

HEINONLINE

Citation: 24 Health Law. 1 2011-2012



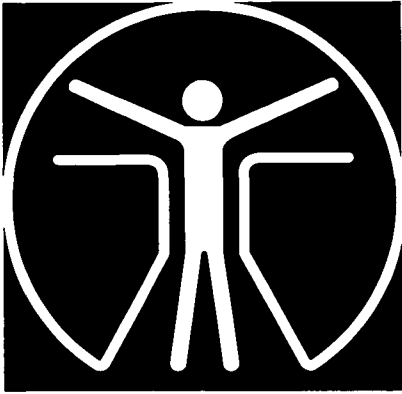
Content downloaded/printed from
HeinOnline (<http://heinonline.org>)
Fri Dec 6 14:28:13 2013

-- Your use of this HeinOnline PDF indicates your acceptance
of HeinOnline's Terms and Conditions of the license
agreement available at <http://heinonline.org/HOL/License>

-- The search text of this PDF is generated from
uncorrected OCR text.

-- To obtain permission to use this article beyond the scope
of your HeinOnline license, please use:

[https://www.copyright.com/cc/basicSearch.do?
&operation=go&searchType=0
&lastSearch=simple&all=on&titleOrStdNo=0736-3443](https://www.copyright.com/cc/basicSearch.do?&operation=go&searchType=0&lastSearch=simple&all=on&titleOrStdNo=0736-3443)



THE ABA HEALTH LAW SECTION

THE HEALTH LAWYER

IN THIS ISSUE

The Cannabis Conundrum:
Medication v. Regulation..... 1

Can They Do That? Government
Threats to 'Come Down and Look
Around' to Force Settlement
in *Qui Tam* Cases 16

Another Round of
Contractors: The Medicaid
RAC Final Rule..... 20

Federal Courts Grapple with the
Constitutionality of Retroactive
Amendments to the False
Claims Act..... 28

Updates to 2011
Emerging Issues Conference
Presentations 33

THE CANNABIS CONUNDRUM: MEDICATION V. REGULATION

Moira Gibbons, PharmD, JD
National Association of Boards of Pharmacy
Mt. Prospect, IL

Marijuana is highly sought after by both law enforcement officials and medical marijuana advocates. The former seek to control it; the latter desire expanded access to it. The ideological dance between these adversaries is part of a growing national conversation that continues to pose more questions than answers. This article reviews the medical use of marijuana from two perspectives: clinical and regulatory.

Cannabis Sativa – The Call of the Weed

Marijuana, or *cannabis sativa*, is part of the hemp plant family^{1,2} and despite its plain jane Latin name, which translates to “sown hemp,” the debate about its role in medicine remains a high profile issue worthy of continued study. While marijuana is the common name for *Cannabis sativa*, it is also generally used to reference the parts of the plant that are ingested. *Cannabis sativa* has numerous narrow, green, razor-edged leaves and can reach heights of four to ten feet or more depending on the subspecies and growing conditions. Marijuana is a relatively pretty plant during the

leafing, or vegetative state. However, the female plant morphs into sticky, fuzzy-looking, “snowy” masses of trichomes, or hair-like projections, which are located on the small leaves accompanying the flowering tops, a far cry from garden daisies. Interestingly, Illinois, Missouri, Pennsylvania, and West Virginia designate marijuana as a noxious weed,³ with Illinois placing it in the same lowly company as the reviled, allergy-triggering ragweed.⁴ In fact, Illinois law imposes a duty on every person to eradicate marijuana on land owned or controlled by such person.⁵

Recreational marijuana users typically smoke the dried, trichome-covered leafy flower buds of the female plant, which contain the highest concentration of the chemical that produces the much-pursued high. Medical marijuana users may smoke cannabis; they may also vaporize the cannabis or, like some recreational users, ingest food items, such as brownies or sodas, that contain cannabis or active plant extracts.

Cannabinoids

Cannabinoids are a group of chemicals that exert physiological effects when they bind to cannabinoid receptors.⁶ It is believed that there are

continued on page 3





DRUGS

No, I am not referring to the song by Talking Heads, nor am I seeking to conjure the spirits of Jimi, Janis or Hunter S. Rather, recent events have brought into focus the degree to which drugs, and especially the abuse of prescription drugs used to relieve pain, have become part of the array of issues that health lawyers must address when counseling their clients. This realization began, strangely enough, at the Section's Washington Healthcare Summit (more on that event in a future column). According to the attendees' reviews, the most popular event at the Summit was a lunchtime presentation by Joseph Rannazzisi of the Drug Enforcement Administration's ("DEA") Office of Drug Diversion Control. Mr. Rannazzisi began with a harrowing description of the methamphetamine epidemic that plagues America's rural communities in particular. By halfway through his presentation, his listeners had learned how to "cook" meth in the rear of a car traveling the back roads of Appalachia using ingredients largely obtainable at a store like Wal-Mart. The second half of his presentation focused on a different epidemic, that of the abuse of prescription drugs, principally those of the opioid class. Think Michael Jackson or Rush Limbaugh. Think Florida, where recent articles in the national press have described a flourishing industry of "pill mills" dispensing prescriptions for Schedule II narcotics to all comers and whose state government, on "privacy" grounds, had until recently blocked efforts to establish the same data base linking doctors, pharmacies, patients and controlled drug prescriptions that exists in other states. Similar problems with pill mills, of a lesser magnitude perhaps, exist in other states. That is the enforcement view of the world.

Yet, the larger picture is more complex. Prisons and jails are bursting with incarcerated drug users. Treatment programs, underfunded in the best of times, face a dire future as government budgets are slashed. Especially troubling are the disproportionate penalties for "crack" as opposed to "powder" cocaine, which have resulted in African-Americans receiving substantially longer sentences than white Americans, based solely on their preferences for the form of drug. This issue, among other concerns, is detailed in a recent article in the *New York Review of Books* by Justice John Paul Stevens, "Our 'Broken System' of Criminal Justice." Last year Congress passed the Fair Sentencing Act of 2010, which lessened

continued on page 27



THE HEALTH LAWYER

THE ABA HEALTH LAW SECTION

The *Health Lawyer* (ISSN: 0736-3443) is published by the American Bar Association Health Law Section, 321 N. Clark Street, Chicago, IL 60654-7598. Address corrections should be sent to the American Bar Association, c/o Member Records.

Requests for permission to reproduce any material from *The Health Lawyer* should be addressed in writing to the editor.

The opinions expressed are those of the authors and shall not be construed to represent the policies or positions of the American Bar Association and the ABA Health Law Section.

Copyright © 2011 American Bar Association.

2011-2012 Officers and Council of the ABA Health Law Section are as follows:

- | | | |
|---|---|---|
| Chair
David H. Johnson
Bannerman & Johnson
Albuquerque, NM
505/837-1900
dhj@nmccounsel.com | Vice Chair
Kathleen Scully-Hayes
Social Security Administration
Baltimore, MD
866/613-3960 x11443
kathleen.scully-hayes@ssa.gov | Budget Officer
Daniel A. Cody
Reed Smith LLP
San Francisco, CA
415/659-5909
dcody@reedsmith.com |
| Chair-Elect
David L. Douglass
Shook Hardy & Bacon
Washington, DC
202/662-4861
ddouglass@shb.com | Secretary
Michael E. Clark
Duane Morris, LLP
Houston, TX
713/402-3905
meclark@duanemorris.com | Budget Officer-Elect
Alexandra Hien McCombs
Concentra
Addison, TX
972/364-8241
alexandria_mccombs@concentra.com |
| Immediate Past Chair
Linda A. Baumann
Arent Fox, LLC
Washington, DC
202/857-6239
baumann.linda@arentfox.com | | |

Section Delegates to the House of Delegates

- | | |
|---|---|
| Gregory L. Pemberton
Ice Miller
Indianapolis, IN
317/236-2313
gregory.pemberton@icemiller.com | J. A. (Tony) Patterson, Jr.
Northwest Healthcare Corporation
Kalispell, MT
406/751-4175
jpatterson@krmc.org |
|---|---|

Council

- | | | |
|--|--|--|
| Gregory E. Demske
U.S. DHHS/OIG
Washington, DC
202/205-0568
gregory.demske@oig.hhs.gov | Eugene M. Holmes
Proskauer Rose LLP
Washington, DC
202/416-5866
eholmes@proskauer.com | Charity Scott
Georgia State University
College of Law
Atlanta, GA
404/413-9183
cscott@gsu.edu |
| Robert W. Friz
PricewaterhouseCoopers LLP
Philadelphia, PA
267/330-6248
robert.w.friz@us.pwc.com | William W. Horton
Haskell Slaughter Young & Rediker, LLC
Birmingham, AL
205/254-1448
wwh@hsy.com | Robyn S. Shapiro
Drinker Biddle & Reath LLP
Milwaukee, WI
414/221-6056
robyn.shapiro@dbri.com |
| C. Joyce Hall
Watkins & Eager
Jackson, MS
601/965-1982
jhall@watkinseager.com | Priscilla Keith
Indiana University School of Law
Indianapolis, IN
317/274-1951
pdkeith@iupui.edu | Hilary H. Young
Joy & Young, LLP
Austin, TX
512/330-0228
hyoung@joyounglaw.com |

Young Lawyer Division

Marc M. Meyer
Law Office of Marc Meyer PLLC
Magnolia, TX
281/259-7575
marc@marcmeyerlawfirm.com

Publication Co-Chair

Michael E. Clark
Duane Morris, LLP
Houston, TX
713/402-3905
meclark@duanemorris.com

Board of Governors Liaison

R. Kinnan Golemon
KG Strategies, LLC
Austin, TX
512/479-9707
kg@kgstrategies.com

Publication Co-Chair

Charles M. Key
Wyatt, Tarrant & Combs, LLP
Memphis, TN
Liaison to the Publications Committee
901/537-1133
ckey@wyattfirm.com

Section Director

Wanda Workman
American Bar Association
321 N. Clark Street
Chicago, IL 60654-7598
T: 312/988-5548 F: 312/988-5814
wanda.workman@americanbar.org

The Health Lawyer Editor

Marla Durben Hirsch
Potomac, Maryland
301/299-6155
mdhirsch@comcast.net

The Cannabis Conundrum: Medication v. Regulation

continued from page 1

more than 100 types of cannabinoids, which are found naturally in humans and other animals as well as plants such as marijuana.⁷ Cannabinoids can also be made synthetically: examples are the Food and Drug Administration (“FDA”)-approved cannabinoids dronabinol and nabilone, which are discussed below.

An important naturally occurring cannabinoid is Δ^9 -tetrahydrocannabinol (“THC”). THC is considered to be “fatty,” which allows it to readily travel from blood into the brain. It is also the most psychoactive cannabinoid in marijuana, producing a variety of effects including euphoria, diminished anxiety, sedation, hallucinations, and depression. Other cannabinoids may have immunosuppressive effects, benefiting autoimmune diseases such as multiple sclerosis, and may even ameliorate the psychoactive effects of THC, including THC’s involvement in marijuana dependency.⁸

Let’s Get Clinical

When considering pharmacological treatment for a patient, how is the right drug identified? The effectiveness of a medication in treating a patient’s medical condition is typically of primary importance; however, selection of a medication may be tempered by the drug’s side effects, particularly given the patient’s medical conditions and existing drug regimen as well as the availability of therapeutically equivalent alternative medications. If efficacy and side effect profiles are substantially the same for two or more drug options, then costs are considered.

Marijuana doesn’t fit nicely into this model. Medical literature lacks a robust array of studies comparing the efficacy of marijuana to other drugs in the treatment of medical conditions. Further, the FDA has not approved marijuana as a drug that is safe and

effective,⁹ and the Drug Enforcement Administration (“DEA”) has statutorily designated marijuana as a Schedule I controlled substance that cannot legally be prescribed under federal law.¹⁰ Nevertheless, it is generally viewed that physicians can discuss and recommend marijuana to patients without running afoul of federal law.¹¹ But when is marijuana the appropriate drug for recommendation to patients?

First, a little history. In 1999, the Institute of Medicine (“IOM”) published a comprehensive report that researched and evaluated the science of marijuana and its use in medicine.¹² The Office of National Drug Control Policy,¹³ under the Clinton administration, commissioned the IOM report. More than ten years later, the report is still cited by researchers, practitioners, and regulators. For example, the DEA references the IOM report on its Web site, stating “[T]he study concluded that smoking marijuana is not recommended for treatment of any disease condition.”¹⁴

While the DEA declaration is technically true in that the IOM report did not recommend marijuana for treatment of diseases such as cancer or diabetes, the IOM report acknowledged the existence of therapeutic value in marijuana as treatment for disease *symptoms*. In fact, the IOM report recommended that, under certain conditions, short-term smoked marijuana be used by patients with debilitating symptoms such as intractable pain or vomiting.¹⁵ Indeed, the Arizona, Delaware, Michigan, New Jersey, Rhode Island, and Vermont legislatures cited the IOM Report as a basis for passing their medical marijuana laws.¹⁶

IOM and others have recognized marijuana as having therapeutic activity against chemotherapy-induced nausea and vomiting (“CINV”), but

many drugs treat CINV. For example, legally available synthetic cannabinoids such as Marinol¹⁷ and Cesamet have been shown to be as good, or better, than “old school” anti-CINV medications such as Compazine.¹⁹ A 2001 analysis of various studies comparing smoked marijuana and oral THC, including Marinol, indicated that smoked marijuana was at least as effective as oral THC in treating CINV, if not better in some instances.²⁰ On the other hand, two CINV studies comparing cannabinoids and smoked marijuana have shown that neither had an ameliorative effect on CINV, and one study found that oral THC was superior to smoked marijuana.²¹

In 1991, a groundbreaking new drug was introduced that transformed CINV treatment.²² Zofran and others in its class block the effects of the chemical serotonin, which is associated with nausea and vomiting. Newer medications that work in a different manner, such as Emend, help fortify current CINV drug therapy.²³ In fact, studies show “modern” drugs such as Zofran and Emend, either together or Zofran in combination with the steroid dexamethasone, are very good options for treatment of CINV. In fact, these modern medications are recommended by the American Society of Clinical Oncology (“ASCO”) for treatment of CINV.²⁴

But what about “toe-to-toe” CINV studies comparing marijuana to the modern drugs? Unfortunately, none could be found.^{25,26} The dearth of research on this topic may be due, in large part, to the fact that the modern drugs provide very effective treatment for CINV, and FDA-approved oral THC medications provide relief from CINV that is more or less equivalent to that of smoked marijuana. Given the lack of studies evaluating the efficacy of marijuana versus ASCO-recommended

continued on page 4

The Cannabis Conundrum: Medication v. Regulation

continued from page 3

modern medications in the treatment of CINV, and the federal legal status of marijuana as a Schedule I controlled substance, a clinician would be hard-pressed to even consider marijuana as first-line therapy for CINV. Moreover, consistency in the potency of marijuana, which varies by plant type and growing conditions, and whether the quantity of marijuana active ingredients is even known, impact whether a physician can reliably recommend marijuana and if so, the “dose.” Such factors pose little concern for physicians when prescribing standardized, FDA-approved oral or injectable CINV drug therapies.²⁷

Compared to the modern medications in the treatment of CINV, marijuana does not meet the efficacy test in the three-part drug selection process that also considers side effects and costs. Nevertheless, if modern medications fail to treat CINV, synthetic cannabinoids, such as Marinol and marijuana could be considered as back-up therapy for CINV based upon their more or less equivalent efficacy, but side effects should be carefully considered.²⁸ For some patients, the “high” caused by cannabinoids may benefit the patient in coping with the dread or anxiety associated with the underlying disease of cancer.²⁹ Nevertheless, there are serious concerns about abuse of cannabinoids, particularly with marijuana. It is well documented that marijuana is the most widely used illicit substance in the United States, and many studies, clinicians, and patients have documented marijuana dependence and abuse.³⁰

If both efficacy and side effects are deemed to be substantially equivalent between synthetic cannabinoids and marijuana, cost is typically the decision-maker in the drug selection process. Cannabinoids, particularly the synthetic ones, can be expensive. Marinol has an average price of \$18.00 per 5 mg capsule, while its

generic counterpart, dronabinol, is less expensive at about \$13.00 per 5 mg capsule.³¹ If a one-day dose of four capsules is used for CINV treatment, the cost is about \$72.00 per day for Marinol and \$52.00 per day for generic dronabinol.

Marijuana, on the other hand, is generally less expensive than its synthetic counterparts. One organization located in Michigan, a state permitting use of marijuana for medical purposes, offers a particular variety of marijuana for \$15 per gram. Depending on potency and variety of the marijuana, the condition being treated, patient age, and the length of time that he or she has been using marijuana, the dosing amount can differ significantly. A low dose is reportedly one cigarette or 0.5 grams per day;³² however, average doses of eight grams per day or more have reportedly been used by long-term marijuana patients with a variety of ailments.³³ Based upon the \$15 per gram cost and dose variations, the broad marijuana cost range is \$7.50 – \$120 per day.

Notwithstanding the Schedule I status of marijuana, if synthetic cannabinoids and marijuana are generally considered therapeutic equivalents for a patient who has failed first-line modern drug therapy for CINV, then the higher cost of the synthetics likely makes marijuana a better option, particularly if the patient does not have insurance or the means to pay for the synthetic cannabinoids.^{34,35}

Cannabinoids and the Future

Research on endogenous, plant, and synthetic cannabinoids, their pharmacology, and physiologic effects on diseases and symptomology should continue. In fact, the IOM report specifically recommended that plant-derived and synthetic

cannabinoids, as well as marijuana, be studied for physiologic and therapeutic effects.³⁶ Therapeutic value for synthetic and natural cannabinoids may lie, ironically, in their ability to produce a high. Because a number of patients appear to benefit from the sense of well being produced by THC, studies of the anxiety-alleviating effects of cannabinoids could be valuable, particularly if cannabinoid efficacy, dependence, abuse, and withdrawal are compared to such data for existing anti-anxiety medications such as Valium, Xanax, and others in this drug family.³⁷

There are a variety of factors impacting cannabinoid research that should not be ignored. Researchers report difficulty in obtaining marijuana through official government channels, including the procurement of a DEA Schedule I controlled substances license to obtain and handle government-produced marijuana, as well as government approval of the clinical study and its purpose.³⁸ Maintaining consistency in the chemical composition of marijuana plants and their growing conditions, as well as the ability to compare research results across U.S. and international studies pose challenges. Moreover, patients may cloud symptom alleviation with euphoria or the high that results from marijuana or synthetic cannabinoid ingestion, making it difficult for researchers to identify actual pharmacological effects. Published studies may only involve small numbers of participants, so general application of the study results to larger populations may not be accurate or appropriate.

Nevertheless, exploration of cannabinoids for treatment of pain, muscle spasticity, tumors and other areas where they have shown promise, both individually and as a synergistic component to traditional medications, would contribute important information to the growing body of cannabinoid scholarship.

Based on the current body of scientific literature, some researchers and physicians may believe that marijuana is a viable drug option for certain medical conditions, if even as second or third line therapy.³⁹ The federal government does not agree.

Dim Federal View

The federal government's stance on marijuana has not been consistent. Marijuana was listed as a medicinal drug in the United States Pharmacopoeia as early as the 1850s, and medical use of marijuana continued to be recognized, and legally permitted, after passage of the Marijuana Tax Act in 1937.⁴⁰ Nevertheless, in an about-face just four years later, marijuana was removed from the U.S. Pharmacopoeia and in the process was stripped of its designation as acceptable for medical use.⁴¹

In 1968, the federal government launched a program to grow marijuana and make it available to researchers.⁴² Yet two years later, in 1970, Congress enacted the Federal Controlled Substances Act, which officially classified marijuana as a Schedule I controlled substance because it was deemed to be of high abuse potential and lacking in accepted medical use in the United States.⁴³

Despite the Controlled Substances Act designation of marijuana, the federal government formalized an investigational new drug ("IND") program permitting "compassionate use" of marijuana to research its treatment of medical conditions.⁴⁴ In 1976, the Department of Health, Education, and Welfare ("HEW") approved a petition filed on behalf of a 28-year-old glaucoma patient. Robert Randall requested access to government marijuana for research and treatment purposes for his intractable glaucoma.^{45,46} To support his original federal request, Randall stated that he was subject to a comprehensive medical examination and trials of every available glaucoma

medication, all of which failed to treat his eye condition. The National Institute on Drug Abuse ("NIDA")⁴⁷ resumed supplying Randall with medical marijuana in settlement of a lawsuit that he filed in 1978, paving the way for a modest number of additional individuals and their physicians to petition the federal government for access to medical marijuana through the IND process. Nevertheless, in 1992, The Department of Health and Human Services, the successor to HEW, halted the marijuana IND program and declined to admit new enrollees.⁴⁸ However, NIDA continues to provide government-grown marijuana to a handful of remaining patients.⁴⁹

Federal drug regulatory resources focused more on cocaine than marijuana in the 1980s and into the 1990s.⁵⁰ In particular, tighter federal drug control policy, the "Just Say No" anti-drug campaign, and implementation of the Office of National Drug Control Policy defined the Reagan administration in the 1980s.⁵¹ The George H.W. Bush administration also embraced strong drug control policies. In 1992, the DEA denied a petition to reschedule marijuana from Schedule I to Schedule II, citing a lack of adequate and well-controlled studies proving the drug's efficacy and no expert recognition of its medicinal value.⁵² The Clinton administration did not resume the compassionate use marijuana IND program, and continued strict drug control policies related to marijuana.⁵³

It was during President Clinton's presidency that the DEA saw a rise in medical marijuana advocacy at the state level.⁵⁴ In 1994, the DEA began efforts to assist state and local law enforcement agencies to oppose marijuana legalization.^{55,56} Despite DEA initiatives, five states implemented medical marijuana programs from 2001 to 2008 under the George W. Bush administration.⁵⁷ Although the administration reallocated law enforcement resources, including the DEA, to combat terrorism after the

September 11, 2001, attacks,⁵⁸ it did not waiver in its views against legalization of marijuana for medical purposes.

In notable contrast to its predecessors, the Department of Justice ("DOJ") under President Obama announced a significant shift in federal marijuana policy. In October 2009, Attorney General Eric Holder issued guidelines instructing DOJ attorneys to exercise enforcement discretion, and to decline prosecution of individuals using marijuana in compliance with state medical marijuana programs.⁵⁹ Arguably, this policy conferred a modicum of legitimacy on state medical marijuana initiatives and seriously ill patients seeking relief through such programs. Medical marijuana advocates hailed the guidelines as a humane step in support of seriously ill patients.⁶⁰

Eighteen months later, medical marijuana proponents complained that the administration was not adhering to its 2009 policy. In the spring of 2011, the DEA raided marijuana dispensaries in several states, including Washington, where the DEA seizure of dispensaries' marijuana ironically occurred on the same day that marijuana advocacy groups were teaching classes on raid preparedness.⁶¹ The DOJ then issued another memorandum to DOJ Attorneys in June 2011, stating commercial cultivation or distribution of marijuana is subject to federal criminal prosecution, regardless of whether the operation complies with state law.⁶²

Some medical marijuana proponents decried the 2011 memorandum because it purportedly contradicted the October 2009 guidance, which stated that individuals and caregivers in clear and unambiguous compliance with state medical marijuana laws should not be prosecuted. But the 2009 guidance also stated that a prosecution priority was commercial enterprises selling marijuana for profit, including those that may claim compliance with state law. Moreover,

continued on page 6

The Cannabis Conundrum: Medication v. Regulation

continued from page 5

under the controversial 2005 U.S. Supreme Court decision in *Gonzales v. Raich*, the federal government has broad authority to enforce the federal Controlled Substances Act: individuals' non-commercial, intrastate use of personally grown marijuana, in compliance with state medical marijuana laws, is still subject to federal enforcement action pursuant to the government's larger interstate regulatory scheme.⁶³ While the Obama administration initially adopted a policy to refrain from using its enforcement authority under *Raich*, it has clearly signaled that it will not tolerate "non-profit" medical marijuana dispensaries that operate on a large scale or enjoy excessive financial gains.

Most recently, the DEA dealt a blow to medical marijuana advocates hoping for an expansion of federal support beyond the Obama administration's October 2009 policy. In June 2011 the DEA declined to reclassify marijuana from Schedule I to Schedule III, IV, or V, as requested in a 2002 petition.^{64,65} Pursuant to a memorandum of understanding between the FDA and NIDA describing their collaborative procedures for scheduling of drugs of abuse,⁶⁶ the FDA performed a medical evaluation of marijuana and concluded, with the concurrence of NIDA, that eight factors supported general control of marijuana through the federal Controlled Substances Act, and that marijuana additionally met the three factors required to specifically categorize it in Schedule I. The eight factors evaluating drug control, set forth in 21 U.S.C. § 811(c), generally consider pharmacological effects, safety, and data on abuse and dependence.⁶⁷ The three criteria specific to Schedule I classification assess whether marijuana has a high substance abuse potential, has any currently accepted medical use in treatment, and lacks accepted safety criteria for use under medical supervision.⁶⁸

Although the DEA retained marijuana in Schedule I of the Controlled Substances Act, it is not clear whether its June 2011 decision considered data from the decades-old "compassionate use" IND marijuana program in which NIDA provided marijuana to participating patients. The DEA's decision cited only one study related to the program.^{69,70} The petitioner submitted the 2002 Russo study, which evaluated four of the remaining seven compassionate use IND program patients. The study stated that marijuana exerted clinical effectiveness in treating the patients' illnesses, and that only mild adverse physiological effects were observed relating to lung functioning.⁷¹ However, the DEA dismissed the study as inadequate based on the small number of patients involved, and it does not appear that the FDA or NIDA considered the study.⁷²

The DEA's staunch stance against medical marijuana has not stymied federal legislators. While the states have been implementing medical marijuana programs since the mid-1990s, federal legislation has been regularly proposed to reclassify marijuana for medical purposes.⁷³

One of the most prolific supporters of pro-medical marijuana legislation is Massachusetts Congressman Barney Frank. In fact, since 1995, Congressman Frank has continuously introduced legislation to move marijuana from Schedule I to Schedule II under bill names such as the "Medical Use of Marijuana Act" and the "States' Rights to Medical Marijuana Act."⁷⁴ He has not succeeded in this endeavor to date. Nevertheless, Congressman Frank introduced two bills in 2011 aimed at making medical marijuana more accessible.⁷⁵ Unlike his previous bills to reschedule marijuana to Schedule II, the States' Medical Marijuana Patient Protection Act ("Act") directs the Secretary of

Health and Human Services, in cooperation with the IOM, to recommend to the DEA that marijuana be listed in any controlled substances schedule other than Schedules I or II.⁷⁶ The proposed Act further requires the DEA to issue a notice of proposed rulemaking for the scheduling of marijuana as anything other than a Schedule I or Schedule II substance. The proposed Act ignores the established roles of the FDA and the NIDA in evaluating the scientific and medical factors that may make a drug prone to abuse and their roles in recommending whether a substance should be controlled.⁷⁷ Instead, the Act delegates those roles to the IOM, which is a private organization and author of the landmark 1999 report, *Marijuana and Medicine Assessing the Science Base*, that is discussed earlier in this article.⁷⁸ The bill outlining the Act was referred to the House Subcommittee on Health on June 3, 2011, and no further action has been taken as of November 2011.⁷⁹

More recently, Congressman Frank introduced a bill entitled "Ending Federal Marijuana Prohibition Act of 2011."⁸⁰ The June 2011 bill proposes two major amendments to existing law: it removes marijuana from Schedule I and it seeks to limit application of federal marijuana laws to consumption, distribution, and other purposes. Specifically, the bill would make marijuana a non-controlled substance under federal law and would allow an individual to transport or ship marijuana across state lines, without running afoul of federal law, so long as the transported or shipped marijuana is not intended to be received, possessed, or sold in violation of state law.⁸¹ On August 25, 2011, this bill was referred to the Subcommittee on Crime, Terrorism, and Homeland Security, and no further action has been taken.⁸²

While the marijuana battle rages at the federal level, the states are taking matters into their own hands.

State of Medical Marijuana Affairs

Despite the federal designation of marijuana as a Schedule I controlled substance that has no currently accepted medical use,⁸³ states are increasingly turning their backs on the federal government and forging their own regulatory paths. By recognizing therapeutic value in marijuana and believing that the benefits outweigh risks, states are effectively usurping the role of the FDA as the exclusive U.S. arbiter of what is a safe and effective drug.⁸⁴ In fact, 17 U.S. jurisdictions (16 states and the District of Columbia) have passed laws permitting their residents to ingest marijuana for medical purposes: Alaska, Arizona, California, Colorado, Delaware, Hawaii, Maine, Michigan, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, and Washington.⁸⁵

Although it is beyond the scope of this article to address all state “compassionate” marijuana programs, state laws and regulations commonly address issues such as implementation of patient registries through departments of public health and the designation of medical conditions for which marijuana may be used. For example, most states permit marijuana use to treat cachexia (weight loss and physical wasting due to chronic disease), including Alaska, Nevada, Oregon, Rhode Island, and Vermont.⁸⁶ Delaware and New Mexico permit marijuana use for treatment of post-traumatic stress disorder.⁸⁷ These laws also commonly establish criteria for medical marijuana dispensaries, such as location, business model, restrictions or prohibition of on-site consumption, and quantity limits for individuals who possess or grow marijuana for personal medical use. Unlike most jurisdictions that have enacted medical marijuana laws, Delaware, New Jersey, and the District of Columbia prohibit patients from growing marijuana at home for medical purposes.^{88,89}

State medical marijuana programs also typically set standards for

recommending marijuana for medical use. These standards run the gamut from broad and permissive to narrow and rigid. For instance, the District of Columbia requires a comprehensive assessment before a physician can recommend medical marijuana. After reviewing “other approved medications and treatments that might provide the qualifying patient with relief,” the physician must then determine that medical marijuana “is necessary” in order to recommend it.⁹⁰ On the other hand, Colorado regulations establish a relatively low “patient might benefit” threshold when physicians are evaluating whether to recommend marijuana for an individual diagnosed with a state-defined debilitating medical condition.⁹¹

In contrast, New Mexico promulgated a much more stringent regulation: before recommending medical marijuana, other medical therapies must be utilized for the patient’s qualifying medical condition, these therapies must have failed, and the patient must have current, unrelieved symptoms.⁹² New Mexico medical certification also requires that a practitioner attest that the patient has one of the state-recognized debilitating medical conditions and that the benefits of the medical use of marijuana outweigh its health risks.

Interestingly, New Mexico permits appropriately licensed nurse practitioners and physician’s assistants, as well as physicians, to write a certification for medical cannabis.⁹³ Certain debilitating medical conditions require additional supporting documentation as part of the New Mexico certification process. For example, glaucoma must be diagnosed by an ophthalmologist, and severe chronic pain requires two medical certifications from a primary care provider and a specialist with expertise in pain management or the physiological process that causes the pain.⁹⁴

California Sets the Stage

California was the first jurisdiction to decriminalize use and cultivation of marijuana under its Compassionate Use Act of 1996;⁹⁵ however, marijuana

remains a Schedule I substance under the California Uniform Controlled Substances Act.⁹⁶ Given California’s 15 years of experience in medical marijuana matters, its program requirements will be the focus of this state regulation discussion.

The California Medical Marijuana Program (“Program”), codified in § 11362.7, et. seq. of the Health and Safety Code, establishes requirements for physicians to recommend marijuana to patients and the government qualification process for individuals seeking to obtain marijuana for medical purposes. The Program mandates that a validly licensed California attending physician physically examine a patient and determine whether the patient has a serious medical condition for which marijuana may be appropriate. California broadly defines “serious medical condition” to include arthritis, migraines, cancer, multiple sclerosis, seizures, severe nausea, and any other chronic or persistent medical symptom that substantially limits a major life activity or, if not alleviated, may cause serious harm to a patient’s safety or physical or mental health.⁹⁷

Unlike New Mexico, whose regulations require failure of non-marijuana medical therapies before a practitioner can recommend marijuana, the Medical Board of California published guidelines for physicians to consider when recommending medical marijuana for patients, stating that a patient need not wait until all standard medications have been tried, and failed, before recommending marijuana.⁹⁸ Instead, the physician must determine that the risk/benefit ratio of medical marijuana is as good or better than other medications that could be used for the patient. The California guidelines for physician-recommended marijuana anticipate that a medical history, in-person examination, discussion of side effects, and a treatment plan, with periodic review for efficacy, would occur. Nevertheless, these guidelines do not require or specifically

continued on page 8

The Cannabis Conundrum: Medication v. Regulation

continued from page 7

recommend that other medications be tried prior to marijuana, particularly medications regarded as first line therapy by clinical practitioners.⁹⁹

In some instances, compliance with the California risk/benefit medical marijuana guidelines may not provide optimal care for patients. Specifically, the guidelines may permit less effective drugs to be used for treatment. For example, medical evidence and specialty physician associations support the preferential use of modern drugs like Zofran and Emend with a steroid for treatment and prevention of CINV.¹⁰⁰ But studies comparing marijuana and older anti-nausea medications show marijuana is as good, or better, than the older medications in ameliorating CINV.¹⁰¹ Accordingly, under California Medical Board guidelines, marijuana could be recommended for CINV if its safety risks are generally equivalent to the older CINV drugs.¹⁰² Because California does not require that “standard medical therapy” be tried and fail prior to a physician recommending marijuana, California patients using medical marijuana for CINV may be receiving substandard care if these patients have never even tried the modern drugs for prevention and treatment of CINV.

On the other hand, strict adherence to California Medical Board guidelines could be viewed as creating unnecessary obstacles to certain patient populations seeking to use marijuana to alleviate suffering. For example, requiring a pre-recommendation physical examination, standard evaluation of marijuana risks and benefits, or discussion of marijuana addiction or dependence side effects are likely irrelevant to some terminally ill patients and could delay access to those whose remaining days on earth are few.^{103,104,105,106,107}

Controlled Access

The sheen on the California medical marijuana program is losing its luster in some communities. In Anaheim, medical marijuana opponents won a significant victory when the Superior Court in Orange County California ruled that the city’s ban on medical marijuana dispensaries was a valid exercise of its constitution-granted powers and was not pre-empted by state medical marijuana laws.¹⁰⁸ Anaheim enacted the prohibition, pursuant to its nuisance ordinance, in an attempt to limit mass distribution of medical marijuana.

More recently, Los Angeles responded to neighborhood activists’ complaints and a significant increase in dispensaries from four in June 2005 to hundreds by the end of 2009. The city passed an ordinance capping at 70 the number of dispensaries that will be permitted to provide medical marijuana.^{109,110} The ordinance also requires that the dispensing organizations be proportionally distributed throughout the city based on population in a designated neighborhood. On October 14, 2011, the Superior Court in Los Angeles County, California denied injunctive relief to a coalition of medical marijuana advocates and dispensaries that sued Los Angeles over its capping ordinance. The Court upheld the ordinance, declaring that it did not establish an arbitrary process to limit dispensaries.¹¹¹

Efforts to better control access are spreading to other states’ communities. A hotly contested proposal to ban medical marijuana dispensaries was put to a vote in Fort Collins, Colorado in November 2011. Residents voted to prohibit medical marijuana dispensaries from doing business in the city and to require those that are currently operating to close in 90 days.¹¹²

However, medical marijuana advocates are concerned that delays in implementing medical marijuana laws

harm patients, particularly those for whom marijuana is the only effective therapy. The District of Columbia and New Jersey enacted their medical marijuana laws in 2010, but marijuana is not yet available through dispensaries (and qualified patients are prohibited from growing their own marijuana plants). After approving a medical marijuana program in 1998, D.C. voters had to wait 12 years for enactment of its law because Congress continued to block the program until 2010.¹¹³ The first of five dispensaries permitted under the D.C. medical marijuana law is not expected to begin offering medical marijuana until 2012. The volume of inquiries about D.C.’s open application and selection processes, as well as required rulemaking procedures, are causing implementation to take longer than anticipated.¹¹⁴

New Jersey’s medical marijuana law was supposed to become effective six months after it was signed into law on January 18, 2010.¹¹⁵ Newly elected governor Chris Christie took office one day later, and implementation of the medical marijuana program has been slowed due to disagreement among the legislature, the state health department, and the governor’s office on a variety of issues. Background checks for proprietors of dispensaries, known as “alternative treatment centers” in New Jersey, the selection process for organizations applying to become treatment centers, and concerns that state employees of the medical marijuana program could be federally prosecuted for facilitating the availability of marijuana continue to hamper program implementation.¹¹⁶

Noxious Weed

Some proprietors of medical marijuana dispensaries bring an entrepreneurial spirit to their activities. Home delivery services are offered and savvy operators use social media, such as Twitter and Facebook, to provide medical marijuana-related

information to subscribers and facilitate communications with patients.¹¹⁷

However, certain aspects of the business of medical marijuana undermine well-intentioned efforts to expand marijuana research and provide seriously ill patients with access to the medicinal plant. For example, some medical marijuana names are absurd, such as AK 47, Cat Piss, Sour Diesel, and Mr. Nice.¹¹⁸ Although experienced users may be able to identify the type of marijuana by such names, the nomenclature likely confuses those new to medical marijuana and does not readily identify the cannabinoid content or potency of the marijuana product. If the physician or healthcare provider recommending medical marijuana does not fully discuss appropriate dosing or cannabinoid content, or does not have such knowledge, then naïve patients may select the product on their own or may seek such advice from dispensary staff, who may not have appropriate training or education.¹¹⁹

Moreover, some of the pageant-like celebrations and contests centered around medical marijuana, such as the Doesha Cup, which includes a cannabis tasting competition, on site “medicating,” and celebrity appearances are of dubious merit.¹²⁰ News articles describing individuals who submit unsigned or suspicious physician recommendations for medical marijuana and undercover reporters who easily obtain medical marijuana registration cards based on questionable medical complaints further fuel regulators’ concerns.¹²¹ The totality of these elements of the medical marijuana industry may unwittingly support the efforts of medical marijuana opponents and hamper seriously ill patients’ access to medical marijuana.

In addition, crimes involving medical marijuana patients and dispensaries are taxing law enforcement authorities that are already facing dwindling resources. In 2009, the California

Police Chiefs Association issued a white paper with sobering details of murders, burglaries, shootings, and theft related to medical marijuana dispensaries, their operators, and patients.¹²² The founder of two California medical marijuana dispensaries was shot and killed in his home in November 2005, and law enforcement authorities believed it was related to his marijuana cultivation and dispensing.¹²³ Medical marijuana dispensaries throughout California have been subject to attack, with perpetrators stealing marijuana and/or cash in a number of burglaries perpetrated over the years. In July 2011, three men attempted to rob a San Diego medical marijuana dispensary using pepper spray, but were thwarted by employees who activated the locks on security doors.¹²⁴ Reports of California marijuana dispensary customers being held-up at gunpoint and assaulted by robbers only add to law enforcement agencies’ concerns about the safety of medical marijuana operations and whether stricter controls are required.¹²⁵

Medical marijuana-related crimes are not limited to California. Arizona, New Mexico and Washington recently reported theft and assault crimes tied to medical marijuana.¹²⁶ Less restrictive oversight of dispensaries, lower standards for physicians to recommend medical marijuana, the proliferation of dispensaries, difficulty controlling patients who may sell or transfer medical marijuana to non-registered individuals, and cash transactions all reportedly contribute to medical marijuana crime and diversion.¹²⁷

Yet not all law enforcement officials are convinced that medical marijuana dispensaries result in increased crime. The Denver Police Department compared crime statistics for December 2008 and December 2009, which were collected for crimes committed within 1,000 feet of dispensary locations.¹²⁸ In December 2008, no dispensaries were operating;

in December 2009 hundreds of dispensaries had newly opened. The Denver Police Department was unable to determine if having a dispensary in the area resulted in an overall increase in crime.¹²⁹ Although the total number of reported crimes within 1,000 feet of dispensaries decreased by 3.7 percent and violent crime declined or remained the same, loitering and criminal mischief increased.¹³⁰

The Los Angeles police chief stated in 2010 that banks were more likely to get robbed than medical marijuana dispensaries.¹³¹ A 2009 police department analysis of citywide robberies did not demonstrate an increase due to medical marijuana dispensaries.¹³² However, the police chief qualified the analysis by stating that some dispensaries may not report robberies and ATM crimes were not included in the data.¹³³ Notwithstanding the robberies analysis, the chief recommended that medical marijuana diversion, including unlawful sales, be considered in any evaluation of medical marijuana dispensary regulation. The chief also supported increased dispensary oversight and a limit on the number of operating dispensaries in Los Angeles.^{134,135}

Conclusion

The ability to satisfy all stakeholders in the medical marijuana juggernaut seems largely illusory. However, when traditional medications fail patients who have serious or debilitating illnesses and no other viable treatment options are available, providing access to marijuana for medical purposes is humane and arguably a form of public health protection. The mechanism for providing access to marijuana needs to be better controlled in many cases. Permitting marijuana to be used in lieu of traditional or peer-recommended medications, or pursuant to an appropriate medical evaluation, disregards the patient’s best interests and promotes diversion of a widely abused controlled

continued on page 10

The Cannabis Conundrum: Medication v. Regulation

continued from page 9

substance. Moreover, reported difficulties in obtaining and researching marijuana should be identified and resolved. Cannabinoid research should be expanded, particularly studies comparing marijuana and its synthetic counterparts to standard medication regimens. Promoting scholarship in areas such as “designer” cannabinoids that provide maximum therapeutic benefit and minimize undesirable effects may ultimately help bridge the gap between the needs of the medical marijuana community and the obligations of law enforcement agencies.

Moira Gibbons is a pharmacist and an attorney, and currently serves as the legal affairs senior manager for the National Association of Boards of Pharmacy (“NABP”). She oversees legal matters for NABP including contracts, litigation, and intellectual property. Prior to joining NABP in 2000, Ms. Gibbons was a prosecuting attorney for the Illinois Department of Financial and Professional Regulation and represented the Department in licensure hearings concerning pharmacists, nurses, and dentists. Ms. Gibbons is a graduate of the University of Illinois at Chicago College of Pharmacy and Loyola University Chicago School of Law. The views expressed herein are solely Ms. Gibbons’ and are not attributable to NABP or any other organization or person. Ms. Gibbons may be reached at mgibbons@nabp.net.

Endnotes

- 1 Marijuana is not native to the continental United States. Hemp was introduced to New England in the 1600s by, ironically, the Puritans who brought it to New England for household use in weaving. Hemp cultivation in the states increased throughout the 1700s and 1800s, where it was used for cordage and sails for ships. U.S. Dept. of Agriculture, *Industrial Hemp in the United States*, <http://www.ers.usda.gov/publications/ages001e/ages001ec.pdf> (accessed Oct. 9, 2011).
- 2 U.S. Dept. Agriculture, Natural Resources Conservation Service, *Plants Database*, <http://plants.usda.gov/java/profile?symbol=CASA3> (accessed Apr. 10, 2011).
- 3 *Id.* at <http://plants.usda.gov/java/noxious> Driver (accessed Apr. 10, 2011).
- 4 505 Ill. Comp. Stat. § 100/1 (2011).

- 5 Ill. Admin. Code tit. 8, pt. 220 (2002).
- 6 Kenneth Mackie, Presentation, *The Scientific Side of Medical Marijuana*, (Natl. Assn. Bds. of Pharm. Fall Symposium, Dec. 3, 2009), available at <http://www.nabp.net/events/past-educational-sessions/symposium/>. Examples of human cannabinoid receptors include CB₁ and CB₂ receptors located in the brain and body tissues to which internal, or endogenous, cannabinoids and Δ⁹-tetrahydrocannabinol may bind.
- 7 Sunil K. Aggarwal & Gregory T. Carter, Presentation, *Cannabis in the Treatment of Chronic Pain*, (Natl. Assn. Bds. of Pharm. Fall Symposium, Dec. 3, 2009), available at <http://www.nabp.net/events/past-educational-sessions/symposium/>.
- 8 *Id.*
- 9 21 U.S.C. § 355(b)(1)(A) (2008).
- 10 21 U.S.C. § 812(b)(1) (2010).
- 11 *See Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002).
- 12 *See* Janet E. Joy, Stanley J. Watson, Jr., & John A. Benson, Jr., Editors, *Marijuana and Medicine Assessing the Science Base*, (Inst. of Med. 1999), available at http://medicalmarijuana.procon.org/sourcefiles/IOM_Report.pdf. Since 1970, the independent, nonprofit Institute of Medicine has served as an advisor to the government, public, and private sector on a variety of healthcare issues. *See* <http://www.iom.edu/About-IOM.aspx>.
- 13 The Office of National Drug Control Policy (“ONDCP”) was established in 1988 as a component of the Executive Office of the President and advises the President on drug control issues, among other things. ONDCP also produces the National Drug Control Strategy. *See* <http://www.whitehouse.gov/ondcp/about>.
- 14 U.S. Drug Enforcement Admin., *Exposing the Myth of Medical Marijuana*, <http://www.justice.gov/dea/ongoing/marijuanap.html> (accessed Oct. 9, 2011) [emphasis DEA].
- 15 *See* Joy, *supra* n. 12, at 7.
- 16 *See, e.g.*, N.J. Sen. Health, Human Serv. and Senior Citizens Comm., *New Jersey Compassionate Use Medical Marijuana Act*, 213th Leg., Reg. Sess. 2a (January 18, 2010), available at http://www.njleg.state.nj.us/2008/Bills/S0500/119_R3.HTM. For other states’ regulations and legislation addressing medical use of marijuana, visit ProCon.org at <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881>.
- 17 The generic name for Marinol is dronabinol. *See* RxList, *Marinol*, <http://www.rxlist.com/marinol-drug.htm> (last reviewed May 29, 2008) (accessed Nov. 9, 2011).
- 18 The generic name for Cesamet is nabilone. RxList, *Cesamet*, <http://www.rxlist.com/cesamet-drug.htm> (last reviewed Feb. 26, 2009) (accessed Nov. 9, 2011).
- 19 F.C. Machado Rocha, S.C. Stéfano, R. De Cássia Haiek, L.M.Q. Rosa Oliveira, & D.X. Da Silveira, *Therapeutic Use of Cannabis Sativa*

on Chemotherapy-Induced Nausea and Vomiting Among Cancer Patients: Systematic Review and Meta-Analysis, 17 Euro. J. Cancer Care. 431, 440 (2008).

- 20 Richard E. Musty & Rita Rossi, *Effects of Smoked Cannabis and Oral Δ⁹-Tetrahydrocannabinol on Nausea and Emesis After Cancer Chemotherapy: A Review of State Clinical Trials*, 1 J. Cannabis Therapeutics 29, 53 (2001).
- 21 Sunil K. Aggarwal, Gregory T. Carter, Mark D. Sullivan, et.al., *Medicinal Use of Cannabis in the United States: Historical Perspectives, Current Trends, and Future Directions*, 5 J. Opioid Mgt. 153, 156 (May/June 2009).
- 22 *See* Joy, *supra* n. 12, at 110-111. *See also* GlaxoSmithKline, *Prescription Medicines – Zofran*, http://us.gsk.com/products/assets/us_zofran.pdf (accessed Nov. 8, 2011). *See also* Kristi Monson, Arthur Schoenstadt, *Zofran*, <http://cancer.emedtv.com/zofran/zofran.html> (accessed Nov. 8, 2011). The generic name for Zofran is ondansetron, and it is a serotonin receptor antagonist.
- 23 Merck & Co., Inc., *Prescription Products – Emend*, http://www.merck.com/product/usa/pi_circulars/e/emend/emend_pi.pdf, (accessed Nov. 8, 2011). The generic name for Emend is aprepitant, and it is a substance P/neurokinin 1 receptor antagonist.
- 24 Am. Soc. of Health Sys. Pharmacists, *American Hospital Formulary Service Drug Information*, 2969 (ASHP 2011) (noting that the American Society of Clinical Oncology currently recommends a three drug antiemetic regimen consisting of a serotonin receptor antagonist such as Zofran, dexamethasone, and Emend).
- 25 A study comparing smoked marijuana and the serotonin receptor antagonist ondansetron (Zofran) on nausea induced by ipecac, a non-chemotherapeutic agent, showed ondansetron was superior to marijuana, which exerted only modest anti-nausea/vomiting effects. *See* Anna H. Söderpalm, Alyson B. Schuster & Harriet de Wit, *Antiemetic Efficacy of Smoked Marijuana: Subjective and Behavioral Effects on Nausea Induced by Syrup of Ipecac*, 69 Pharmacology, Biochemistry, and Behavior 343 (March/April 2001).
- 26 *See also* Joy, *supra* n. 12, at 111. The 1999 IOM report states that smoked marijuana, like cannabinoids, was apparently effective in treating chemotherapy-induced vomiting in some studies, but efficacy was no greater than that of available antiemetic agents [the “old school” drugs discussed in this article], and that the most effective regimens are oral serotonin receptor antagonists [one of the “modern” drugs discussed in this article such as Zofran] with dexamethasone.
- 27 *Id.* at 161.
- 28 Subject to inter-patient variability and dosage, the adverse effect profiles for cannabinoids and marijuana are relatively similar and include increased heart rate, low blood pressure and fatigue, as well as euphoria, detachment, and drowsiness, which are common central nervous system side effects of cannabinoids.

- 29 On the other hand, geriatric patients and those who are naïve to cannabinoids may not tolerate these substances due to disorientation, depression, paranoia and even hallucinations.
- 30 See Alan J. Budney, Roger Roffman, Robert S. Stephens & Denise Walker, *Marijuana Dependence and Its Treatment*, 4 *Addiction Sci. & Clinical Prac.* 4, 5 (Dec. 2007). Research also shows that dependent marijuana users can experience withdrawal symptoms, particularly in long-term users.
- 31 Synthetic cannabinoid prices reflect an average of prices provided by two Chicago-area pharmacies, a national chain pharmacy and a hospital outpatient pharmacy in May 2011.
- 32 ProCon.org, *How Does the Cost of Marijuana Compare to the Cost of Marinol?*, available at <http://medicalmarijuana.procon.org/view.answers.php?questionID=91> (accessed Aug. 15, 2011).
- 33 See Sunil K. Aggarwal, Muraco Kyashna-Tocha, & Gregory T. Carter, *Dosing Medical Marijuana: Rational Guidelines on Trial in Washington State*, 9 *Medscape Gen. Med.* 52 (Sept. 2007).
- 34 Affordability of cannabinoids poses interesting public policy issues that no doubt affected the implementation of some state medical marijuana programs, but such issues are beyond the scope of this article.
- 35 A new cannabinoid medication may be on its way. Developed by a company in the United Kingdom, Sativex is a mouth spray that contains two cannabinoids, THC and cannabidiol, both of which are extracted from the *Cannabis sativa* plant. It is in Phase III clinical trials in the United States for treatment of cancer pain that is inadequately responding to conventional medications, but has not yet been approved by the FDA. GW Pharmaceuticals, *Sativex*, <http://www.gwpharm.com/Sativex.aspx> (accessed Nov. 4, 2011). See also GW Pharmaceuticals, *FAQs – Where is Sativex available?*, <http://www.gwpharm.com/faqs.aspx> (accessed Nov. 4, 2011).
- 36 See Joy, *supra* n. 12, at 3, 7.
- 37 For example, marijuana withdrawal symptoms appear to be mild compared to those from benzodiazepines, the family of drugs that includes diazepam (Valium). *Id.* at 42. Further, withdrawal symptoms in marijuana-dependent individuals may generally last one to three weeks, whereas the duration of such symptoms in benzodiazepine-dependent individuals may last for weeks or months. See Alan J. Budney, *Are Specific Dependence Criteria Necessary for Different Substances: How Can Research on Cannabis Inform This Issue?*, 101 *Addiction* (Supp. 1) 126 (2006); Steve R. Onyett, *The Benzodiazepine Withdrawal Syndrome and Its Management*, 39 *J. Royal Coll. Gen. Pract.* 160, 161 (Apr. 1989).
- 38 The federal government is the only legal producer of marijuana for medical research in the United States. See Am. College of Phys., *Supporting Research into the Therapeutic Role of Marijuana*, 1, 7 (ACP 2008).
- 39 Of the few studies that have evaluated smoked cannabis in patients with neuropathic pain, the results have led some researchers to suggest that cannabinoid therapy may be an effective option in patients who fail to achieve pain relief using traditional first line medications such as opiates and nonsteroidal anti-inflammatory medications (e.g. ibuprofen). See, e.g., Barth Wilsey, Thomas Marcotte, Alexander Tsodikov, et. al., *A Randomized, Placebo-Controlled, Crossover Trial of Cannabis Cigarettes in Neuropathic Pain*, 9 *J. Pain* 506 (Jun. 2008); Ronald J. Ellis, Will Toperoff, Florin Vaida, et. al., *Smoked Medicinal Cannabis for Neuropathic Pain in HIV: A Randomized, Crossover Clinical Trial*, 34 *Neuropsychopharm.* 672, (Feb. 2009), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3066045/?tool=pubmed> (accessed Oct. 22, 2011). See also, N. Attal, G. Cruccu, R. Baron, et. al., *EFNS Guidelines on the Pharmacological Treatment of Neuropathic Pain: 2010 Revision*, 17 *Euro. J. Neuro.* 1113, 1115 (Sept. 2010), available at <http://www.efns.org/Guideline-Archive-by-topic.389.0.html> (accessed Oct. 22, 2011).
- 40 Kathleen Ferraiolo, *From Killer Weed to Popular Medicine: The Evolution of American Drug Control Policy 1937: 2000*, 19 *J. Policy History Vol.*, 147, 153-155 (2007). The Marihuana Tax Act of 1937 imposed taxes on the importation, manufacture, prescribing, dispensing, administering, and giving away of marijuana, established registration requirements, and set forth penalties if tax payments were not made.
- 41 During the 1930s, the Federal Bureau of Narcotics (“FBN”), a predecessor of the DEA, took steps to increase control of marijuana by supporting the Marihuana Tax Act and warning the public of serious dangers associated with marijuana. Despite requests from the American Medical Association for evidence of the reported dangers, the Marihuana Tax Act was enacted and FBN continued its efforts. In fact, FBN reportedly was a primary force behind the removal of marijuana from the U.S. Pharmacopoeia. *Id.* at 154-55.
- 42 ProCon.org, *Did You Know? Little Known Facts in the Medical Marijuana Debate*, available at <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000091> (accessed Nov. 9, 2011).
- 43 U.S. Drug Enforcement Admin., *Drug Scheduling*, <http://www.justice.gov/dea/pubs/scheduling.html> (accessed Aug. 6, 2011). Other substances currently designated as Schedule I drugs include PCP, Ecstasy, and heroin.
- 44 Natl. Inst. on Drug Abuse, *Provision of Marijuana and Other Compounds for Scientific Research – Recommendations of the National Institute on Drug Abuse National Advisory Council*, <http://archives.drugabuse.gov/about/organization/nacda/MarijuanaStatement.html> (January 1998) (accessed Aug. 7, 2011).
- 45 Robert Randall, 53; *Sued for Marijuana*, N.Y. Times Archives, <http://www.nytimes.com/2001/06/08/us/robert-randall-53-sued-for-marijuana.html> (June 8, 2001) (accessed Aug. 6, 2011).
- 46 Alice O’Leary, Speech. *A Remembrance of Bob Randall*, (Santa Barbara, Cal., Apr. 7, 2006), http://www.drugscience.org/Archive/bcr1/n1_oleary1.html (accessed August 6, 2011).
- 47 Natl. Inst. On Drug Abuse, *About NIDA*, <http://www.nida.nih.gov/about/welcome/milestones/Milestones.html>, (accessed Oct. 22, 2011). The U.S. government established the National Institute on Drug Abuse (“NIDA”) in 1974; it became a part of the National Institutes of Health in 1992. NIDA seeks to focus on scientific research to answer questions about drug abuse and addiction.
- 48 Natl. Inst. on Drug Abuse, *Drug Facts Chat Day 2009 – The Transcript*, <http://drugfactsweek.drugabuse.gov/chat/2009/index.php> (accessed Aug. 6, 2011).
- 49 *Id.*
- 50 See generally Frontline, *Thirty Years of American’s Drug War – A Chronology*, <http://www.pbs.org/wgbh/pages/frontline/shows/drugs/cron/> (Oct. 2000) (accessed Nov. 9, 2011).
- 51 See generally *Id.*
- 52 *DEA History Book Part 2 3*, <http://www.justice.gov/dea/pubs/history/> (accessed Aug. 7, 2011).
- 53 See Frontline, *supra* n. 50.
- 54 See generally ProCon.org, *16 Legal Medical Marijuana States and DC, Laws, Fees, and Possession Limits Summary Chart*, <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881> (accessed Nov. 9, 2011). Alaska, California, Colorado, Hawaii, Maine, Nevada, Oregon, and Washington passed laws permitting use of marijuana for medical purposes during the William J. Clinton administration.
- 55 *Id.* at 27.
- 56 Natl. Crim. Just. Ref. Serv., *Speaking Out Against Drug Legalization*, <http://www.ncjrs.gov/App/Publications/abstract.aspx?ID=158530> (1994) (accessed Oct. 23, 2011). See also U.S. Drug Enforcement Admin., *A Message from the Drug Enforcement Administration*, <http://www.justice.gov/dea/demand/speakout/director.htm> (2010) (accessed Oct. 23, 2011). In August of 1994, the DEA held an “Anti-Legalization Forum” in Quantico, Virginia, in which police chiefs, government representatives, and members of the private sector participated to identify arguments against drug legalization and effective communication methods. Following the forum, the DEA issued a report citing 10 major bases for its opposition to drug legalization, including increased crime, proliferation of drug addiction, and the fact that there are no compelling medical reasons to prescribe marijuana to sick individuals.
- 57 ProCon.org, *supra* n. 54 (accessed Aug. 7, 2011). Michigan, Montana, New Mexico, Rhode Island, and Vermont passed laws permitting use of marijuana for medical purposes during the George W. Bush administration.
- 58 See, e.g., U.S. Drug Enforcement Admin., *Fact Sheet: Justice Department Counter-Terrorism Efforts Since 9/11*, <http://www.justice.gov/opa/pr/2008/September/08-nsd-807.html> (Sept. 2008) (accessed Oct. 23, 2011). The DEA has assisted Afghan authorities in targeting terrorist organizations funded through illicit drug transactions, and has worked with its counterparts to gather intelligence on illicit drug manufacturing and trafficking routes in Afghanistan.
- 59 Memo from David W. Ogden, Deputy Attorney General, to Selected United States Attorneys, *Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana* (Oct. 19, 2009) available at <http://blogs.usdoj.gov/blog/archives/192> (accessed Aug. 7, 2011).

continued on page 12

The Cannabis Conundrum: Medication v. Regulation

continued from page 11

- 60 CBS/AP, *Medical Marijuana Arrest Guidelines Eased*, <http://www.cbsnews.com/stories/2009/10/19/politics/main5395248.shtml> (Nov. 9, 2009) (accessed Nov. 9, 2011).
- 61 Rob Kauder, *Authorities Raid Spokane Medical Marijuana Dispensaries*, <http://www.kxly.com/news/27708933/detail.html> (April 28, 2011) (accessed Aug. 7, 2011).
- 62 C.J. Ciaramella, *Justice Department and Obama Reverse Stance on Medical Marijuana Raids*, <http://dailycaller.com/2011/07/01/justice-department-and-obama-reverse-stance-on-medical-marijuana-raids/> (July 1, 2011) (accessed Aug. 13, 2011).
- 63 See *Gonzales v. Raich*, 545 U.S. 1 (2005).
- 64 76 Fed. Reg. 40551 (July 8, 2011), available at <http://www.gpo.gov/fdsys/pkg/FR-2011-07-08/html/2011-16994.htm>.
- 65 In 1972, two years after the federal Controlled Substances Act was passed, the National Organization for the Reform of Marijuana Laws ("NORML") filed the first petition to remove marijuana from Schedule I. See *NORML, et. al., v. Ingersoll*, 497 F.2d 654, (D.C. Cir. 1974). After 22 years of legal wrangling, the United States Court of Appeals for the District of Columbia denied NORML's and its fellow petitioners' petition to review the 1989 DEA order. The DEA refused to reschedule marijuana on the basis that that it had no accepted medical use. *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, (D.C. Cir. 1994), available at <http://law.justia.com/cases/federal/appellate-courts/F3/15/1131/536307/> (accessed Oct. 29, 2011).
- 66 U.S. Food and Drug Administration, *MOU 225-85-8251 Memorandum of Understanding Between the National Institute on Drug Abuse and the Food and Drug Administration*, <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116365.htm> (December 1984) (accessed Oct. 23, 2011).
- 67 The eight factors that are determinative of control or removal from controlled substance schedules, pursuant to 21 U.S.C. § 811(c), are: 1) actual or relative potential for abuse; 2) scientific evidence of pharmacological effect, if known; 3) state of current scientific knowledge regarding the drug; 4) history and current pattern of abuse; 5) scope, duration and significance of abuse; 6) what, if any, risk there is to public health; 7) its psychotic or physiological dependence liability; and 8) whether the substance is an immediate precursor of a substance that is already controlled under the federal Controlled Substances Act.
- 68 21 U.S.C. § 812(b)(1) (2010).
- 69 Ethan Russo, Mary Lynn Mathre, Al Byrne, Robert Velin, et. al., *Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis*, 2 J. Cannabis Therap. 3, 51 (2002), available at <http://medicalmarijuana.procon.org/sourcefiles/RussoChronicCannabisUse.pdf>.
- 70 Patients Out of Time, *Presentations for the Second Clinical Conference on Cannabis Therapeutics*, Portland, OR May 2-3, 2002, <http://www.medicalcannabis.com/Video/2002-conference-videos> (accessed Nov. 8, 2011).
- 71 *Id.* at 4.
- 72 Beyond the 2002 Russo study, it is not clear what other data has been collected from the compassionate use IND marijuana program and, if the data is available, why it was not considered in the June 2011 DEA decision. About thirty patients have participated in the compassionate use IND marijuana program since its inception in 1978. This program seemingly represents a solid opportunity to collect and evaluate abuse, efficacy, and safety data for long-term use of standardized, government-approved cannabis, and whether marijuana continues to meet the three criteria requiring its current Schedule I status. See ProCon.org, <http://medicalmarijuana.procon.org/view.answers.php?questionID=257> (accessed Nov. 8, 2011); see also Patients Out of Time, *Presentations for the Second Clinical Conference on Cannabis Therapeutics*, Portland, OR May 2-3, 2002, <http://www.medicalcannabis.com/Video/2002-conference-videos> (accessed Nov. 8, 2011); and Russo, *supra* n. 69, at 5.
- 73 California was the first state to implement a medical marijuana program: the Compassionate Use Act of 1996. Cal. Health & Safety Code, § 11362.5, available at <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=11001-12000&file=11357-11362.9>.
- 74 H.R. 2618, 104th Cong. (November 10, 1995); H.R. 1782, 105th Cong. (June 4, 1997); H.R. 912, 106th Cong. (March 2, 1999); H.R. 1344, 107th Cong. (April 3, 2001); H.R. 2233, 108th Cong. (May 22, 2003); H.R. 2087, 109th Cong. (May 4, 2005); H.R. 5842, 110th Cong. (April 17, 2008); H.R. 2835, 111th Cong. (June 11, 2009); and H.R. 1983, 112th Cong. (May 25, 2011) all are available at <http://thomas.loc.gov/home/multicongress/multicongress.html> (accessed Oct. 29, 2011).
- 75 H.R. 1983, 112th Cong. (May 25, 2011); H.R. 2306, 112th Cong. (June 23, 2011) available at <http://thomas.loc.gov/home/LegislativeData.php?&n=BillText> (accessed Oct. 29, 2011).
- 76 H.R. 1983, 112th Cong. (May 25, 2011).
- 77 In determining the scheduled status, if any, of a drug, § 811 of the Controlled Substances Act requires the DEA to obtain a scientific and medical evaluation of a drug and a recommendation regarding whether it should be controlled from the Secretary of Health and Human Services. See 21 U.S.C. § 811(b). The Secretary, through the Assistant Secretary for Health, has delegated this evaluation process to the FDA. The FDA and NIDA agreed to collaborate on the evaluation pursuant to a Memorandum of Understanding. See U.S., *supra* n. 66.
- 78 IOM is an independent, non-profit organization. In its 1999 report, IOM did not recommend rescheduling marijuana to a class below Schedule I for purposes of medical use or prescribing to patients. IOM did, however, recommend changes in the Controlled Substances Act to eliminate the Act's barriers to conducting clinical research. See *About the IOM*, available at <http://www.iom.edu/About-IOM.aspx> (accessed Oct. 29, 2011). See also Joy, *supra* n. 12, at 151.
- 79 See The Lib. Of Cong. Thomas, *Bill Summary & Status*, H.R. 1983, All Congressional Actions, available at <http://thomas.loc.gov/cgi-bin/bdquery/D?d112:1:./temp/~bdjhKF:@@X|/home/LegislativeData.php> (accessed Oct. 30, 2011).
- 80 H.R. 2306, 112th Cong. (June 23, 2011), available at <http://www.gpo.gov/fdsys/pkg/BILLS-112hr2306ih/pdf/BILLS-112hr2306ih.pdf> (accessed Oct. 30, 2011).
- 81 *Id.*
- 82 See The Lib. Of Cong. Thomas, *Bill Summary & Status*, H.R. 2306, All Congressional Actions, available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d112:HR02306:@@X> (accessed Oct. 30, 2011).
- 83 *Supra* n. 10.
- 84 *Supra* n. 9.
- 85 Natl. Conf. State Legis., *State Medical Marijuana Laws*, <http://www.ncsl.org/default.aspx?tabid=19587> (updated May 2011) (accessed July 9, 2011).
- 86 See, e.g., Alaska Stat. § 17.37.070 (2011) available at <http://medicalmarijuana.procon.org/sourcefiles/ASTitle17Ch37.pdf> (accessed Nov. 5, 2011).
- 87 Del. Code tit. 16, § 4902A(3)(a) (2011) available at <http://delcode.delaware.gov/title16/c049a/index.shtml> (accessed Nov. 5, 2011); N.M. Dept. of Health, *Medical Cannabis Program Frequently Asked Questions*, available at http://www.health.state.nm.us/idb/mcp_faq.shtml#qualifying (accessed Nov. 5, 2011).
- 88 See, e.g., ProCon.org, *16 Legal Medical Marijuana States and DC – Home Cultivation Note*, <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881#NewJersey> (accessed Nov. 5, 2011).
- 89 Of the five states that have pending bills permitting marijuana to be used for medical purposes, Illinois, Massachusetts, New Hampshire, New York, and Pennsylvania, four of them would permit registered patients to possess marijuana plants. See Ill. H.B. 0030, 97th Gen. Assembly (Jan. 12, 2011); Mass. H. 00625, 187th Leg. (Jan. 14, 2011); Ohio H.B. 214, 129th Gen. Assembly (Apr. 26, 2011); and Pa. S.B. 1003, 2011 Session (Apr. 25, 2011).
- 90 D.C. Code § 7-1671.04 (a), (b) (West 2011) available at <http://weblinks.westlaw.com/result/default.aspx?cite=UUID%28N9A355C20A6%2DF911DF91FBC%2DD97B415A7D%29&db=1000869&findtype=VQ&fn=%5Ftop&pb=DA010192&rl=CLID%5FFQR LT734211512511&rp=%2FSearch%2Fdefault%2Ew1&rs=WEBL11%2E10&service=Find&spa=DCC%2D1000&sr=TC&vr=2%2E0> (accessed Nov. 5, 2011).
- 91 5 Colo. Code Regs. 1006-2, Regulation 2.B.5 (2011).
- 92 7.34.3.8(A)(1) NMAC (2010).

- ⁹³ Washington State permits physician assistants, advanced registered nurse practitioners, and naturopaths to recommend marijuana for medical purposes. See Wash. Rev. Code § 69.51A.010 (2) (2011) available at <http://apps.leg.wa.gov/RCW/default.aspx?cite=69.51A&full=true#69.51A.030> (accessed Nov. 5, 2011).
- ⁹⁴ N.M. Dept. of Health, *New Mexico Medical Cannabis Program Patient Application Set*, <http://www.nmhealth.org/IDB/medicalcannabis/Patient%20Packet%201-24-11.pdf> (Jan. 20, 2011) (accessed Nov. 9, 2011).
- ⁹⁵ Cal. Health & Safety Code, § 11362.5, available at <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=11001-12000&file=11357-11362.9>.
- ⁹⁶ Cal. Health & Safety Code, § 11054(d)(13), available at <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=11001-12000&file=11053-11058>. Unlike California, New Mexico took a bold step and listed marijuana as a Schedule II controlled substance if it is medically used by certified patients in conformance with the state's "Lynn and Erin Compassionate Use Act."
- ⁹⁷ The California Medical Marijuana Program has various administrative components. Physician marijuana recommendations must be documented in the patient's medical record, which is then used by the patient to obtain an identification card through the health department in the county where the patient resides. Upon the patient's submission of an application and payment of fees imposed by the state and county, the health department reviews the application for approval or denial. As part of the review, the department obtains a patient photo, verifies that the attending physician holds a valid California physician license in good standing, and contacts the physician to confirm that the patient-submitted medical record recommending marijuana is authentic and accurate. Those with an identification card can purchase or grow marijuana for medical purposes. Fifty-six of California's 58 counties have implemented the Program and, as of May 2011, have collectively issued over 50,000 identification cards since implementation of the Program. Cal. Dept. Pub. Health, *California Department of Public Health Medical Marijuana Program (MMP) Facts and Figures (MMP Fact Sheet)*, <http://www.cdph.ca.gov/programs/mmp/Pages/Medical%20Marijuana%20Program.aspx> (July 8, 2011) (accessed July 9, 2011).
- ⁹⁸ Med. Bd. of Cal., *Medical Marijuana Statement*, http://www.mbc.ca.gov/medical_marijuana.html (May 7, 2004) (accessed Nov. 8, 2011).
- ⁹⁹ Am. Soc., *supra* n. 24, at 2969.
- ¹⁰⁰ See *Id.* See also Joy, *supra* n. 12, at 111. The IOM report states that smoked marijuana, like cannabinoids, was apparently effective in treating chemotherapy-induced vomiting in some studies, but efficacy was no greater than that of available antiemetic agents [the "old school" drugs discussed in this article], and that the most effective regimens are oral serotonin receptor antagonists [one of the "modern" drugs discussed in this article such as Zofran] with dexamethasone.
- ¹⁰¹ See the following three studies: F.C. Machado Rocha, S.C. Stéfano, R. De Cássia Haiek, L.M.Q. Rosa Oliveira, & D.X. Da Silveira, *Therapeutic Use of Cannabis Sativa on Chemotherapy-Induced Nausea and Vomiting Among Cancer Patients: Systematic Review and Meta-Analysis*, 17 Euro. J. Cancer Care. 431, 440 (2008); Richard E. Musty & Rita Rossi, *Effects of Smoked Cannabis and Oral Δ-Tetrahydrocannabinol on Nausea and Emesis After Cancer Chemotherapy: A Review of State Clinical Trials*, 1 J. Cannabis Therapeutics 29, 53 (2001); Sunil K. Aggarwal, Gregory T. Carter, Mark D. Sullivan, et. al., *Medicinal Use of Cannabis in the United States: Historical Perspectives, Current Trends, and Future Directions*, 5 J. Opioid Mgt. 153, 156 (May/June 2009).
- ¹⁰² *Id.*
- ¹⁰³ See generally Karl E. Miller, Martha M. Miller & Monica R. Jolley, *Challenges in Pain Management at the End of Life*, 64 Am. Fam. Physician 1227-1235 (Oct. 1, 2001) available at <http://www.aafp.org/afp/2001/1001/p1227.html> (accessed Oct. 30, 2011); Leah Shafer, *Too Little, Too Late: Treating the Pain of the Terminally Ill*, Rx.magazine (March 28, 2011) available at http://rx.magazine.tripod.com/eol_20010328.htm (accessed Oct. 30, 2011).
- ¹⁰⁴ The California Program establishes few requirements for marijuana providers, authorizing the state Attorney General to promulgate requirements to prevent diversion and counties or municipalities to implement their own requirements consistent with California law. In 2008, the California Attorney General issued guidelines to help prevent diversion of medical marijuana. Those guidelines recommend that patients submit applications to the organization distributing medical marijuana, and that the organization verify that the patient is qualified to receive marijuana for medical purposes by checking the validity of the patient's state medical marijuana identification card or personally contacting the recommending physician. Additionally, the Attorney General recommended that accepted business practices be followed, such as tracking and documenting the source of marijuana, making regular cash drops at a bank and maintaining accurate financial records. See Edmund G. Brown, Jr, Attorney General, *Guidelines for the Security and Non-Diversion of Marijuana Grown for Medical Use* (Aug. 2008) available at http://medicalmarijuana.procon.org/view_additional-resource.php?resourceID=001735 (accessed Oct. 30, 2011).
- ¹⁰⁵ California cities and counties typically require dispensaries to apply for a permit; their proprietors must submit to a criminal background check; dispensary business hours are limited; they cannot be located near schools or parks; patients must be verified; and patient records and a security system must be maintained. Interestingly, Los Angeles County requires dispensaries to post a readable sign identifying the facility as a medical marijuana dispensary; however, marijuana cannot be grown on site. On the other hand, San Mateo County permits signage only for the dispensary address, but marijuana can be grown and processed on site so long as it is not visible from outside the dispensary. The city of Santa Barbara requires dispensaries to provide the Chief of Police with contact information for its on-site "community relations" staff person in the event that the city needs to report operational problems. See generally Cal. State Assn. of Counties, *CSAC Advocacy – Medical Marijuana*, <http://www.counties.org/default.asp?id=2848> (accessed Nov. 4, 2011). See also Los Angeles Co. Code (Cal.) § 7.55 (2011) available at http://search.municode.com/html/16274/_DATA/TITLE07/Chapter_7_55_MEDICAL_MARIJUANA.html (accessed Nov. 4, 2011); San Mateo Co. Code (Cal.) § 5.148 (2009) available at http://library.municode.com/HTML/16029/level2/TIT5BURE_CH5.148RECOCODIMEMA.html (accessed Nov. 4, 2011); and Santa Barbara Mun. Code (Cal.) Ch. 28.20 (2011) available at http://www.santabarbaraca.gov/Government/City_Hall/Municode/ (accessed Nov. 4, 2011).
- ¹⁰⁶ State law establishes quantities of medical marijuana that a patient may possess. Under § 11362.77 of the California Health & Safety Code, qualified patients are permitted to possess up to eight ounces (240 grams) of dried marijuana and no more than six mature or 12 immature marijuana plants, unless a doctor recommends a larger amount to meet the patient's needs. However, in 2010, the California Supreme Court affirmed a lower court decision deeming these limits unconstitutional. Instead, the Court deferred to the language of Proposition 215, the Compassionate Use Act, which states that the marijuana possessed or grown must be for the patient's personal medical purposes. In essence, the amount a California patient needs to treat her medical malady is the quantity the patient can possess. *People v Kelly* 47 Cal.4th 1008 (2010).
- ¹⁰⁷ Additionally, California created exemptions for certain third parties that are likely to encounter issues related to medical marijuana. For example, employers are not required to accommodate or allow use of medical marijuana on their properties. Similarly, hospitals and clinics are not required to permit patients to smoke medical marijuana, and health insurers do not have to pay for the costs incurred in the medical use of marijuana. Nevertheless, employers and healthcare organizations may wish to draft or update their policies to designate the status of medical marijuana and its use by employees or patients on premises. Hospital pharmacy and therapeutics committees may wish to identify alternative medications or equivalent therapeutic doses of synthetic cannabinoids that pharmacists may recommend, and physicians may prescribe, if patients are not allowed to use their personal supply of marijuana for medical purposes. See Cal. Health & Safety Code, § 11362.785, 11362.79, available at <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=11001-12000&file=11362.7-11362.83>. See also Gregory T. Carter, Patrick Weydt, Muraco Kyashna-Tocha, & Donald I. Abrams, *Listening to Marinol: Rational Guidelines for Dosing*, J. Cal. Cannabis Research Med. Group, available at <http://www.ccrmg.org/journal/05aut/marinol.html> (Autumn 2005) (accessed July 25, 2011).
- ¹⁰⁸ *Qualified Patients Association v. City of Anaheim*, No. 07CC09524, Minute Order at 2 (Cal. Sup. Ct. August 15, 2011) available at http://www.safeaccessnow.org/downloads/Anaheim_Superior_Court_Trial_Ruling.pdf (accessed Nov. 5, 2011). See also John Hoeffel, *Superior Court Sides with Anaheim in Lawsuit Over Medical Pot Ban*, <http://articles.latimes.com/2011/aug/20/local/la-me-dispensaries-20110820> (accessed Nov. 5, 2011). The *Los Angeles Times* article quotes estimates from the Americans for Safe

continued on page 14

The Cannabis Conundrum: Medication v. Regulation

continued from page 13

- Access organization, which states that 161 California cities and 17 counties ban medical marijuana dispensaries; the Coalition for a Drug Free California, a group that opposes medical marijuana, states that 224 cities and 15 California counties prohibit dispensaries.
- ¹⁰⁹ John Hoefel, *L.A. Acts to Cap Medical Marijuana Dispensaries*, <http://articles.latimes.com/2009/dec/09/local/la-me-medical-marijuana9-2009dec09> (accessed Nov. 5, 2011).
- ¹¹⁰ Los Angeles Mun. Code (Cal.) § 45.19.6.2 (2011) available at http://www.amlegal.com/nxt/gateway.dll?f=templates&fn=default.htm&vid=amlegal:lamc_ca (accessed Nov. 5, 2011).
- ¹¹¹ *Americans for Safe Access, et. al. v. City of Los Angeles, et. al.*, No. BC433942, (Cal. Sup. Ct, Oct. 14, 2011) (Plaintiffs filed a second amended complaint in this case) available at <https://www.lasuperiorcourt.org/OnlineServices/CivilImages/> (accessed Nov. 5, 2011). See also John Hoefel, *L.A.'s Much-Contested Medical Pot Ordinance is Upheld*, <http://articles.latimes.com/2011/oct/15/local/la-me-pot-decision-20111015> (Oct. 15, 2011) (accessed Nov. 5, 2011).
- ¹¹² Fox31 Denver, *Fort Collins Medical Marijuana Ban Passes*, http://www.kdvr.com/news/kdvr-fort-collins-medical-marijuana-ban-passes-20111102_0,1371662.story (Nov. 2, 2011) (accessed Nov. 5, 2011). Opponents of medical marijuana believe that Fort Collins dispensaries lead to an increase in crime; advocates are concerned that legitimate dispensaries will be closed, resulting in patients having to travel farther to obtain marijuana. Fort Collins is one of more than 75 Colorado communities prohibiting medical marijuana dispensaries. Moreover, Livonia, Michigan successfully dismissed a lawsuit in July 2011. The American Civil Liberties Union unsuccessfully sued to overturn Livonia's zoning ordinance, which banned marijuana production because such land use violated federal law. The City of Livonia, *Judge Upholds Livonia Ordinance Banning Marijuana Growing Operations*, <http://www.ci.livonia.mi.us/tabid/1155/Government/Press%20Releases/Press%20Releases.aspx> (July 28, 2011) (accessed Nov. 5, 2011).
- ¹¹³ Martin Austerhuhle, *Yet Another Delay for D.C. Medical Marijuana Program* http://dcist.com/2011/10/25/another_delay_in_dc_medical_mar.php (Oct. 25, 2011) (accessed Nov. 5, 2011). See also Tim Craig, *Council Approves Medical Marijuana Bill*, http://voices.washingtonpost.com/dc/2010/05/council_approves_medical_marj.html?hpid=moreheadlines (May 4, 2010) (accessed Nov. 5, 2011); Tim Craig *Medical Marijuana Now Legal*, http://voices.washingtonpost.com/dc/2010/07/medical_marijuana_now_legal.html (July 27, 2010) (accessed Nov. 5, 2011). In 2010, Congress did not intervene and block the medical District of Columbia marijuana law, as it had done since about 1998, so the law became effective 30 days after the Mayor signed it.
- ¹¹⁴ D.C. Code § 7-1671.01, § 7-1671.06 (West 2011) available at <http://weblinks.westlaw.com/toc/default.aspx?Abbr=dc%2Ddst%2Dweb&Action=ExpandTree&AP=N174E4570A6F811DF91FBCDE97B415A7D&ItemKey=N174E4570A6F811DF91FBCDE97B415A7D&RP=%2Ftoc%2Fdefault%2E1&ServiceTOC&RS=WEBL11.10&VR=2.0&SPa=DCC-1000&pbca=DA010192&fragment#N174E4570A6F811DF91FBCDE97B415A7D> (accessed Nov. 5, 2011).
- ¹¹⁵ N.J. Stat. § 24:GI-1 (2011) available at http://lis.njleg.state.nj.us/cgi-bin/om_isapi.dll?clientID=6722203&Depth=2&depth=2&expandheadings=on&headingswithhits=on&hitsperheading=on&infobase=statutes.nfo&record={9DEE}&softpage=Doc_Frame_PG42 (accessed Nov. 6, 2011).
- ¹¹⁶ Phil Gregory, *More Delays for New Jersey's Medical Marijuana Program*, <http://www.wbgo.org/newsarticle/more-delays-for-new-jerseys-medical-marijuana-program> (Oct. 24, 2011) (accessed Nov. 6, 2011); NJ.com, *Gov. Christie to Delay Implementing N.J.'s Medical Marijuana Law*, http://www.nj.com/news/index.ssf/2011/06/christie_to_delay_implementing.html (June 16, 2011) (accessed Nov. 6, 2011). A New Jersey alternative treatment center was the first to be denied a permit by a local zoning board, which would prefer that the center be located close to a hospital. Geoff Mulvihill, *Zoning Board Turns Down 1st NJ Medical Pot Site*, <http://www.businessweek.com/ap/financialnews/D9QBEMM00.htm> (Oct. 13, 2011) (accessed Nov. 6, 2011).
- ¹¹⁷ See, e.g., *The Green Cross*, <http://thegreencross.org/index.php> (accessed Nov. 5, 2011) (based in California); *Local Product of Colorado*, www.localproductco.com (accessed Nov. 5, 2011) (based in Colorado).
- ¹¹⁸ See, e.g., *Medical Marijuana Strains*, www.medicalmarijuanastrains.com (accessed Nov. 6, 2011).
- ¹¹⁹ Few states' medical marijuana regulations require education or training for dispensary owners or staff. The District of Columbia has comprehensive training mandates for dispensary staff that address compliance with law, medical marijuana use, security, and theft prevention. See D.C. Code § 7-1671.06(h)(3) available at <http://government.westlaw.com/linkedslice/default.asp?RS=GVT1.0&VR=2.0&SP=dcc-1000&Action=Welcome> (accessed Nov. 6, 2011). Maine established rules requiring dispensaries to provide medical marijuana educational materials and information to patients. See Code Me. R. 10 144 122 (Weil 2010) available at <http://www.maine.gov/dhhs/dlrs/mmm/index.shtml> (accessed Nov. 6, 2011).
- ¹²⁰ Doesha Cup, <http://doeshacup.weebly.com/index.html> (accessed Nov. 6, 2011) (www.doeshacup.com Web site was not operational on access date).
- ¹²¹ Lisa Leff & Marcus Wohlsen, *Medical Marijuana Doctors Help Make Pot Available in California*, http://www.usatoday.com/yourlife/health/healthcare/doctorsnurses/2010-11-01-marijuana-california_N.htm (Nov. 1, 2010) (accessed Nov. 6, 2011); Jonathan Martin, *No Medical Records? No Problem. Got My Pot Card at Hempfest*, http://seattletimes.nwsources.com/html/localnews/2015969811_marijuana21m.html (Aug. 20, 2011) (accessed Nov. 6, 2011).
- ¹²² Cal. Police Chiefs Assn., *White Paper on Marijuana Dispensaries*, http://californiapolicechiefs.org/files/marijuana_files/TaskForce.html (2009) (accessed July 31, 2011).
- ¹²³ *Id.* at 8.
- ¹²⁴ 10News.com, *Man Trapped in Pot Dispensary Arrested After Failed Robbery*, <http://www.10news.com/news/28543884/detail.html> (July 14, 2011) (accessed July 19, 2011).
- ¹²⁵ See generally Report Presented to the California Chiefs of Police Association, *Medical Marijuana Dispensaries and Associated Issues*, page 4, http://www.californiapolicechiefs.org/files/marijuana_files/files/CCOP_Presentation_01.pdf (accessed Nov. 9, 2011).
- ¹²⁶ In June and July 2011, robberies were allegedly committed in Vancouver, Washington and Phoenix, Arizona related to medical marijuana. In the Arizona incident, a medical marijuana grower shot and killed a person who reportedly attempted to rob him at gunpoint. In October 2011, New Mexico law enforcement officials arrested a man who allegedly stabbed a home-grower of medical marijuana and stole the owner's plants. KATU, *Two in Custody After Allegedly Robbing Medical Marijuana Grow*, <http://vancouver.katu.com/news/crime/two-custody-after-allegedly-robbing-medical-marijuana-grow/441947> (July 19, 2011) (accessed Nov. 6, 2011); Deborah Stocks, *Medical Marijuana Buy Ends in Shooting*, http://www.abc15.com/dpp/news/region_phoenix_metro/central_phoenix/medical-marijuana-buy-ends-in-shooting (June 3, 2011) (accessed Nov. 6, 2011); David Romero, *Medical Marijuana Stolen at Knifepoint*, <http://www.krqe.com/dpp/news/crime/Medical-marijuana-stolen-at-knifepoint-dr> (Oct. 5, 2011) (accessed Nov. 6, 2011). Additionally, pursuant to SB0423, Montana tightened its medical marijuana program requirements, effective July 1, 2011, to address concerns about the diversion of medical marijuana for recreational and other uses. A basis for the legislation was the number of registered users in Montana's medical marijuana program, which exploded from 7,300 to 30,000 in approximately an 18-month period from 2009 to 2011. Although the First Judicial District Court of Montana issued a preliminary injunction prohibiting implementation of certain portions of the new law, such as a prohibition on dispensaries receiving compensation from patients, other aspects of the law, including patient fingerprinting, have been implemented. See generally Laura Wilson, *Dispensaries Adjust to New MT Medical Marijuana Law*, <http://www.kpax.com/news/dispensaries-adjust-to-new-mt-medical-marijuana-law/#!prettyPhoto/0/> (Oct. 10, 2011) (accessed Nov. 6, 2011); Montana

Dept. of Pub. Health & Human Serv., *Montana Marijuana Program Changes to Marijuana Law*, <http://www.dphhs.mt.gov/marijuanaprogram/> (accessed Nov. 6, 2011) (court decision and information about modified law is available at the Web site); *Montana Cannabis Industry Association v. State of Montana*, No. DDV-2011-518 (Mont. 1st Jud. Dist. Ct. June 30, 2011).

¹²⁷ Susan K. Livio, *Colorado Residents Say Legal Pot has Economic, Medical Benefits; Officials Criticize Unregulated Industry*, http://www.nj.com/news/index.ssf/2010/06/medical_marijuana_pot_nj_color.html (June 6, 2010, updated Jan. 11, 2011) (accessed Nov. 6, 2011); Jacob Applesmith, Presentation, *California and Medical Marijuana* (Nat'l. Assn. Bds. of Pharm. Fall Symposium. Dec. 3, 2009) available at <http://www.nabp.net/events/assets/Applesmith.pdf>; Cal. Police Chiefs Assn., *Summit on the Impact of California's*

Medical Marijuana Laws – Dispensary Related Crime, http://californiapolicechiefs.org/files/marijuana_files/files/DispensarySummitPresentation.ppt (Apr. 23, 2009) (accessed Nov. 6, 2011).

¹²⁸ See Livio, *supra* n.127.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ Tony Castro, *LAPD Chief: Pot Clinics Not Plagued by Crime*, http://www.dailynews.com/news/ci_14206441 (Jan. 17, 2010) (accessed Nov. 6, 2011).

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.* The article quoted the following Los Angeles police department 2009 robbery statistics: 71 robberies per 350 banks and 47

robberies per at least 800 medical marijuana dispensaries.

¹³⁵ Interestingly, in September 2011, the RAND Corporation issued a study evaluating Los Angeles crime data near dispensaries, concluding that closure of medical marijuana dispensaries caused increases in local crime rates. In October, however, the Corporation retracted its study when it discovered that the crime data from a site only considered Los Angeles County sheriff department data and had omitted Los Angeles police department crime statistics. See RAND Corporation, *RAND Retracts Report About Medical Marijuana Dispensaries and Crime*, <http://www.rand.org/news/press/2011/10/24.html> (Oct. 24, 2011); see also Tim Cavanaugh, *RAND Pot Dispensary Crime Study Retracted*, <http://reason.com/blog/2011/10/25/rand-pot-dispensary-crime-stud> (Oct. 25, 2011) (accessed Nov. 6, 2011).

The Editorial Board provides expertise in specialized areas covered by the Section. Individual Board members were appointed by the Interest Group Chairs and Editor Marla Durben Hirsch. If you are interested in submitting an article to *The Health Lawyer*, you may contact one of the Editorial Board members or Ms. Hirsch. With the establishment of the Editorial Board, the Section strengthens its commitment to provide the highest quality analysis of topics in a timely manner.

Marla Durben Hirsch
Potomac, Maryland
301/299-6155
mdhirsch@comcast.net

Lisa L. Dahm
South Texas College of Law
Houston, TX
eHealth, Privacy & Security
Editorial Board Chair
713/646-1873
ldahm@stcl.edu

Sherine B. Hargrove
US DHHS/OGC
Office of the General Counsel
Rockville, MD
Young Lawyer Division
301/443-2211
sherine.hargrove@hhs.gov

**serving in her private capacity, not as a representative of OGC or HHS, and no endorsement by them should be implied.*

Howard D. Bye-Torre
Stoel Rives LLP
Seattle, WA
Employee Benefits & Executive Compensation
206/386-7631
hdbye@stoel.com

Michael A. Clark
Sidley Austin Brown & Wood
Chicago, IL
Tax & Accounting
312/853-2173
mclark@sidley.com

Marcelo N. Corpuz III
Walgreens Health Services
Deerfield, IL
Business and Transactions
847/964-8228
marcelo.corpuz@walgreens.com

Jason W. Hancock
Hospital Corporation of America
Brentwood, TN
Health Care Facility Operations
615/372-5480
jason.hancock@hcahealthcare.com

Bruce F. Howell
Bryan Cave
Dallas, TX
Medical Research, Biotechnology & Clinical Ethical Issues
214/721-8047
bruce.howell@bryancave.com

Charles M. Key
Wyatt, Tarrant & Combs, LLP
Memphis, TN
Liaison to the Publications Committee
901/537-1133
ckey@wyattfirm.com

Rakel M. Meir
Tufts Health Plan
Watertown, MA
Managed Care and Insurance
617/923-5841
Rakel_Meir@tufts-health.com

Monica P. Navarro
Thomas M. Cooley Law School
Auburn Hills, MI
Physician Issues
248/751-7800
navarrom@cooley.edu

C. Elizabeth O'Keeffe
University of Mississippi Medical Center
Jackson, MS
Public Health & Policy
601/815-5297
cokeeffe@umc.edu

Leonard M. Rosenberg
Garfunkel, Wild & Travis, PC
Great Neck, NY
Healthcare Litigation & Risk Management
516/393-2260
lrosenberg@gwtlaw.com

Felicia Y. Sze
Hooper, Lundy & Bookman, P.C.
San Francisco, CA
Payment & Reimbursement
415/875-8503
fsze@health-law.com

Andrew B. Wachler
Wachler & Associates
Royal Oak, MI
Healthcare Fraud & Compliance
248/544-0888
awachler@wachler.com