

Amendment 1225: Requires the Food and Drug Administration to regulate state-legalized marijuana in the same manner as other drugs marketed for medical purposes, as well as marijuana products intended to be consumed as a cigarette in the same way the underlying bill regulates tobacco. Also applies the “Synar Amendment” to marijuana—current law which requires States to take action against retailers that sell tobacco to minors.

Purpose: Requires ‘medical’ marijuana products to be regulated in the same manner as other drugs marketed for medical purposes, and marijuana products intended to be consumed as a cigarette in the same manner as tobacco products.

S. 982 requires the FDA to regulate harmful tobacco products—cigarettes and smokeless tobacco. This amendment would ensure that State-permitted “medical” marijuana would also be subject to the appropriate FDA regulations and that current efforts to reduce and eliminate youth smoking would also apply to youth marijuana smoking.

Marijuana is a Schedule I Controlled Substance, which means it is classified as “having a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use of the drug or other substance under medical supervision.”

The similarities between the health risks of smoked marijuana and cigarettes are obvious and striking. Marijuana smoke is actually more toxic than cigarettes--smoking one cannabis joint is as harmful to a person's lungs as having up to five cigarettes.

The FDA has officially stated that, “Efforts that seek to bypass the FDA drug approval process would not serve the interests of public health.... FDA has not approved smoked marijuana for any condition or disease indication.” Advocates for decriminalizing smoked marijuana conveniently omit the fact that FDA has approved a pharmaceutical product—Marinol—that is widely available through prescription and has the same active ingredient (THC) as smoked marijuana.

Regardless, thirteen states^[1] have passed laws allowing smoked cannabis to be sold as medication despite the fact that the drug has not been approved by FDA. As a result, manufacturers are exempt from the patient safety precautions that apply to all other drugs that are marketed for medical uses.

This amendment would require those who produce, market or sell marijuana for so-called medical uses comply with the same rules that pharmaceutical manufacturers are legally bound to follow.

This amendment would also require smoked marijuana to be subject to the same safety regulations and requirements as tobacco products under this act. Given the similarities between smoking cigarettes and marijuana, there is little reason to exclude marijuana sellers from the regulations and user fees as tobacco companies.

Finally, this amendment would apply the “Synar Amendment” which requires states to enforce laws to prohibit the sale of tobacco products to minors and conduct “sting” operations to determine the percentage of retailers breaking the law. Recent surveys show the initiation rates of youth tobacco and

^[1] Alaska, California, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Mexico, Oregon, Rhode Island, Vermont and Washington

youth marijuana smoking are virtually identical. If the real purpose of this bill is to reduce and eliminate youth smoking, we should not ignore the problem of youth marijuana use.

MARIJUANA AND TOBACCO POSE COMPARABLE HEALTH RISKS

There are striking similarities between the health risks of smoked marijuana and cigarettes, though smoking cannabis is a greater threat to an individual's health.

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.

According to a recent report, Marijuana smoke is actually more toxic than cigarettes. Researchers who compared marijuana smoke to tobacco smoke found that ammonia levels were 20 times higher in the marijuana smoke, and that hydrogen cyanide and nitrogen-related chemicals also were more prevalent in the marijuana smoke.

A 2007 study done by British researchers found that Smoking one cannabis joint is as harmful to a person's lungs as having up to five cigarettes. Those who smoked cannabis damaged both the lungs' small fine airways, used for transporting oxygen, and the large airways, which blocked air flow, the researchers said. It meant cannabis smokers complained of wheezing, coughing, and chest tightness, the study by experts at the Medical Research Institute of New Zealand found.

Other studies have found that long-term marijuana smokers are prone to develop bullous lung disease at a much younger age than cigarette smokers, because they tend to inhale more deeply and hold hot smoke in their lungs up to four times longer. A January 2008 study found that Marijuana smokers get bullous lung disease 20 years before tobacco smokers. Bullous lung disease is a condition where air trapped in the lungs causes obstruction to breathing and eventual destruction of the lungs.

A 2008 Johns Hopkins study found that withdrawal from heavy marijuana use is about as harsh for users as withdrawal from nicotine addiction is for tobacco users.

MARIJUANA HAS ADDITIONAL HARMFUL EFFECTS COMPARED TO TOBACCO

While all of the long-term effects of marijuana use are not yet known, there are studies showing serious health concerns, beyond those that are analogous to smoked tobacco. 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.

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 abuse is also linked to social problems. According to the National Crime Prevention Council, "Recent research has indicated that for some people there is a correlation between frequent marijuana use and aggressive or violent behavior."

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."

According to the American Psychiatric Association "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.

YOUTH MARIJUANA SMOKING IS AS MUCH OF A PROBLEM AS YOUTH TOBACCO SMOKING

According to the Youth Risk Behavior Survey conducted by the CDC—the number of high school students smoking marijuana and tobacco was virtually identical in 2007—20 percent.

With this particular legislation, we are trying to prevent the initiation of youth tobacco use. In 2007, there were 1.197 million adolescents that started smoking tobacco, compared to an almost identical 1.167 that started smoking marijuana.

'MEDICAL' MARIJUANA IS VIRTUALLY UNREGULATED

Unlike nearly every other product sold in the U.S. for human, or even animal, consumption, so-called 'medical' marijuana is virtually unregulated.

In recent years, the FDA has reviewed and approved drugs to treat dogs for obesity and car sickness. The agency is examining whether or not the butter flavoring of microwave popcorn poses any dangers and mulling which types of seafood can be labeled as "lobsters," according to news reports.

The Associated Press reported in May 2007 that a Las Vegas company selling an energy drink using the name "Cocaine," was sent a warning letter by the FDA and given 15 days to notify the agency of its plans to correct the violations of federal law. While the "Cocaine" energy drink contained no actual cocaine, it was being marketed as "The Legal Alternative" to the illegal drug, according to its Web site. Its logo spelled out cocaine in a white powder that resembles the drug.

FDA said Redux Beverages LLC was illegally marketing the drink as both a street drug alternative and a dietary supplement, according to a warning letter dated April 4, 2007. The FDA cites as evidence the drink's own labeling and Web site, which include the statements "Speed in a Can," "Liquid Cocaine" and "Cocaine — Instant Rush," according to the letter.

Yet FDA has made no similar threats to the countless growers and sellers of 'medical' marijuana.

In June 2005, the *New York Times* published an expose on 'medical' marijuana in San Francisco:

"The best sellers at the Green Cross medical marijuana dispensary here are whipped up in the kitchen of Kevin Reed, the founder and president. Fresh-baked marijuana cakes. Marijuana cookies with Ghirardelli chocolate chips. Marijuana peanut butter, lollipops, peanut brittle and espresso truffles. Each comes packaged with a warning: 'Please keep out of the reach of children and pets.'

"Mr. Reed, 31, a former mobile home salesman from Alabama who moved here after being arrested twice for marijuana possession, said the warning was added to the sweets when a customer reported that 'their grandma ate one of them.'

"The Incredible Edibles, as the confections are called, account for 40 percent of sales at the Green Cross, a thriving nonprofit organization in a neighborhood of hip bars, trendy restaurants and Victorian row houses. The 150 or so customers it serves each day can pay with Visa or MasterCard and need only a doctor's recommendation to gain entry.

"It has been nine years since voters in California passed the first state law allowing sick people to use marijuana for medical purposes. The measure passed in San Francisco with 78 percent of the vote, the largest percentage in the state. But the city, where dozens of dispensaries like the Green Cross, known as pot clubs, have sprouted, is now among many struggling with the excesses of the law. ...

"Even in states where its use for medical purposes is legal, city officials, dispensary owners and medical marijuana advocates in San Francisco had begun questioning how much of the drug was enough.

"The San Francisco Board of Supervisors imposed a six-month moratorium on new dispensaries after health officials counted at least 43 unregulated facilities, including one in a building where formerly

homeless people were receiving drug and alcohol abuse counseling. Even with the moratorium, there have been reports of new clubs setting up shop.

“The absence of laws has allowed adverse opportunities to emerge,’ said Supervisor Ross Mirkarimi, who proposed the moratorium.

“Capt. Rick Bruce of the San Francisco police said more marijuana was on the streets than at any other time in his 30 years with the department. Captain Bruce said that while there were many sick people who legitimately turned to the drug for treatment, countless dealers had used the dispensaries as a cover for illegal sales.

“It's a huge scam,’ said Captain Bruce, who heads the city's Bayview station, which covers some of the highest-crime neighborhoods. ‘We see guys coming out of these places, and the only description I can come up with is that.... they are what you would call your traditional potheads; whether they have a medical condition beyond that is subject to debate.’ ...

“An estimated 100,000 people in California use the drug for medicinal purposes, far more than in any other state, according to the Drug Policy Alliance, a group that supports medical uses of marijuana. ...

“Getting inside the dispensaries, many patients say, is not difficult. Under the state law, would-be marijuana users seeking relief from a range of ailments, from chronic pain or nausea to cancer or AIDS-related symptoms, must receive a doctor's recommendation, which is roughly the equivalent of a prescription for federally approved medicines. If their usual doctors are reluctant to make a referral, patients can turn to "compassionate physicians" who advertise their services in newspapers and on the Web.

“One of those physicians, Dr. R. Stephen Ellis, whose practice is explained on www.potdoc.com, promises to refund examination fees if an appointment does not result in a recommendation. MediCann, a chain of 10 clinics in the state run by a Santa Cruz doctor, Jean Talleyrand, processes about 700 patients a week, with about three-quarters of them getting a recommendation, said a spokesman, Nicholas Jarrett. ...

“Dr. Joshua Bamberger, the medical director for housing and urban health at the San Francisco Department of Public Health, said ... the county had no ability under the law to control how much marijuana patients buy. ... The county does not keep records of who has received a card or the name of the doctor who provided the recommendation, but it does number each card for tracking purposes.

“When some drug dealers are arrested, even with large quantities of marijuana, Captain Bruce said, many of them produce a medical marijuana card and insist they have done nothing wrong.”

SMOKED MARIJUANA IS NOT ‘MEDICAL’ MARIJUANA

Marijuana is 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.

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.

Despite anecdotal claims, smoked marijuana has not been found to be safe or 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, 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 any therapeutic effects of smoking marijuana were modest. IOM recommended marijuana's active components should be tested rigorously in controlled clinical trials.

According to the Food and Drug Administration, "In 2001, [the Department of Health and Human Services (HHS or DHHS)] 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."

On April 20, 2006, FDA released a statement noting "a past evaluation by several Department of Health and Human Services (HHS) agencies, including the Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA) and National Institute for Drug Abuse (NIDA), concluded that no sound scientific studies supported medical use of marijuana for treatment in the United States, and no animal or human data supported the safety or efficacy of marijuana for general medical use. There are alternative FDA-approved medications in existence for treatment of many of the proposed uses of smoked marijuana."

STATE DECRIMINALIZED 'MEDICAL' MARIJUANA UNDERMINES FDA AUTHORITY AND DRUG SAFETY

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 Food and Drug Administration (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.

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 as well as additional regulation of pharmaceuticals awaiting FDA approval. This contradiction is inconsistent and undermines the credibility and validity of both arguments.

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.

Doctors cannot prescribe a non-FDA approved substance. In states that have bypassed the FDA's approval process, doctors can merely recommend it. Doctors are not covered by insurance for recommending a non-FDA approved drug, and there is an undetermined impact on a patient's right to sue for malpractice. Although many support cannabinoid research, most of the major medical associations in the US are against the use of smoked or raw marijuana.

A vote against this amendment is essentially a vote to provide an exemption from FDA rules and regulations for all drugs and drug makers who can simply seek state level approval without undergoing the rigors of clinical trials or even having to prove safety or efficacy.

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.

A pharmaceutical product, Marinol, is widely available through prescription and contains the same active ingredient—THC—which has been found to relieve the nausea and vomiting associated with chemotherapy for cancer patients and to assist with loss of appetite with AIDS patients. It is currently a pill, but researchers are studying its suitability for other delivery mechanisms (though other methods, such as the patch or through an inhaler have been found to be problematic).

There are also plenty of other alternatives. 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.

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 cancer 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.
- Opioids Analgesics such as Morphine (and analogs) from *Papaver somniferum* L.
- 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.

Additionally, a new report from the National Center on Addiction and Substance Abuse (CASA) confirms recent federal reports claiming that marijuana has become more potent over the past decade and a half, adding that treatment admissions for marijuana problems increased dramatically during the same time frame.

The report, dubbed "Non-Medical Marijuana III: Rite of Passage or Russian Roulette?," cites a 175-percent increase in the THC content of marijuana between 1992 and 2006, alongside a 492-percent rise in teen treatment admissions involving marijuana abuse or dependence and a 188-percent increase in treatment admissions where marijuana was named as the primary drug of abuse.

"The message for teens is clear -- today's pernicious pot is not your parent's pot," said CASA chairman and CEO Joseph A. Califano, Jr. "