemorrhage, and dysmenorrhea. Treatment responses were unpredictable or nonexistent. These marijuana-laced products were subsequently discarded as science developed disease- and symptom-specific medications.

Every American is familiar with aspirin, and some know that it was first found in willow bark, from which the therapeutic agent acetylsalicylic acid was eventually synthesized. Surely no physician today would recommend chewing willow bark, much less smoking a piece of tree, to cure a headache. Likewise, no legitimate physician would prescribe smoked opium to relieve the pain of cancer when many semi-synthetic and synthetic opioids are currently in use for pain. Moreover, there is no clamor from legitimate medical organizations to get a smoked weed on the medications formulary.

Marijuana legalizers want to set the clock of modern medicine back to a time before the passage of the Pure Food and Drug Act in 1907, when Americans were exposed to a host of patent medicine "cure-alls" -- everything from vegetable "folk remedies" to dangerous mixtures with morphine. The major component of most "cures" was alcohol, which probably explains why people reported that they "felt better." Claimed benefits were erratic and irreproducible. The case is the same with marijuana. As Dr. Mark Krauss of the Connecticut Society of Addiction Medicine will explain, marijuana cannot be equated with credible medications. The Institute of Medicine (IOM), in its 1999 report commissioned by ONDCP, stated:

Scientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation; smoked marijuana, however, is a crude delivery system that also delivers harmful substances.¹

In the 1970s and subsequent years, anecdotal claims surfaced that marijuana relieved a number of medical conditions. These claims were investigated in a number of studies supported by the National Institutes of Health (NIH). The National Cancer Institute (NCI), in collaboration with the National Institute on Drug Abuse (NIDA), initiated clinical trials on a synthetic, orally administered form of delta-9-tetrahydrocannabinol (THC), the primary psychoactive ingredient in marijuana. In 1985, the FDA approved synthetic THC, marketed under the trade name Marinol®, for nausea associated with cancer chemotherapy.

FDA approval means that the product was subjected to rigorous clinical trials that established its medical value, profiled its side effects and contraindications, established appropriate standards for dosing, and detailed pertinent drug-drug interactions. As outlined by the Institute of Medicine,

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, the FDA approves new drugs for entry into the marketplace after their safety and efficacy are established through controlled clinical trials ... FDA approval of a drug is the culmination of a long, research-intensive process of drug development, which often takes well over a decade.²

¹ *Institute of Medicine, Marijuana and Medicine: Assessing the Science Base, Executive Summary (visited Oct. 5, 2003) <<http://books.nap.edu/html/marimed/es.html>>.*

² *Institute of Medicine, Marijuana and Medicine: Assessing the Science Base, Chapter 5 (visited Oct. 5, 2003) <<http://books.nap.edu/html/marimed/ch5.html>>.*

For each symptom or disease that marijuana legalizers suggest can be treated with smoked marijuana, there is a variety of existing, scientifically proven options available to the clinician. Among these is Marinol®. Claims that smoking marijuana is more effective than taking Marinol® remain unproven. Interestingly enough, the only property that Marinol® lacks is the capacity to create a euphoric mood or "high."

DRUG USE THRIVES ON MYTHS AND LIES

Legalizers argue that government is oppressive and unjust because elected representatives and government officials will not let a few people who are at the end of their lives smoke a plant material in lieu of expert medical care utilizing prescribed medications. This is not, in fact, the problem. The real problem exists where wealthy advocates for drug legalization mislead well-intentioned and compassionate voters into passing local referenda to allow the use of a smoked weed as medicine. These efforts subvert the integrity of the scientific process, upon which 21st century medicine is based.

Look to Maryland to see how big and how soon the problems emerge from efforts to construe marijuana as medicine. On October 1, 2003, a Maryland law took effect allowing anyone convicted of possessing marijuana to argue for a maximum penalty of a \$100 fine if the drug was used for medical purposes. The ink was barely dry on the bill before defense attorneys were preparing arguments to defend any marijuana using criminal who would claim that he or she had a legitimate, quasi-legitimate, or imagined symptom or disease.

As The Washington Post reported,

Defense lawyers would constantly test the law's reach and would be "neglecting their clients if they did not try to find out what physical, emotional, or psychological pain" causes them to use the drug. "Sometimes people are self-medicating without even realizing it."³

Self-medication hypotheses also support the normalization of non-dependent drug use.⁴

In addition to sending the wrong message about drug use, these laws will allow attorneys to argue that any use of marijuana can be construed "medical." If any use can be deemed "medical," and "medical marijuana" use carries a maximum fine of only \$100, marijuana laws are not worth enforcing at all, they say.

ENVIRONMENTAL FACTORS

As Dr. Berthas Madras of Harvard Medical School has stated, "The environment is a major influence on whether a youth will experiment with drugs or develop an aversion to them." The big threat in the environment of drug use today is the active campaign to blur the distinction between illegal and legal drugs and corrupt the judgment of the American people.

Simply stated, alcohol, tobacco, and the illegal drugs, including marijuana, are not "medicines."⁵ But by characterizing the use of illegal drugs as quasi-legal, sanctioned, medicinal use, legalizers destabilize the societal norm that drug use is dangerous and drug use is wrong. Such attempts to blur the line between the use of an addictive, illegal drug and the use of a medicine undercut the goals of stopping initiation of drug use and preventing addiction.

³ Tim Craig, "Maryland Starts To Allow Marijuana Court Plea," *The Washington Post*, October 1, 2003, at B01.

⁴ Robert M. Dupont, ***Biology and the Environment -- A Rethinking of Demand Reduction (visited October 5, 2003)*** <http://www.ourdrugfreekids.org/article_46.htm>.

⁵ *Id.*

The key to the environment of addiction is a strong focus on the individual who makes the decision to use or not to use drugs. Risk factors, as described by Dr. Madras, can reduce an individual's capacity to make reasonable, responsible decisions. However, they do not mitigate personal responsibility for such decisions.

Individuals are more likely to avoid drug use if they see clear warnings and know they are responsible for their behaviors. The distinction between illegal and legal drugs is important. It warns would-be users of illegal drugs that the use of particular drugs is so dangerous that it is prohibited by criminal law.

To the extent that the environment is tolerant, or even encouraging, of the use of addicting drugs, the rates of use rise. Rates of the problems resulting from that use also rise. To the extent that the environment rejects, in meaningful ways, the use of addicting substances, the

levels of drug use and resultant problems decline.⁶

NEUROBIOLOGICAL REWARD PATHWAYS

Dr. Madras has shown that over the past decade, science has made remarkable progress in clarifying the biological changes elicited by drugs. The study of brain biology is important because it shows that the human brain is permanently vulnerable to the siren call of addicting substances. Vulnerability to drugs is hardwired into the brain and is deepened by repeated use of addicting drugs.

The best hope for reducing drug use is in the software, the brain's operating instructions for deciding to use or not to use addicting drugs.⁷ Thirty years of prevention research have shown that prevention works best in an environment where the rules are clear, the rules are known, and the rules are enforced.

⁶ *Id.*

⁷ *Id.*

As Dr. Billy Martin of Virginia Commonwealth University will tell you, science is moving at a rapid pace. There have been major breakthroughs over the last 15 years in understanding the cannabinoid receptor system. Scientists agree that the best scientific course for developing new medications to address a range of diseases and symptoms lies in our ability to alter this biological system. Regardless of what individuals think marijuana does for them medically, "medical marijuana" will become obsolete very quickly based upon the advances brought about by a process of scientific research. The advances on cannabinoids administered by inhalers, for example, are encouraging.

WE ARE NOT AFRAID OF ANY COMPOUND

As an American physician with more than 20 years of experience, I have practiced medicine in the most advanced medical system in the world. Americans today receive care in the world's safest, most effective system of medical practice, built on a process of scientific research, testing and oversight that is unequalled.

Proponents of using a smoked plant as a medicine would have you believe that modern medicine is afraid of marijuana and we are motivated by this fear in our response of outrage and incredulosity at attempts to turn fantasy into reality. Medical science does not fear any compound, even those with a potential for abuse. If a substance has a proven capacity to serve a medical purpose, then it will be accepted. Only if compounds from marijuana pass the same tests of research and scrutiny that any other medication must undergo will they become part of the modern medical arsenal. These tests are described as:

- Phase I studies, which test the product for its adverse effects on a small number of healthy volunteers;*
- Phase II studies, which probe the drug's effectiveness in patients who have the disease or condition the product is intended to treat; and,*
- Phase III studies, which seek to determine the drug's safety, effectiveness and dosage. In these trials, hundreds or thousands of patients are randomly assigned treatment either with the tested drug or a control substance, most frequently a placebo.*

The results of Phase III trials are submitted to the FDA for review by a team of chemists, physicians, epidemiologists and other specialists. This group's crucial task, which is frequently shared with an advisory panel of outside experts, is to judge whether the trials have demonstrated that the product's health benefits outweigh its risks. Only products that pass this test may be approved for marketing.⁸

These are the tests marijuana has yet to pass! Medical science is at risk if we do not defend the proven process by which medicines are brought to the market.

GRAVE DANGER POSED BY FRAUDS IN WHITE COATS DISTORTING THE TRUTH

Pockets of well-funded individuals and organizations pursuing a political agenda are behind the efforts to legalize drugs and are using the pain and suffering of patients to gain the attention of people in many communities across the country. Many of the organizations supporting this effort have, in fact, been trying to legalize marijuana and other drugs for over 20 years.

It is a well-known and established fact that the same people who want to legalize marijuana and other drugs outright are behind the "medical marijuana" movement. ⁹ This is their wedge issue. These wealthy businessmen and aging hippies who are caught up in halcyon memories of smoking weed in dorm rooms during the '60s and '70s are pursuing the same goal decades later.

⁸ *FDA and the Drug Development Process: How the Agency Ensures that Drugs are Safe and Effective (visited Oct. 5, 2003)*

<<http://www.fda.gov/opacom/factsheets/justthefacts/17drgdev.html>>.

⁹ *See, e.g., Jim McDonough, "They Just Said No," The Washington Times, Nov. 26, 2002, reprinted at*

<<http://www.myflorida.com/myflorida/government/governorinitiatives/drugcontrol/editorials/washington.html>>.

Dr. Kraus will discuss the medical issues, complications, and contraindications surrounding so-called "medical" use of this plant. In every instance claimed by legalizers as a use for the smoked weed, far better, legitimate, and safe alternatives are available. Marijuana advocates also claim that the smoked weed is superior to the constituent part that has been shown to be responsible for the effects on the brain.

Marijuana is composed of over 480 different chemicals. Our medical system relies on proven scientific research -- science that is extremely difficult to deliver with a smoked plant containing

a variable mixture of biologically active compounds. Dr. Martin will tell you the problems associated with the study of a plant material in which no agreement exists on the standardized material.

Dr. Martin will also explain that those who are inclined to support proposals to use marijuana as medicine do so without considering the scientific and medical evidence. This evidence is necessary before any credible scientist or physician can recommend the use of marijuana as a medicine because a strong justification is needed when one wants to deliver a medication as a plant. Dr. Martin will also provide us with the data that shows that while some who inhale the smoke of marijuana do feel better, none get better.

The rhetorical arguments for marijuana as a medicine are not enough to legitimize it. Similarly, a few wealthy individuals putting on white coats and declaring that marijuana is medicine cannot substitute for the FDA process of approving drugs. Marijuana must be subjected to the same efficacy and safety standards. It is the opinion of the world's finest scientists and physicians, however, that because marijuana cannot withstand the rigors of science, it will never be added to medical treatment formularies. Cannabinoid derivatives, on the other hand, offer tremendous promise for more specific cannabinoid medications.

Many legalizers and well-meaning individuals who support the use of this weed for medicine call for its availability on the basis of compassion. Dr. Kraus is a compassionate physician. But Dr. Kraus will not allow his patients to be persuaded that smoking a plant is a reasonable alternative to conventional medicines that have been deemed to be safe and effective.

Medicine is at its most compassionate when the patient knows that she is getting the best that modern science can provide to ease suffering and cure the cause of that suffering. In cases where a cure cannot be offered, management of disease to prevent progression and preserve function is a highly desired outcome. Marijuana has none of these attributes of medicine and offers none of these benefits. Marijuana is not medicine.