This file contains the following articles, all of which are required readings;

- Harrop, “Gallup’s new poll” Real Clear Politics (*Time* and CNN), Oct. 20, 2009
- Stateman, “In California Marijuana Truce, a Legal Gray Area” *Time*, March 29, 2009
- Lorber, “Gonzales v Raich: The US Supreme Court’s Consideration Captured the Public Policy Debate About the Medical Use of Marijuana” *Gender Medicine* 2, no. 3 (2005)
Don Duncan says he is not a pot smoker. "I haven't in eight or nine years now," says Duncan, 37. "It wasn't the right thing for me." Which is ironic, since he spends most of his day around plenty of cannabis as part owner of ĕ West Hollywood, Calif. dispensary of medical marijuana, a storefront operation where as many as 100 customers — Duncan is careful to call them patients — line up daily with letters from their doctors to procure products with names like L.A. Confidential and Purple Urkel.

Lately, however, Duncan directed more energy toward his role as California director of Americans for Safe Access, a group of merchants, doctors and patients that aims to make it easier to dispense and obtain marijuana for medical purposes. The organization's central mission: fighting U.S. Drug Enforcement Administration raids on dispensaries.

California is the largest of 12 states allowing marijuana for certain medical uses, but the federal government considers all marijuana illegal. The conflicting statutes have led to an uncomfortable existence for California's growing ranks of marijuana providers. "At any moment, the DEA can come kicking down the door," says Duncan.

That is just what happened on May 27 to Virgil Edward Grant III, 41, owner of six L.A.-area dispensaries. Grant and his wife Psyhra Monique Grant, 33, were charged with 41 counts, including, drug conspiracy and money laundering and aiding and abetting the distribution of marijuana near a school. Grant pleaded not guilty on June 2. An employee, Stanley Jerome Cole, 39, pleaded not guilty to charges of selling a pound of marijuana to an undercover agent from the back door of one dispensary.

Timothy J. Landrum, special agent in charge of the DEA in Los Angeles, called the suspects "nothing more than drug traffickers." Prosecutors say Cole sold marijuana to a motorist charged with gross vehicular manslaughter in connection with a December accident near Ventura, Calif. His truck hit a parked car on a highway shoulder, killing the driver and seriously injuring a California Highway Patrol officer. Police said the driver was under the influence of marijuana that he said he had purchased at a dispensary in Compton, where one of Grant's operations is located.

Even before the Grants' arrest, Duncan's group had stepped up its efforts to fight the DEA, securing letters from six California mayors to U.S. Rep. John Conyers, a Democrat from Michigan who is chair of the House Judiciary Committee, requesting that the DEA halt the raids. In an April letter, Conyers asked the DEA to explain its use of "paramilitary-style enforcement raids" against medical marijuana patients and suppliers in California. Duncan's
group also backs a California state senate bill that would call on the federal government to respect the state's marijuana laws.

In fact, the day the Grants were arrested, Duncan was at L.A.'s city hall with a group of protesters delivering a petition to enlist the help of Mayor Antonio Villaraigosa (who has not taken a position on the issue). When they learned that DEA agents were at one of Grant's dispensaries, just a few blocks away, the group quickly moved to the dispensary, surrounding its entrance while the DEA agents were still inside. The bust proceeded as Los Angeles Police Department officers stood by, but also not interfering with the peaceful rally.

Duncan has been an activist for more than a decade, starting out by helping to gather signatures for the 1996 initiative that legalized marijuana for medical purposes. At first skeptical, the Texas-born son of a physician and a nurse was moved by meeting a Berkeley schoolteacher who used marijuana to cope with the pain of glaucoma. "I thought, 'this isn't somebody wanting to get high — this is real,'" recalls Duncan. "I want to help."

Four years ago, he moved to Los Angeles, helping to open a dispensary and working to recruit activists and local politicians to the cause. Now he does that from a small office just upstairs from his four-room dispensary, which sits next to a Tattoo parlor and around the corner from a Target store. Two beefy security guards watch the door and a smiling receptionist sits next to a case displaying bongs and other paraphernalia. Inside, patients examine samples in glass cases. Some day, Duncan says, this will be as normal as visiting Walgreens. For now, he's less focused on his inventory than on his group's efforts to supply activists with "raid kits" — protest signs, bullhorns, and sunscreen — so they can show up on a moment's notice to confront DEA agents. Says Duncan: "I predict we're going to have a very long summer."

Find this article at:
http://www.time.com/time/nation/article/0,8599,1811992,00.html
A collective sigh of relief — or was that the long exhale of bong hits? — no doubt followed Monday's announcement from Attorney General Eric Holder that federal prosecutors will not go after medical-marijuana users who abide by state laws governing the drug's use for legitimate treatment purposes. (See pictures of cannabis culture.)

"It will not be a priority to use federal resources to prosecute patients with serious illnesses or their caregivers who are complying with state laws on medical marijuana," Holder said in a statement accompanying the release of the new policy guidelines.

The announcement codified a major policy shift from the Bush Administration, which aggressively pursued medical-marijuana users and distributors in states that had relaxed their drug laws to allow patients with certain conditions — including glaucoma and AIDS — to use marijuana to ease their symptoms. Fourteen states now make allowances for medical-marijuana use, including California, Colorado, Maryland, Michigan, New Mexico and Oregon. (Watch a video about a medical-marijuana home-delivery service.)

Holder had described the broad outlines of the policy in March, but Monday's announcement represented the official Administration position, laying out the policy in a memorandum from Deputy Attorney General David W Ogden to U.S. Attorneys.

Holder made clear that the department would not turn a blind eye to those who use medical-marijuana laws as a fig leaf for illegal use, saying that traffickers exploiting the laws should still expect to be pursued. "We will not tolerate drug traffickers who hide behind claims of compliance with state law to mask activities that are clearly illegal," Holder said. (See pictures of the great American pot smoke-out.)

The announcement sparked a range of reactions. Calvina Fay, executive director of the Drug Free America...
Foundation, gave little weight to the announcement, saying that the policy has essentially been in place since early this year. An opponent of medical-marijuana laws, she said the policy may provide "free rein" to prosecutors previously unsure of whether those who used medical-marijuana laws as a smokescreen for trafficking should be prosecuted, which she would support.

"We think they should be even more aggressive, and we could have said the same thing about the previous Administration too. We think the [marijuana] dispensaries should be shut down — all of them should be shut down, and they should be shut down yesterday," she told TIME.

In contrast, NORML, the National Organization for the Reform of Marijuana Laws and a leading proponent of legalization, called the move a "major victory" for those seeking drug-law reforms. Tim Lynch, director of the Project on Criminal Justice at the libertarian Cato Institute, says the new policy announcement was a significant step that was "long overdue."

"The memorandum is a recognition that they have got to deploy or employ these resources in a rational and an effective way, and using police time to arrest people who are ill and are using marijuana for medical purposes is a gross misallocation of resources," he says.

He pointed out another dividend, this one political: to help the Administration draw a clear distinction from its predecessor for the benefit of left-leaning Obama supporters angered with the continuing war in Afghanistan and the renewal of the U.S. Patriot Act.

"This may be an attempt to show, Look there are differences, we are reversing some of the policies and priorities of the Bush Justice Department," he says, "and this is an example of that."

See pictures of stoner cinema.

See a TIME cover on marijuana.

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October 20th, 2009

War on pot, in retreat

Posted by Froma Harrop | Email This | Permalink | Email Author

Gallup's new poll showing record support for legalizing pot arrived just as the Obama administration announced it would ease up on medical marijuana. Atty. General Holder said that the feds have better things to spend money on than going after people who use or sell medical marijuana under their state laws.

Fans of the War on Drugs see efforts to normalize medical marijuana as part of a strategy to legalize all marijuana. “By directing federal law enforcement officers to ignore federal drug laws, the administration is tacitly condoning the use of marijuana in the United States,” said Texas Republican Lamar Smith.

I hope he's right. The Gallup poll, which found that four in 10 Americans want to legalize and tax marijuana, would lend credence to suspicions that the war on marijuana, at least, is on the ropes. But was anyone under the impression that the war was working in any sense?

Mexican drug gangs are now in Sequoia National Park, for heaven's sake, growing pot and spooking hikers. Marijuana is easier to buy in a schoolyard than cigarettes. The last three presidents have smoked it. Legalize pot and put the gangs out of business.

Then there's the money. The the ban on marijuana costs federal and state governments $7.7 billion a year for enforcement — and $6.2 billion in lost tax revenues. Harvard economist Jeffrey Miron explains the numbers.

If Obama's new directive is a camel's nose going deeper under the tent of legalizing marijuana, then more power to the dromedary's schnoz.

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Marijuana advocates were not the only ones who were overjoyed when U.S. Attorney General Eric Holder confirmed that he was ending federal raids on medical-marijuana facilities unless they were in violation of both state and federal laws. In budget-strapped California, for one, taxpayers are grateful. There, the fed crackdowns, which had continued despite the end of the state's own raids, got in the way of upwards of $100 million in revenue from medical-marijuana sales taxes in 2007, according to Americans for Safe Access (ASA), an advocacy group for prescription pot.

The federal Drug Enforcement Agency (DEA) is estimated to have spent more than $10 million from 2005 to 2007 on raids on California dispensaries alone. (Twelve other states have legalized medical marijuana.) Legal costs are almost impossible to calculate in the Golden State. "I suspect it's well above $10 million, and that doesn't even take into account the fee for the time it's taking me to defend these cases. The government doesn't have to pay for that, but it's certainly an expense," says Joe Elford, ASA staff attorney. "It's the beginning of the end, hopefully, and it will save the taxpayers millions if not tens of millions of dollars." He estimates that $500,000 is spent on the prosecution and incarceration of each individual facing charges. (See pictures of classic Hollywood stoner cinema.)

However, though enforcement on the state and federal level may now be virtually the same in the affected states, a large legal gray area remains. "They've only begun to scratch the surface on this," says Dale Gieringer, California coordinator for NORML, a group lobbying to legalize marijuana. "They're going to have to change the whole treatment of marijuana under federal law because you can't just have a law lying around and say, 'Well, we're just not going to enforce it in this case,' and leave it like that. If they don't change the law, there are going to be issues for years to come."

The problem is clearly evidenced by the cases of Charles C. Lynch and 30 to 40 other individuals who faced or were incarcerated for medical-marijuana-related charges before the Obama Administration relaxed its policy. Lynch was convicted in federal court in 2008 on five counts, including distributing marijuana through his dispensary, Central Coast Compassionate Caregivers, in Morro Bay, Calif. Lynch, 47, who believed he was complying with state laws regarding his clinic — he had a business license for his dispensary, a nursery license for the marijuana plants he cultivated and the blessing of city officials, including the mayor — was charged with
violating both state and federal laws. Lynch's defense team was not allowed to inform the jury that medical marijuana was legal in the state or that Lynch was compliant with state law. (See if pot is good for you.)

On March 23, the judge postponed Lynch's sentencing until April 30 and requested that prosecutors provide a written clarification from the Justice Department on the Obama Administration's position that federal agents target marijuana distributors only if they violate both state and federal laws. Thom Mrozek, spokesman for the U.S. State Attorney's Office for the Central District of California, said they were reviewing the judge's request but declined further comment.

Lynch's attorney, Reuven Cohen, a deputy federal defender, said, "The bottom line is this: If this case were brought today, Charlie would not be prosecuted, period. And anyone who says otherwise is either completely lying or does not know the truth or the facts. If the people at main justice are provided with full and accurate information, they will dismiss this case. If they are serious about what [Holder] said — in other words, that someone had to be in violation of federal and state law — then they will dismiss the case." (Read "An American Pastime: Smoking Pot."

The prosecution paints a more complex picture, contending that Lynch's operation was pervaded by marijuana transactions outside the store by his employees and customers; they claim evidence shows that, though Lynch may not have known of such transactions, "the atmosphere and example that defendant set, and that his employees and customers followed, was not one of strict compliance with the law but rather a casual, almost carnival-like attitude toward the use and distribution of marijuana." One of the most serious federal charges leveled against Lynch was that he sold the drug to more than 250 minors, which is defined as under 18 under state law and under 21 under federal laws. (Read "Can Marijuana Help Rescue California's Economy?"

Furthermore, the feds can still cite the double requirement — violation of both state and federal laws — to justify a raid. Just a week after Holder's announcement, the DEA raided Emmalyn's California Cannabis Clinic in San Francisco, claiming it violated both sets of laws. Evidence used to justify the raid is currently sealed and not available to the public. However, the San Francisco Chronicle reported that a source in the city government said the state law that was broken was a sales-tax violation. Emmalyn's attorney and a former district attorney for the city, Terence Hallinan, says, "They've done everything they're supposed to do. They haven't done any of the things they're accused of. Here a week after the Attorney General makes a statement, they go ahead and make this raid. I think it's just a slap in Obama's face."

Marijuana advocates believe that what happens with Lynch will be a bellwether for other individuals facing charges related to medical marijuana. "All of these people are in a wild state of flux that Mr. Holder and Mr. Obama have placed them in," says Allen St. Pierre, executive director of NORML. "[Lynch] is the case that will probably inform society where we're going to go on this because he got arrested under the Bush Administration. He was a Main Street medical distributor who enjoyed the support of the town council, the mayor — quintessential local acceptance. His case has been caught up for months now in the [transition between the two]
Administrations. These defendants are caught in this sort of Alice in Wonderland of medical marijuana, between the states and Federal Government."

While the Obama Administration cannot reverse the charges against Lynch, St. Pierre says it has great latitude over his sentencing. (State prosecutors have recommended the minimum mandatory sentence of five years in federal prison.) "They could commute his sentence. They can pardon his sentence," says St. Pierre. "That will be very demonstrative as to what this new Administration will do about medical marijuana. They can influence it. They can dial back what had been overt federal opposition to medical marijuana and allow, as they should have from the beginning, local mores and values to dictate who is going to run afoul of the law."

Read an interview with Tommy Chong.

Cast your votes for the TIME 100.

Find this article at: http://www.time.com/time/nation/article/0,8599,1888172,00.html
tive market, the price should settle at the costs of production plus a reasonable profit to the producer.

But of course the patent system for pharmaceuticals makes their market anything but competitive. As a matter of law, patents allow drug companies to charge whatever they can command, and in practice, the major purchasers of drugs in this country have limited or no ability to bargain for lower prices. That is not, however, an ethical justification for charging whatever the market will bear. Suppose we discover that Avastin combined with a very cheap older chemotherapeutic agent that is off patent is vastly more effective in the treatment of breast and lung cancer than previously thought—in stead of extending life on average for five months, it extends life for five years, twelve times as long as originally thought. On Genentech’s reasoning, they would now be justified in charging twelve times the $100,000 now proposed for the five months gain in life extension, despite no increase in the costs of developing and producing the drug. But that surely is not ethically correct. Absent patent protection, Genentech would not be able to increase the price to reflect the increase in benefit. Other competitors would come into the market to sell it closer to the costs of production, which don’t change when it is discovered to be far more beneficial than originally thought. Even with patent protection, insurers who could consider the drug’s cost-effectiveness, either at the current proposed price or at the new higher price if it were found to be more effective, could reasonably deny coverage on grounds that it was not cost effective and exceeded their willingness to pay a limit of, say, $100,000 per QALY.

So there are two fundamental ethical problems with Genentech’s defense of the price of Avastin. First, it greatly exceeds any of the usual standards for economic evaluation of life-extension. Even granting that it can justifiably be priced in terms of the economic value of extending life, it is very overpriced. Only the combination of patent protection together with purchasers’ failure to consider cost-effectiveness and to bargain with Genentech will enable it to sell Avastin at the proposed price. Second, even the $100,000 standard should be understood as a cap on prices, not what is ethically justified regardless of the costs of development and production.

Drug companies’ traditional justification for high drug prices—that they were needed to cover the very high costs of developing new drugs—is at least plausible in principle, even if controversies remain about what those costs really are. This new justification—that high prices reflect the value of extending life—does not stand up to even minimal scrutiny.

2. Ibid.


Medical Marijuana, Compassionate Use, and Public Policy: Expert Opinion or Vox Populi?

BY PETER J. COHEN

A recent article in the Hastings Center Report reviewed the Supreme Court’s current (but undoubtedly not final) delineation of the boundaries of federal power as set forth by the Constitution’s commerce clause. The question before the Court was straightforward: Did federal authority asserted under the Controlled Substance Act of 1970 (CSA) trump California’s legalization of “medical marijuana” when these plants were grown within the state and were not bought, sold, or transported into another state? By a six to three vote, the Raich court held that the federal Drug Enforcement Administration could enforce the CSA against two individuals who were growing marijuana for their own medical use in full compliance with California’s Compassionate Use Act (Proposition 215). At the same time, the Court’s holding neither struck down Proposition 215 nor demanded

that California bring criminal charges against its citizens who were using marijuana on the advice of their physicians.

Unfortunately, the far more significant policy question raised by Proposition 215 was never adjudicated. In effect, Proposition 215 declared that some compounds used to treat disease could be evaluated and approved by a vote of the people rather than “by experts qualified by scientific training and experience,” as mandated by the Food, Drug, and Cosmetic Act. But Proposition 215 was wrong as a matter of public policy. Anecdotes, Internet blogs, and advertisements do not provide a sound basis for assessing the safety and efficacy of pharmacologic agents. “Medical marijuana” should be subjected to the same scientific scrutiny as any drug proposed for use in medical therapy, rather than made legal for medical use by popular will.

In Raich and other cases involving Proposition 215, marijuana’s advocates presented this compound to the courts as a drug, a pharmaceutical agent efficacious in the treatment of serious and even life-threatening illnesses:

Indeed, for Raich, 39, a mother of two teenagers who says she has been suffering from a litany of disabling ailments since she was a teenager herself, medical cannabis has worked where scores of other prescribed drugs have failed. . . . It relieves pain, she said, from progressive sclerosis, endometriosis and tumors in her uterus. Raich even believes it has something to do with arresting the growth of an inoperable brain tumor.

She is convinced that her use of medical marijuana, which began in 1997 after she had been using a wheelchair for two years, made her strong enough to stand up and learn to walk again. She said doctors could find no other explanation.

These extravagant claims notwithstanding, marijuana has been used as a therapeutic agent throughout history, as Matthew W. Grey noted in a 1996 review of the use of medical marijuana:

Cannabis, more commonly referred to as marijuana, has a long history of medical use in this country and worldwide. Accounts dating back as far as 2700 B.C. describe the Chinese using marijuana for maladies ranging from rheumatism to constipation. There are similar reports of Indians, Africans, ancient Greeks and medieval Europeans using the substance to treat fevers, dysentery and malaria. In the United States, physicians documented the therapeutic properties of the drug as early as 1840, and the drug was included in the United States Pharmacopoeia, the official list of recognized medical drugs, from 1850 through 1942. During this period, lack of appetite was one of the indications for marijuana prescription.

Such anecdotal reports have been used by marijuana’s adherents to support their wish to exempt the drug from the same scrutiny required for any other compound that is used to treat, ameliorate, or prevent human disease. Specifically, they have never campaigned vigorously for medical marijuana’s evaluation by the Food and Drug Administration. Had those who favored the use of smoked marijuana as a drug elected not to circumvent the Food, Drug, and Cosmetic Act, and had smoked marijuana successfully traversed the same FDA regulatory process required for any drug proposed for use in medical treatment, it would have attained the status of an approved pharmaceutical. It could then have been purchased legally and used for medical purposes when prescribed by a properly licensed physician.

Why should FDA approval have been sought? Why should “medical marijuana” have been classified as a drug rather than a botanical, an herbal medication, or a folk remedy? The answer is in the Food, Drug, and Cosmetic Act itself: “The term ‘drug’ means articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man . . . and articles (other than food) intended to affect the structure or any function of the body of man.” That smoked marijuana is both a “controlled substance” and a plant product is extraneous to this discussion. Controlled substances have widespread use in legitimate medical practice. As an anesthesiologist, I have legally administered more narcotics (in the course of providing medical care) than many low-level illegal drug dealers. Plants and their derivatives can be potent medications. During my internship, I used digitalis leaf (derived from the foxglove plant) to treat congestive heart failure. Botanicals are the active ingredients in tincture of opium and belladonna suppositories, both of which are legal and FDA-approved when employed for legitimate therapeutic use. Smoked marijuana could achieve the same status were the FDA to find it safe and effective for medical use.

A Consensus Conference convened by the National Institutes of Health on February 19-20, 1997, to discuss the role of legitimate scientific research in evaluating the safety and efficacy of smoked marijuana reiterated the need for accurate and unbiased scientific investigation of medical marijuana. The final report from the conference acknowledged that the FDA has approved a drug known as Marinol, which contains tetrahydrocannabinol (THC, the active psychotropic ingredient of Cannabis sativa, and a controlled substance), for oral use in treating both loss of appetite due to the AIDS-wasting syndrome and chemotherapy-induced nausea and vomiting, but then offered a caution:

[This] does not fully satisfy the need to evaluate the potential medical utility of marijuana. The Expert Group noted that, although [THC] is the principal psychoactive component of the cannabis leaf, there may be other compounds in the leaf that have useful therapeutic properties. Furthermore, the bioavailability and pharmacokinetics of THC from smoked marijuana are substantially different than those of the oral dosage form.

The Consensus Conference also observed that other pharmacologic agents had already been approved to treat many of the disorders for which marijuana’s claims had not been scientifically substantiated. Yet, the report stated, “this does not mean, however, that the issue should be foreclosed. It simply means...
that in order to evaluate various hypotheses concerning the potential utility of marijuana in various therapeutic areas, more and better studies would be needed."

Finally, the consultants felt that the evidence to date showed medical marijuana might have a significant role in the areas of appetite stimulation and cachexia (bodily wasting in the late stages of cancer), nausea and vomiting following anti-cancer therapy, neurological and movement disorders, analgesia, and glaucoma. At the same time, they made it clear that these possibilities would never reach fruition in the absence of scientific data:

> Until studies are done using scientifically acceptable clinical trial design and subjected to appropriate statistical analysis, the questions concerning the therapeutic utility of marijuana will likely remain much as they have to date—largely unanswered. To the extent that the NIH can facilitate the development of a scientifically rigorous and relevant database, the NIH should do so.33

The Food, Drug, and Cosmetic Act requires that drugs may not be advertised and sold in the absence of "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved."14 However, the road to approval is not easy, and many investigators attempting to carry out scientific studies of marijuana have encountered political obstacles. Consider, for example, the difficulties faced by Donald Abrams, Professor of Medicine at the University of California, San Francisco, and chair of the Bay Area’s Community Consortium on HIV research, in his attempts to study the effects of smoked marijuana on AIDS wasting. Abrams, a clinical pharmacologist, had proposed a study to provide objective data on whether smoked marijuana could ease the symptoms of AIDS wasting and produce gains in body weight. His university’s institutional review board had approved the study, the FDA had approved it, and the university planned to fund it. Nonetheless, his request to import marijuana from the Netherlands was rejected.

> Had Cannabis sativa not been proscribed by the Controlled Substances Act, every “medical marijuana” case would have been moot.

> As long as smoked marijuana was not advertised as an FDA-approved pharmaceutical, it would have become one of this century’s premier herbal medications.

Since the National Institute on Drug Abuse (NIDA) grows marijuana that is supplied to appropriate scientific investigators, the professor requested their assistance. However, because his funding had originated at his university, and not the NIH, of which NIDA is a part, he was denied access to the product. The NIH stated that its policy was to make marijuana available only to investigators who had received a peer-reviewed NIH grant to conduct the proposed study.

In May of 1996, Dr. Abrams resubmitted his study proposal to the National Institute of Health, believing that he had addressed NIDA’s concerns. At that time, the study was still approved and funded at the university level. In October 1996, four years after he had initiated requests to obtain marijuana legally, he was again informed that NIH’s Mississippi marijuana “farm” would not supply the needed cannabis.

> The following month, the people of California voters passed Proposition 215 by a wide margin.15

Political barriers to the performance of scientifically valid studies of medical marijuana do not obviate the argument that marijuana should be assessed in the same way as other drugs proposed for therapy. The sick still need medically sound treatments. In the case of Angel Raich, unfortunately, scientific evidence of this drug’s efficacy in curing her inoperable brain tumor is simply nonexistent.

Decades ago, the Supreme Court gave an ample argument for protecting people from the vain hope of unproven therapy:

> Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs, and ammonia; peat moss; arrangements of colored flood-lamps; pastes made from glycerine and limburger cheese. . . . In citing these examples, we do not, of course, intend to deprecate the sincerity of Laetrile’s current proponents, or to imply any opinion on whether that drug may ultimately prove safe and effective for cancer treatment. But this historical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less
than other patients, from the vast range of self-styled panaceas that inventive minds can devise.16

Smoked marijuana ought not to be allowed to take the easy path to drug approval. Marinol, containing pure THC, has already been approved in the United States. Sativex, another formulation of THC, has been approved in Canada and is under consideration in the United States. Smoked marijuana might also be approved and legally prescribed for appropriate therapeutic uses.

I cannot resist a final thought. Had Cannabis sativa not been proscribed by the Controlled Substances Act (and been taxed and regulated, as are alcohol and tobacco, two substances that cause far more “societal pathology”), every “medical marijuana” case would have been moot. And under this scenario, as long as smoked marijuana was not advertised as an FDA-approved pharmaceutical (which would hardly have been necessary), it would undoubtedly have become one of this century’s premier herbal medications.

Acknowledgment

I wish to acknowledge Cynthia B. Cohen, senior research fellow at the Kennedy Institute of Ethics, Georgetown University, for her help, encouragement, and insightful comments and suggestions.

2. Ashcroft v. Raich, 124 S. Ct. 2909 (2004). “Medical marijuana” refers to any form of Cannabis sativa used to treat a wide variety of pathologic states and diseases. Its adherents claim (with pharmacologic justification) that smoking allows easy titration and rapid onset of its pharmacologic effects.
8. Food, Drug, and Cosmetic Act, United States Code, Title 21, as amended, sec. 201(g)(1)(B) and (C).
12. Ibid., 4.
13. Ibid., 4.
The US Supreme Court voted 6 to 3 in June 2005 that Congress could regulate—and ban—the medical use of marijuana, even in states with laws affirmatively allowing its use. The case, *Gonzales v Raich*, captured the different sides of the public debate about the use of medical marijuana, even as the Supreme Court (hereinafter referred to as “the Court”) ruled that it would not address the public policy issues. Instead, the case pivoted on a relatively narrow but important question of law: Does Congress or the state have the last word on regulating activities that take place entirely within a state? The Court ruled that Congress does, at least where there is reason to believe that the activities have a substantial effect on interstate commerce, which Congress has the constitutional authority to regulate.

The Raich case illustrates a clash of myriad interests: patients, medical providers, drug abuse prevention advocates, and federal and state policy makers. This article describes the legal case and the public policy arguments about medical marijuana presented by those interested in the debate.

**Facts and History**

*Gonzales v Raich* arose out of the use of home-grown marijuana for medical purposes by two California women, Diane Monson and Angel McClary Raich. In 2002, federal drug enforcement agents and local sheriff’s deputies raided Monson’s home. After a 3-hour standoff, the federal agents confiscated 6 marijuana plants, which, following her doctor’s recommendation, Monson used to relieve severe chronic back pain and constant painful muscle spasms caused by a degenerative disease of her spine. The federal agents deemed that her possession and use of marijuana for medical purposes violated the federal Controlled Substances Act (CSA), passed by Congress in 1970 as part of a comprehensive anti-drug abuse legislative package. On the other hand, the sheriff’s deputies concluded that Monson was covered by California’s Compassionate Use Act, a state law expressly allowing the medical use of marijuana.

Federal agents did not raid Raich’s property or seize her marijuana, but she was concerned that they might do so in the future. Raich was diagnosed with medical conditions that included an inoperable brain tumor, life-threatening weight loss, a seizure disorder, nausea, and several chronic pain disorders. She found that other treatments were ineffective or caused intolerable side effects. Her doctor said that she might die if she were to forgo marijuana treatments. Because Raich was unable to cultivate her own medical marijuana, two caregivers did so for her, using only materials and equipment obtained within California.
Fearing more raids and the prospect of being deprived of the drug, Monson and Raich, along with Raich's unnamed caregivers, filed a lawsuit against the US Attorney General and the head of the Drug Enforcement Administration (DEA) for an injunction to prevent future federal law enforcement activity targeting their medical marijuana use. They also asked the federal district court to find the federal CSA unconstitutional as applied to their medical use of marijuana. The federal district court denied the plaintiffs' motion for a preliminary injunction. It ruled that "despite the gravity of plaintiffs' need for medical cannabis, and despite the concrete interest of California to provide it for individuals like them," the plaintiffs had not been able to show it was likely that the CSA would be found unconstitutional as applied to their medical use of marijuana. On appeal, this ruling was overturned and the district court was ordered to enter a preliminary injunction for the plaintiffs. The US Court of Appeals for the Ninth Circuit found that the plaintiffs showed a "strong likelihood" they would succeed with their constitutional claim. The Ninth Circuit also noted the burden that would be faced by the plaintiffs if they were denied access to medical marijuana and found that the public as a whole had a strong interest in the medical use of marijuana, as evidenced by the enactment of the Compassionate Use Act through a voter ballot initiative.

The US Supreme Court agreed to hear the case after petitioning by the defendants. A number of interested groups that were not parties to the case filed briefs with the Court to provide additional perspective on and analysis of the issues, called amici curiae briefs. These groups included national associations representing medical providers, patients, and medical students; anti-drug abuse organizations; members of Congress interested in drug policy; and former Executive Branch drug policy makers.

**Marijuana and Government Regulation**

Marijuana has been heavily regulated by the states and federal government since the early 1900s. Marijuana was among the drugs addressed by Congress in the Pure Food and Drug Act of 1906, which established the modern system of medical drug regulation and created the agency now known as the US Food and Drug Administration (FDA). After formation of the Federal Bureau of Narcotics in 1930, Congress passed the Marihuana Tax Act of 1937 to require all marijuana users to register with the federal government and pay a tax. The Act did not distinguish between recreational and medicinal users, and as a result, significantly reduced the use of marijuana for medical reasons because the drug became expensive and difficult to obtain. In 1942, the US Pharmacopeia stopped recognizing marijuana as a medicine.

In the 1960s, marijuana became a popular recreational drug, with marijuana-related arrests increasing by 1000%. Incoming president Richard Nixon made the federal government's war on drugs a focal point of his administration. In 1970, he ushered through Congress the Comprehensive Drug Abuse Prevention and Control Act, also known as the CSA. The CSA categorized drugs based on their potential harm and value to society, and placed marijuana and tetrahydrocannabinol in Schedule I, the most restrictive category reserved for drugs with "a high potential for abuse," a "lack of accepted safety for use under medical supervision," and "no currently acceptable medical use in treatment in the United States." The possession, manufacture, dispensing, and distribution of marijuana became federal crimes.

Efforts to allow the medical use of marijuana began soon after the CSA was enacted. In 1972, the Presidential Commission on Marijuana and Drug Use reported that marijuana was not as dangerous as suggested by its classification and recommended lessening the penalties for marijuana offenses. That same year, advocates for the use of medical marijuana filed with the federal government the first of several unsuccessful petitions to reclassify marijuana in light of its medicinal qualities. The Court of Appeals for the District of Columbia Circuit reviewed the federal government's rejection of this petition on 5 separate occasions in the past 30 years, in 1972, 1974, 1977, 1991, and 1994. In 1988,
an administrative law judge recommended reclassification in Schedule II; however, the DEA Administrator rejected the ruling, leading to the 1991 appeal, and has continued to classify marijuana as a Schedule I drug. The DC Circuit ultimately upheld the DEA Administrator's final order in 1994.

In 1976, the FDA established a program that allowed doctors and patients to seek individual approval to use marijuana for medicinal purposes. States also could receive permission under the FDA program to make marijuana available for medical use if they established a formal research program. This proved to be too burdensome and expensive for many states; two thirds of the states enacted enabling legislation but only 10 established such programs. By 1989, fewer than a dozen patients had received permission from the FDA to use marijuana. That changed with the burgeoning AIDS epidemic, as physicians began to prescribe marijuana to combat AIDS-related weight loss. The increasing number of applications to the FDA concerned the Public Health Service and, in 1991, the Service issued a statement that the program violated the spirit of the federal government's war on drugs. A year later, the FDA suspended the program altogether.

At the state level, all states regulated the use of marijuana by 1937. From the 1970s to the present, legislative efforts, voter ballot initiatives, and court rulings have led to medical marijuana laws in 26 states. At the time of the Court's ruling in Raich, at least 9 states authorized the medical use of marijuana: Alaska, California, Colorado, Hawaii, Maine, Nevada, Oregon, Vermont, and Washington.

**Medical Use of Marijuana and Competing Public Policies**

Since the 1900s, medical marijuana use has been the focus of a tug of war between competing interests. Patients and their physicians have an interest in using marijuana for what they believe to be the most effective therapy to treat specific medical problems. The federal government has an interest in protecting society at large from the adverse health and welfare effects of illegal drugs. The Raich case illustrates these interests and highlights a number of other issues implicated in allowing states to approve the medical use of marijuana within their borders.

**Medical Benefits of Marijuana**

At present, marijuana use has been recommended by doctors to alleviate conditions such as glaucoma, multiple sclerosis, epilepsy, and other muscle spasm-related ailments; asthma; migraine headaches; certain mood disorders; AIDS-related and other wasting disorders; and the nausea and vomiting that can accompany chemotherapy. For example, a 1991 Harvard survey of over 2400 oncologists found that over 40% of respondents had recommended the use of marijuana to control nausea and vomiting to at least one cancer patient. Almost half of the physicians surveyed considered it to be therapeutically useful and would prescribe it if lawful to do so.

Government-sponsored studies in the United States and Great Britain have recognized that some patients benefit from the medical use of marijuana. Both doctors who recommend its use and their patients who have tried marijuana have said that it often provides the best relief of pain or symptoms. A "small but significant" number of seriously ill patients, such as plaintiffs Monson and Raich, benefit from smoking marijuana but do not benefit from or cannot tolerate current medical treatments. As national health organizations, a former federal drug policy maker, and a patient wrote in their joint amici curiae brief: "For certain persons the medical use of marijuana can literally mean the difference between life and death. At a minimum, marijuana provides some seriously ill patients the gift of relative health and the ability to function as productive members of society.

Indeed, Monson and Raich asked the Court to find that their use of medical marijuana was a "medical necessity," as Raich's doctor had determined that without medical marijuana she would "quickly" suffer "precipitous medical deterioration" and "could very well" die. Monson's doctor had determined that only marijuana would relieve her symptoms.
Those against the medical use of marijuana, including certain groups that filed *amicus curiae* briefs in the Raich case, have said that botanical marijuana is ineffective, has problematic side effects, and cannot pass the strict scientific standards necessary to receive FDA approval as a safe and effective drug. One concern is the quality and consistency of the marijuana available, a concern shared by those who use medical marijuana and support its legalization on that basis. The Institute of Medicine at the National Academy of Sciences has suggested that developing treatments from the active ingredients in marijuana may be a better approach than smoking the marijuana itself. The House of Lords in the United Kingdom recommended a similar approach. In 1985, the FDA approved pure tetrahydrocannabinol in pill form for treating nausea in cancer patients and wasting in AIDS patients, and pharmaceutical companies are actively developing new treatments made from marijuana components.

**Medical Use of Marijuana and Its Implications for Drug Trafficking**

The US Attorney General and the DEA Administrator, who were the defendants in the case, and various anti-drug abuse groups and anti-drug trafficking advocates informed the Court of their concerns that allowing states sole authority to regulate the medical use of marijuana purely within their borders would undercut federal drug-trafficking enforcement efforts. The defendants explained to the Court that the interstate market for marijuana is well established and substantial. For example, American marijuana users spent about $10.5 billion on the drug in 2000, with marijuana prices, an indication of its steady availability, remaining stable for years.

The defendant, US officials and 7 members of Congress interested in drug policy further informed the Court that to be effective, the enforcement of federal drug law needs to reach all levels of the drug trade, from its production to its local distribution and protection. In other words, a purely local market cannot be carved out. These federal officials explained that because marijuana is fungible—markers cannot be used to identify the source, as with cocaine and heroin—there is no way to discern if marijuana that was solely destined for medical purposes originated within the state.

An exception to the comprehensive federal drug regulations for intrastate medical marijuana production, use, and possession would foster a number of problems. It would create a loophole for drug traffickers to argue that any marijuana found in their possession was intended for medical use, and thereby impose an additional burden on the government to prove the marijuana was intended for illegal purposes. Certain states would become “safe havens” for drug smuggling, with residents depending on the revenue from marijuana production, creating a mindset hostile to federal drug policy. It also could create a “slippery slope” leading to attempts to gain approval for the medical use of other currently illegal drugs.

If states allowed the use of medical marijuana within their borders, the defendants and members of Congress argued, this would likely eventually increase purely recreational use. A number of anti-drug abuse advocates informed the Court that a 2000 report commissioned by the Department of Health and Human Services found that the states which have passed medical marijuana laws have among the highest levels of past-month marijuana use, past-month other drug use, drug addiction, and drug and alcohol addiction.

The defendant federal officials and certain interested groups explained to the Court that approval of the medical use of marijuana would increase recreational use because of the increased availability of distribution channels for the drug. Some doctors might prescribe marijuana more broadly than just for currently accepted medical uses. Allowing the medical use of marijuana could increase the avenues for obtaining it illegitimately—through fraudulently written or altered prescriptions, “doctor shopping,” illegal resale of the legally obtained drug to others, and theft or robbery from lawful suppliers. Prices on the black market would drop due to the drug’s increased availability, creating
a buyer's market, and the public's awareness of the dangers of marijuana use would decrease due to the government's official approval of even a limited use of the drug.18,21,24,26

Monson and Raich told the Court that their use of marijuana would have no appreciable impact on the larger scheme of federal law enforcement.27 The San Francisco DEA office targets the most significant drug traffickers, setting the threshold for DEA involvement in marijuana arrests in the range of 1000 pounds or 500 plants.28 In 1999, the most recent year for which statistics were available, 38,288 people whose most serious alleged offense involved a controlled substance were evaluated for prosecution by US Attorneys nationwide.29 Only 471 (1.2%) were evaluated for prosecution for simple possession of marijuana. “This pattern of federal prosecution indicates that exempting application of the CSA to medical cannabis patients and caregivers would have virtually no impact on the effectiveness of the federal regulation of controlled substances,” Monson and Raich explained.4

Medical Marijuana Laws and Their Impact on Physicians

Physicians may be placed in an “impossible position” because of the lack of standards in state medical use laws for the prescription of marijuana, particularly laws enacted through ballot initiatives, according to 3 doctors who served as federal government drug policy advisors and supported the defendant federal officials’ stance.25 Although the state of California placed doctors in the role of “legal gatekeepers” of the lawful use and possession of marijuana, the state also failed to provide objective scientific standards and data with which to exercise that authority. Moreover, state medical boards would face difficult political and medical decisions about regulating the use of medical marijuana.24

On the other hand, in light of the conflict between the CSA and growing evidence that marijuana has a number of medical benefits, as pointed out by the California Nurses Association and the regulatory watchdog group DKT Liberty Project, physicians and other medical care providers currently are placed in the difficult position of being forced to choose between “withhold[ing] potentially life-saving, and certainly life-enhancing treatment, or risk[ing] violating federal law.”30 Also, if the medical use of marijuana were legalized nationally or on a broad scale, accepted scientific standards for its use would develop. This would be less likely with a state-by-state patchwork of different laws.

Impact on FDA Drug Approval and Regulation

Permitting states to allow and regulate the medical use of marijuana within their borders is likely to undermine the FDA's effective system of regulating the development and marketing of drugs, threatening harm to public health and safety, according to the former drug policy advisors.25 They also explained that as the only agency authorized to approve medical products as safe and effective for use in the United States, the FDA provides a uniform nationwide standard for drug production, and its decision making on drug approval is based on a rigorous scientific process performed by highly qualified experts. Moreover, they explained that if individual states enact laws allowing the medical use of marijuana, particularly through ballot initiatives, patients likely would not be able to rely on the FDA's rigorous scientific efforts to assure the safety and efficacy of a drug before it receives market approval, at least initially.25

Pro- and anti-medical marijuana advocates alike recognize the varying strengths of the drug, and the FDA has explained that “there are many variables that can influence the strength, quality, and purity of marijuana as a botanical substance.”31 As a result, the FDA has said it “cannot conclude that marijuana has an acceptable level of safety without assurance of a consistent and predictable potency and without proof that the substance is free of contamination. If marijuana is to be investigated more widely for medical use, information and data regarding the chemistry, manufacturing, and specifications of marijuana must be developed.”31

However, this problem would most likely be addressed if the medical use of marijuana was
allowed nationwide. As the California Nurses Association and DKT Liberty Project explained, “[w]ere the federal government to lift the ban and allow medical uses, market mechanisms would certainly ensure that pharmaceutical companies would quickly solve whatever problems of purity and potency exist.”

The Supreme Court's Ruling: Congress Makes the Ultimate Decision

The Court explained at the beginning of its opinion that it found the facts of the case “troubling,” and acknowledged that Monson and Raich had “strong arguments” that they would be “irreparably harmed” if the CSA barred their medical use of marijuana “because, despite a congressional finding to the contrary, marijuana does have valid therapeutic purposes.” The Court, however, was charged with determining “not whether it is wise to enforce the statute in these circumstances; rather, it is whether Congress’ power to regulate interstate markets for medicinal substances encompasses the portions of those markets that are supplied with drugs produced and consumed locally.”

The Court determined that the intrastate production and use of medical marijuana was an economic activity that could have a “substantial effect” on interstate commerce. In doing so, it accepted the argument by the federal government and its supporters that Congress could have rationally found that the intrastate use of marijuana could, in the aggregate, have a substantial impact on the nationwide illegal drug market. The Court wrote: “Indeed, that the California exemptions will have a significant impact on both the supply and demand sides of the market for marijuana is not just ‘plausible’ [as one dissenting justice wrote], it is readily apparent.” The Court also agreed that giving states the primary power to regulate drugs purely inside their borders could upset the comprehensive statutory scheme set forth in the CSA “to foster the beneficial use of medications, to prevent their misuse, and to prohibit entirely the possession or use of substances listed in Schedule I, except as a part of a strictly controlled research project.” The 3 dissenting justices disagreed with both of these arguments.

Because the Court found the law to be “well settled” that Congress can regulate intrastate activities that substantially effect interstate commerce, it found that Congress could regulate the intrastate use of marijuana for medical purposes under the CSA.

Ultimately, the Court stated, Congress was the appropriate forum for the public policy decision about legalizing marijuana for medical use, referring Monson and Raich to the “democratic process, in which the voices of voters allied with these respondents may one day be heard in the halls of Congress.” On June 15, 2005, the US House of Representatives voted 161 to 264 against quickly introduced legislation that sought to prohibit the Department of Justice from using any funds in its budget to prosecute people who use medical marijuana in states that allow such use.

REFERENCES

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10. Alliance for Cannabis Therapeutics v DEA, 930 F2d 936 (DC Cir 1991) (remanding petition to DEA Administrator due to federal government errors in administrative proceedings); National Org. for the Reform of Marijuana Laws (NORML) v DEA, 559
F2d 735 (DC Cir 1977) (remanding petition to DEA Administrator due to federal government errors in 1975 administrative proceedings); National Org. for the Reform of Marijuana Laws (NORML) v Ingersoll, 497 F2d 654 (DC Cir 1974) (remanding petition to DEA Administrator due to errors in federal government administrative proceedings and describing 1972 court ruling denying review on court procedural ground).

11. Alliance for Cannabis Therapeutics v DEA, 15 F3d 1131 (DC Cir 1994).


