

“MEDICAL” MARIJUANA BACKGROUNDER

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Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Committee on Government Reform
U.S. House of Representatives
202-225-2577

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HOW DRUG DEALERS ARE ABUSING STATE LAWS ON “MEDICAL” MARIJUANA

- Just last month, the California Highway Patrol busted the largest marijuana growing operation ever found in Oakland – almost 2,000 plants worth millions of dollars, hidden in a warehouse owned by a man with an arrest record for narcotics trafficking. The men found at the site ran from the police and the owner denied knowledge of the operation. It would be hard to find a more textbook case of illegal drug trafficking. Almost immediately, however, so-called “medical” marijuana advocates went to the media and claimed that this clandestine drug operation was a legitimate “medical” enterprise. (“Big Dispute in City Pot Bust,” *Alameda Times Star*, July 1, 2004.)
- If “medical” marijuana advocates claim this is legal under California law, then the Hinchey Amendment will simply end all federal marijuana enforcement in that state. The promoters of marijuana have pushed the definition of “medical” so far that it now covers virtually all use of the drug (indeed, the original drafter of California’s medical marijuana law once claimed that 90 percent of marijuana use was medicinal).

HUMAN TRAGEDY

IRMA PEREZ:

- Marijuana doesn't promote health and it is not medicine – it is harmful. In fact, the rhetoric is itself harmful to the health of American youth who may be led to believe that marijuana is not dangerous. There is no more tragic example than the death of Irma Perez, a 14-year-old California girl who died of an Ecstasy overdose. Instead of seeking immediate medical attention for her, her companions tried to give her marijuana because they believed “that drug is sometimes used to treat cancer patients.” The medical examiner said she likely would have lived if she had received early medical attention.

HOW DOCTORS ARE ABUSING THE STATE LAWS ON “MEDICAL” MARIJUANA:

- Proponents of “medical” marijuana often urge us to “leave decisions about treatment to doctors and patients.” We certainly want to give doctors considerable freedom to decide what treatments are best for their patients. However, we cannot simply trust that every doctor will always do what is best – otherwise we'd have no regulation at all. There has to be some oversight to ensure that doctors aren't abusing the process, and aren't giving unsafe, untested drugs to patients for the wrong conditions.
- Sadly, many doctors are abusing the process. Some are more interested in legalizing pot by any means necessary, and write prescriptions for marijuana without doing anything like a proper medical examination. In Oregon, for example, Dr. Phillip E. Leveque, a pro-marijuana activist and physician, has personally written recommendations for over 4,000 people to use marijuana over the last several years. In March his license to practice medicine was finally suspended by the Oregon Board of Medical Examiners for his failure to provide proper examinations or oversight of this “treatment.”
- Some doctors are even taking advantage of state laws to prescribe marijuana to children. In April 2004, the Subcommittee on Criminal Justice, Drug Policy, and Human Resources received testimony from Dr. Claudia Jensen, a California physician who has recommended marijuana to teenagers who suffer from attention deficit disorder and hyperactivity, despite the fact that there is no serious scientific basis for using marijuana to treat those conditions.
- One California doctor, Dr. Frank H. Lucido, has written marijuana prescriptions for 348 patients, for a wide variety of conditions, including anxiety, depression, insomnia, post-traumatic stress disorder, asthma, bipolar disorder, attention deficit disorder, obsessive compulsive disorder, and “restless leg syndrome.” (“Implementation of the Compassionate Use Act in a Family Medical Practice: Seven Years' Clinical Experience,” *O'Shaughnessy's Journal*, Spring 2004.)

- It's pretty clear that this doctor (and others like him) has no qualms about prescribing pot for any condition whatsoever. If we permit this kind of medical quackery to trump federal regulation of pharmaceuticals, we may as well not have an FDA.
- [NOTE: Some proponents of medical marijuana claim that doctors aren't really "prescribing" marijuana – and in fact, the state laws only require that a doctors make a written "recommendation" of medical marijuana use. This is just a legal fiction, however, designed to allow doctors to escape DEA regulation of prescription licensing. If you have to get a written "recommendation" from a licensed physician to use a medicine, that's the same as a prescription – no one can seriously argue there's a substantive difference.]

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

THE NEED FOR FDA REGULATION:

- Ensuring that any drug – whether derived from marijuana or not – is safe and effective is the responsibility of the U.S. Food and Drug Administration (FDA), not individual physicians. The FDA must review, test and approve each medicine, determine what conditions or diseases each drug may be used to treat, and at what level.
- All drugs bought, sold and prescribed in the U.S. must first undergo rigorous clinical trials and be proven to be safe and effective by the FDA before they can be made legally available to patients. This process ensures patient safety, protects the public health and, in cases of injury, ensures accountability and liability.
- Individual physicians don't have the ability to run their own clinical trials and tests to determine if something is safe – all they have is personal and anecdotal evidence to rely on. That kind of “evidence” is often faulty, and is never a substitute for thorough research and testing by the FDA. For the protection of patients, who need safe and effective medications, the FDA approval process must not be undermined.
- Making any drug available without FDA review or proof of safety and effectiveness sets a dangerous precedent that threatens patient safety.
- Smoked marijuana has never been approved for medical use by the FDA. For several years, in fact, FDA allowed a limited number of seriously ill patients to use smoked marijuana. The program was terminated in 1992 when the Public Health Service (PHS) stated there was no scientific evidence that the drug was assisting patients, and issued a warning that using smoked marijuana as a form of medical therapy may actually be harmful to some patients.
- Like marijuana, other drugs in their raw form, such as tobacco and cocaine, contain beneficial ingredients. Many proponents of allowing marijuana to be available for patient use without FDA review and approval have advocated FDA regulation of tobacco. This contradiction is inconsistent and undermines the credibility and validity of both arguments. And few would foolishly suggest that “medical” cocaine be made available to the public in the same manner that some states have permitted “medical” marijuana.
- Proponents of marijuana legalization-- for medical or other purposes—have bypassed the standard legal and scientific procedures required to determine a drug's safety and effectiveness. The public's health would be best served if science continued to be used to judge a drug's safety and effectiveness.

QUOTES FROM FDA ON “MEDICAL” MARIJUANA:

[from responses to follow-up questions for the record for the 4/1/04 Subcommittee on Criminal Justice, Drug Policy, and Human Resources hearing]

- "In 2001, HHS completed an extensive analysis in response to a request to reschedule marijuana to a less restrictive schedule. After looking at all the relevant data on marijuana, HHS concluded that the weight of the scientific evidence supported the findings that marijuana should continue to be scheduled as Schedule I because it has a high potential for abuse, no currently accepted medical use in the United States, and a lack of accepted evidence about the safety of using marijuana under medical supervision."
- "Approval of marijuana as a drug for specific medical indications still remains within the purview of FDA. Several states have passed referenda making marijuana available for a variety of medical conditions, but these laws are in conflict with the CSA and often with the FD&C Act. Our position continues to be that these ballot measures send the wrong message to the public- too many of whom do not recognize the dangers of marijuana - and that these measures are inconsistent with our efforts to ensure that approved medications have undergone rigorous scientific scrutiny and FDA's approval process. FDA will continue to state, as it did in its Congressional testimony, that marijuana is not an approved drug and that only the disciplined, systematic, scientific conduct of clinical trials can establish whether there is any medicinal value to marijuana, smoked or otherwise."
- "1) FDA has not approved marijuana for any indication,
2) DHHS' current evaluation indicates that sound scientific studies sufficient to support claims of marijuana's usefulness as a medication are lacking, despite anecdotal claims to the contrary, and
3) there is a lack of accepted safety for use of smoked marijuana, the known risks of which are not outweighed by any potential benefits."
- "FDA has also made a number of public statements, including through congressional testimony, that marijuana has not been approved by the Agency as safe and effective for any medical use and that its use may be harmful to health."

SMOKED MARIJUANA IS NOT “MEDICAL” MARIJUANA

- Marijuana itself remains a Schedule I controlled substance, meaning that it has no commonly accepted medical use.
- In considering potential medical uses of marijuana, it is important to distinguish between whole marijuana and pure tetrahydrocannabinol (THC) or other specific chemicals derived from cannabis.
- Whole marijuana contains hundreds of chemicals, some of which are clearly harmful to health.
- Despite anecdotal claims, smoked marijuana has not been found to be safe and effective for treating any medical condition, primarily because its alleged therapeutic utility has yet to be sufficiently demonstrated in well-controlled clinical trials.
- For several years, the Food and Drug Administration (FDA) allowed a limited number of seriously ill patients to use smoked marijuana. The program was terminated in 1992 when the Public Health Service (PHS) stated there was no scientific evidence that the drug was assisting patients, and issued a warning that using smoked marijuana as a form of medical therapy may actually be harmful to some patients.
- In 1997, the National Institutes for Health (NIH) convened an Ad Hoc Group of Experts, which concluded that scientific evidence was insufficient to definitively assess marijuana’s therapeutic potential and advised that the traditional scientific process should be followed to evaluate the drug’s use for certain disorders. In its 1999 report *Marijuana and Medicine: Assessing the Science Base*, the Institute of Medicine (IOM) concluded that the therapeutic effects of smoking marijuana were modest. IOM recommended marijuana’s active components should be tested rigorously in controlled clinical trials.

SMOKING MARIJUANA IS HARMFUL, NOT HELPFUL, TO PATIENTS' HEALTH

- While all of the long-term effects of marijuana use are not yet known, there are studies showing serious health concerns. The volume of literature detailing the harmful effects of whole, smoked marijuana, in fact, continues to grow. Marijuana can be harmful in a number of ways, through both immediate effects and damage to health over time.
- Marijuana hinders the user's short-term memory, and may cause trouble for a user in handling complex tasks. With the use of more potent varieties of marijuana, even simple tasks can be difficult. Because of the drug's effects on perceptions and reaction time, users could be involved in auto crashes.
- Under the influence of marijuana, students may find it hard to study and learn. A new study presented at a conference on global health economics in San Francisco earlier this year found that high school students who smoke marijuana are likely to see lower math scores, and ultimately, lower wages, than peers.
- The immune system protects the body from many agents that cause disease. Both animal and human studies have shown that marijuana impairs the ability of T-cells in the lungs' immune defense system to fight off some infections.
- Scientists have found that marijuana smokers studied have more sick days and more doctor visits for respiratory problems and other types of illness than did a similar group who did not smoke.
- Findings show that the regular use of marijuana or THC may play a role in cancer and problems in the respiratory, and immune systems.
- Marijuana smoke contains some of the same cancer-causing compounds as tobacco, sometimes in higher concentrations. Studies show that someone who smokes five joints per day may be taking in as many cancer-causing chemicals as someone who smokes a full pack of cigarettes every day. Tobacco smoke and marijuana smoke may work together to change the tissues lining the respiratory tract. Marijuana smoking could contribute to early development of head and neck cancer in some people.
- People who smoke marijuana regularly may develop many of the same breathing problems that tobacco smokers have, such as daily cough and phlegm production, more frequent chest colds, a heightened risk of lung infections, and a greater tendency toward obstructed airways. Cancer of the respiratory tract and lungs may also be promoted by marijuana smoke, since it contains irritants and carcinogens. Marijuana smokers usually inhale more deeply and hold their breath longer, which increases the lungs' exposure to carcinogenic smoke. Thus, puff for puff, smoking marijuana may increase the risk of cancer more than smoking tobacco does.

- Marijuana abuse is also linked to social problems. “Recent research has indicated that for some people there is a correlation between frequent marijuana use and aggressive or violent behavior,” according to the National Crime Prevention Council.
- Drug users also may become involved in risky sexual behavior. There is a strong link between drug abuse and the spread of HIV.
- According to the National Institute on Drug Abuse (NIDA), “High doses of marijuana can induce psychosis (disturbed perceptions and thoughts), and marijuana use can worsen psychotic symptoms in people who have schizophrenia. There is also evidence of increased rates of depression, anxiety, and suicidal thinking in chronic marijuana users.”
- “Marijuana use may trigger panic attacks, paranoia, even psychoses, especially if you suffering from anxiety, depression or having thinking problems,” according to the American Psychiatric Association. A majority of patients who smoke marijuana do so for mental health reasons according to a recent study. Patients suffering from mental health problems that have turned to marijuana as a form of medicine are, however, worsening both their mental and physical health while forgoing real treatment that could improve their lives.

ACCEPTED MEDICAL ALTERNATIVES EXIST TO ADDRESS HEALTH PROBLEMS MARIJUANA IS BEING PROMOTED TO TREAT

- Proponents of marijuana claim patients suffering from weight loss or AIDS wasting can benefit from smoking marijuana. This claim has never been substantiated by the FDA and smoking marijuana has never been deemed safe or effective for these or other medical conditions. Legal alternatives that have been evaluated and approved as safe and effective to treat these conditions do, however, exist.
- Serono Inc. received FDA approval for Serostim, which treats wasting in AIDS patients. The drug has been on the market since 1996 under the FDA's orphan drug program. Serono said it got final approval after confirmatory multi-center, placebo-controlled study substantiated previous findings of increased lean body mass and improvement in physical endurance in AIDS patients. Megestrol acetate (Megace) is also approved by the FDA for the management of anorexia, cachexia and unexplained weight loss in patients with AIDS. In clinical trials, Megestrol led to increased appetite and weight gain. AIDS patients also reported improvement in their sense of well being.
- HIV-associated wasting is a chronically debilitating and potentially life-threatening condition. It is a metabolic disorder that causes the body to use vital muscle and organ tissue, which is critical for survival, for energy instead of primarily using the body's stored fat. Loss of lean body mass, which consists of muscle tissue, important body organ tissue and blood cells, can lead to increased risk of opportunistic infections, illness, and extreme fatigue and can profoundly diminish a person's quality of life.
- Dronabinol, a synthetic version of THC, may reduce agitation and lead to weight gain in patients with Alzheimer disease, according to data presented at the annual meeting of the International Psychogeriatric Association.

"Our research suggests dronabinol may reduce agitation and improve appetite in patients with Alzheimer's disease, when traditional therapies are not successful," said Joshua Shua-Haim, MD, lead investigator in the study and medical director of the Meridian Institute for Aging, a continuum of senior health programs and services in Central New Jersey affiliated with Meridian Health System. "In the study, dronabinol appeared to be safe and effective for these patients."

- Other drugs approved by the FDA used alone or in combination to prevent nausea and vomiting after cancer chemotherapy include: Ondansetron, metoclopramide (reglan, and others), cortico-steroids, prochlorperazine (Compazine, and others), lorazepam (Ativan), granisetron and aprepitant (Emend).

“MEDICAL” MARIJUANA IS BEING LARGELY USED FOR “RECREATIONAL” OR EMOTIONAL REASONS RATHER THAN FOR MEDICAL PURPOSES

- Data from a survey of patients at California’s San Mateo Medical Center presented this year at the American Psychiatric Association conference revealed that one-third of HIV patients who smoked “medical” marijuana do so for “recreational” reasons.
- “We expected to see people smoking marijuana to alleviate nausea, pain and to increase their appetite-- all the reasons that are commonly cited,” said Diane Prentiss, a research epidemiologist with the Medical Center. “We were surprised that 57 percent say they smoked to relieve anxiety or depression.”
- Ironically and tragically, patients suffering from mental health problems that have turned to marijuana believing it to be a legitimate form of medicine are actually worsening both their mental and physical health while forgoing real treatment that could improve their lives. The National Institute on Drug Abuse (NIDA) has found that “High doses of marijuana can induce psychosis (disturbed perceptions and thoughts), and marijuana use can worsen psychotic symptoms in people who have schizophrenia. There is also evidence of increased rates of depression, anxiety, and suicidal thinking in chronic marijuana users.” “Marijuana use may trigger panic attacks, paranoia, even psychoses, especially if you suffering from anxiety, depression or having thinking problems,” according to the American Psychiatric Association.

OTHER HARMFUL SUBSTANCES HAVE BENEFICIAL COMPONENTS BUT ARE NOT ADVOCATED FOR MEDICAL USE IN THEIR RAW FORM

- Like marijuana, there are other drugs and substances that are harmful but have properties that can if extracted can have beneficial effects depending upon the circumstances under which they are taken. Examples include nicotine, cocaine, amphetamine, opiates, benzodiazepines, barbiturates, and many others.
- First, it is important to note that at this time, there is insufficient scientific data to conclude that smoked marijuana has therapeutic benefits, or that any benefits it may have will outweigh the risks of harm due to the inhalation of the marijuana smoke.
- NIH conducted a workshop in 1997 and the Institute of Medicine (IOM) did an exhaustive 18-month study that was released in 1999 (commissioned by the Office of National Drug Control Policy) of the extant research on the medical uses of marijuana and its active constituents, primarily tetrahydrocannabinol (THC). Both reports found that there was insufficient data to determine marijuana's therapeutic utility, but that more research is needed to determine the benefits of marijuana or related compounds for certain conditions or diseases including pain, neurological and movement disorders, nausea in patients who are undergoing chemotherapy for cancer, and loss of appetite and weight (cachexia) related to AIDS. Dronabinol, an oral form of THC, currently has FDA approval for use in the latter two conditions.
 - Prescription medicines that are clearly beneficial can nevertheless be harmful if abused. When used for legitimate medical purposes and managed by properly trained clinicians, medications such as ritalin, methadone, oxycontin, morphine, and countless others, improve the quality of life for millions of Americans with debilitating diseases and conditions. All medications can cause side effects and when intentionally or carelessly misused they can pose significant risks.
 - Nicotine, the main addictive component of tobacco, also has beneficial properties when used in replacement products, such as the therapeutic patch, gum, spray and inhalers, to assist with smoking cessation.
 - Cocaine has legitimate medical use in eye and nasal surgeries.
 - Amphetamines and other stimulant drugs can be useful in the treatment of ADD (attention deficit disorder) or ADHD (attention deficit hyperactivity disorder) and narcolepsy.
 - Some cancers Chemotherapeutic drugs have been isolated from dangerous sources. Paclitaxel (taxol) was initially isolated from a poisonous plant pacific yew (*Taxus brevifolia* Nutt.) and was later find in other *Taxus* plants. Vinblastine, Vincristine and other vinca alkaloids have been extracted from *Vinca rosea* L.

- o Opioids Analgesics such as Morphine (and analogs) from *Papaver somniferum* L.
- o The antimalarial agent artemisinin (Qing-hao-su) from *Artemisia annua* L.

ERRONEOUSLY PROMOTING MARIJUANA AS MEDICINE MAY ENCOURAGE DRUG ABUSE

- As of 2002, around 21 percent of teens and 54 percent of young people aged 18 to 25 said they had used marijuana at least once. Marijuana remains the most commonly used illegal drug, with 14.6 million users, according to new data from the National Survey on Drug Use and Health prepared by the Substance Abuse and Mental Health Services Administration (SAMHSA).
- Giving the false impression that smoking marijuana has been approved as being safe and effective may be contributing to its abuse, especially among young people. More young people are now in treatment for marijuana dependency than for alcohol or for all other illegal drugs combined. Of all teenagers in drug treatment, about 60 percent have a primary marijuana diagnosis. The average age of initiation for marijuana use generally has been getting younger. In 2001, 84 percent reported first using marijuana between the ages of 12 and 17. A 1999 survey found that 57 percent of kids age 12-17 agreed that marijuana would be “fairly easy” or “very easy” to obtain and was available from a wide variety of sources.

IS THERE “MEDICAL” MARIJUANA?

- The Food and Drug Administration has approved THC, manufactured into a pill (marinol) that is taken by mouth-- not smoked-- to treat the nausea and vomiting that go along with certain cancer treatments and is available by prescription. Another chemical related to THC (nabilone) has also been approved for treating cancer patients who suffer nausea. The oral THC is also used to help AIDS patients eat more to keep up their weight.
- There are other pharmaceutical products, such as Sativex, that utilize components of marijuana that are being studied and reviewed for potential medical uses.