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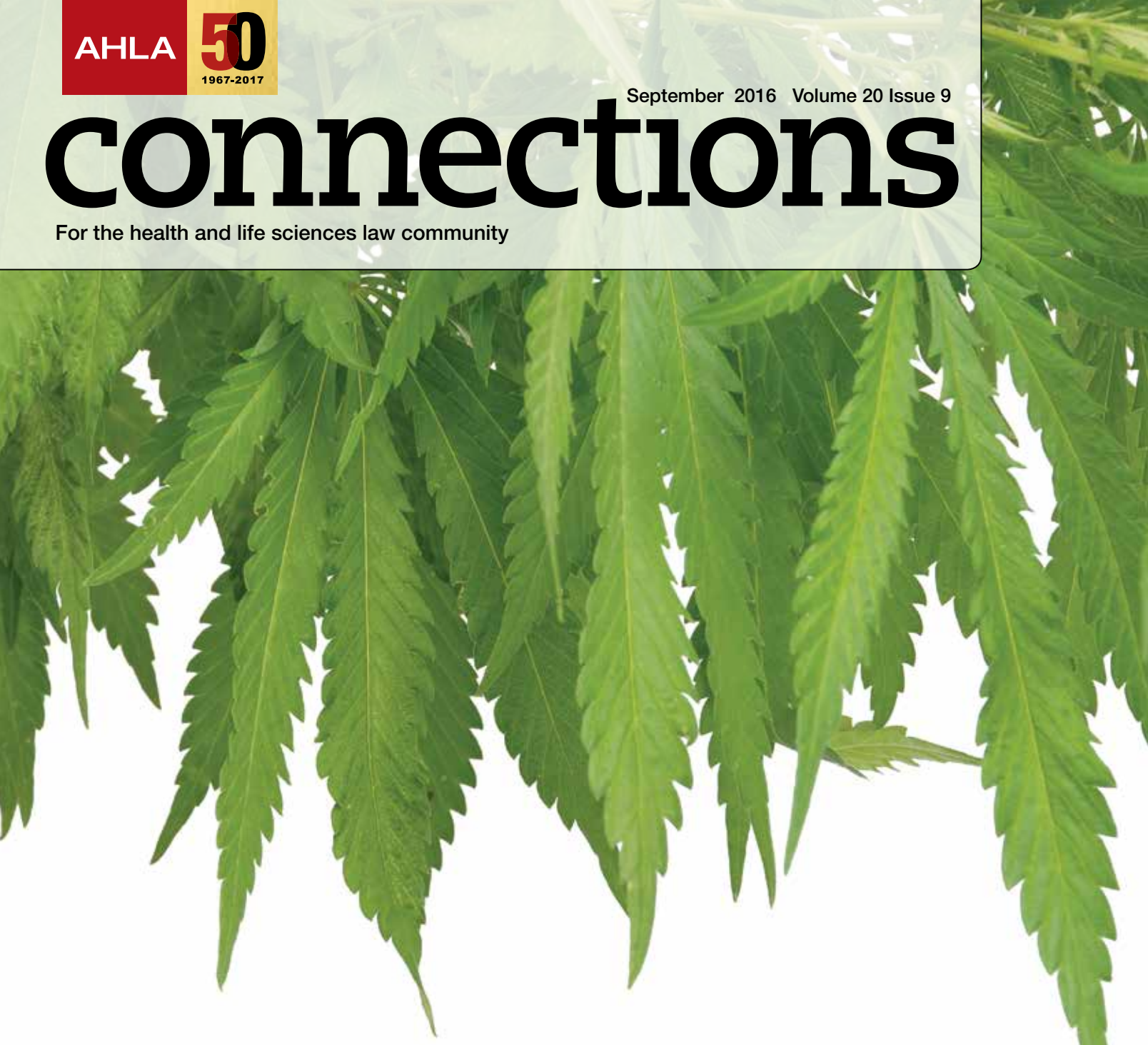

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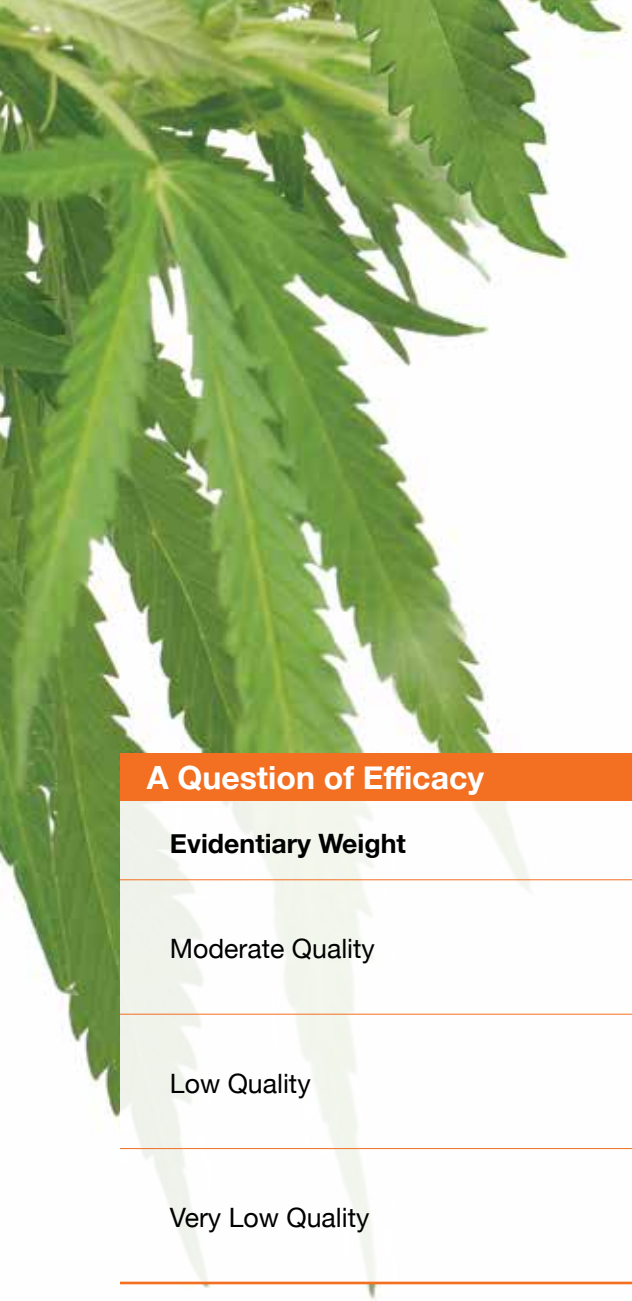
OFFICIAL MAGAZINE OF AMERICAN HEALTH LAWYERS ASSOCIATION

Mary Jane: The Challenges of Marijuana's Foray into Health Care

By Mark Pearlman, Nathan Reitinger, Laura Miron Napiewocki, and V. Kenneth Stecker

Catching up to society's general acceptance of medicinally-purposed marijuana, hospitals, perhaps benignly, have started to "inhale." Historically harrowed in controversy, state legalization of medicinal marijuana has surreptitiously placed one actor at the fore, physicians. By approving qualifying diagnoses, recommending medicinal use, and conducting clinical trials, physicians remain a key player in our national debate.

Behind the scenes, however, the burden truly falls on general counsel, those who advise the physician recommenders and the hospitals who treat the patients, those who craft relevant policies, and those who are tasked with structuring compliance amid the morass of overlapping state and federal laws. In this Feature Article, we make accessible pertinent highlights of the medical marijuana debate, breaking the topic down into three parts: (1) marijuana's foundations in science; (2) outer boundaries of the law; and (3) how hospitals and physicians can strike a balance, policy-wise, between competing regulations.



Foundations of Delta-9-Tetrahydrocannabinol (THC)

Medical marijuana is in no way new. For decades, the plant's psychoactive properties (attributed mostly to THC, one of the most active cannabinoids in the *sativa* species[1]) have been associated with a variety of medicinal purposes, including the treatment of malaria and rheumatic pain in ancient China as well as extensive medical use in 19th century England.[2] Despite this, the true value of marijuana—to date—seems perpetually shrouded in ethical controversy, making it difficult to separate genuine clinical value based on data from scientifically valid studies from poorly designed studies, anecdotal experience, legal barriers, or societal stigma about marijuana use (or the user).[3] Only recently, with the development of clinical evidence of efficacy for certain medical conditions, has this stigma started to wane.

A 2015 meta-analysis by Penny Whiting illuminates, in part, the limited data from studies designed similarly to pharmaceutical drugs approved through the Food and Drug Administration (FDA).[4] Table 1 lists a series of diseases—with corresponding effectiveness, in terms of evidentiary weight—that may be treated by medical marijuana.

Table 1

A Question of Efficacy

Evidentiary Weight	Disease or Symptom Treated
Moderate Quality	• Chronic neuropathic pain • Chronic cancer pain • Spasticity due to multiple sclerosis
Low Quality	• Nausea and vomiting due to chemotherapy • Weight gain and appetite stimulation in persons with HIV/AIDs • Tics due to Tourette's syndrome
Very Low Quality	• Effect on psychosis

Importantly, Whiting's review demonstrates that cannabinoids are simply not an all-purpose "miracle compound."[5] Only for specific indications does a recommendation for medical marijuana have sufficient medical evidence that supports its use. Moreover, due to marijuana's constrained legal environment—e.g., the Controlled Substances Act's (CSA's) classification of marijuana as a Schedule I substance[6]—a host of tertiary issues apply.

First, the difficulty of acquiring an illegal substance contributes to the difficulty in obtaining vigorous, scientific data demonstrating evidence of effectiveness for certain serious disease states (e.g., refractory childhood seizures).[7] Additionally, clinical studies have largely been designed comparing marijuana to a placebo rather than FDA-approved treatments. Finally, divergent federal and state laws have also led to medical marijuana utilization that lacks FDA quality and safety oversight, whereby patients may use "doses" that are inconsistent from batch to batch.[8] Overall, what this means is that despite recent attempts to verify marijuana's clinical efficacy, many hurdles still remain. Though helpful, Whiting's meta-analysis should not be taken as a standalone conclusion. In the absence of more scientific research, careful adherence to state and federal law should act as pillars for any health care provider taking a foray into medical marijuana territory. Indeed, a recent viewpoint article from the State Board of Medical Licensure sets a variety of expectations for physicians who are recommending marijuana to their patients, including that they should be thoughtful in their approach to this recommendation, similar to prescribing pharmaceutical medications. The recommendations include: providing advice about a patient's alternative options for managing their condition; determining whether the patient would benefit from the recommendation for marijuana; counseling the patient on the potential harms resulting from marijuana (including inconsistencies in doses and "cannabis use disorder") and additional treatments that may be equally or more effective; and outlining the patient's overall treatment plan.[9]

Out-of-Bounds: Criminal Implications

Generally, most states accept the proposition that marijuana has accepted medical uses.[10] Yet, the federal government continues to classify marijuana as a Schedule I substance, meaning that the drug has a high potential for abuse, would not be safe in a medically supervised environment, and does not have an accepted medical use.[11] Violation of the CSA could lead to life imprisonment or fines exceeding hundreds of thousands of dollars;[12] indeed, prescribing a non-FDA-approved substance would entail the loss of a Drug Enforcement Administration (DEA) license for physicians.[13] And, all of this has been upheld by the courts—constitutionally, the federal government is vested with the authority to "prohibit the local cultivation and use of marijuana."[14]

Amalgamating the federal and state law here points most pertinently to the doctrine of preemption.[15] Preemption is built on the Constitution's Supremacy Clause, U.S. Const. art VI, § 2: The "Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land." Whenever both federal law and state law seek to govern the same activity, preemption becomes an issue.[16] This necessarily leads to an attempt at understanding Congress' intent.[17]

Looking at the whole picture, it has been proposed that the CSA does not preempt most states' medical marijuana laws because the CSA requires "positive" conflict for preemption.[18] Unless a state's law mandates action in violation of the CSA—thereby making it impossible to both comply with the state law and the CSA[19]—then the preemption question tips in the state's favor.[20]

In the absence of more scientific research, careful adherence to state and federal law should act as pillars for any health care provider taking a foray into medical marijuana territory.

This guidepost does not, however, end the conversation. As Table 2 illustrates, violating the CSA may—or may not—nonetheless warrant prosecution. According to various Department of Justice memoranda, to prosecute or not to prosecute remains a tenable question. Additionally, consider that the majority of states did not make marijuana legal; *medical* marijuana (with predefined qualifiers) is the only route to legally usable cannabinoids.[22]

In summary, a state-run or privately-owed hospital would be remiss if it turned a blind eye to the CSA and its own state's particular medical marijuana laws. When advising health professionals, the middle ground—i.e., only permitting FDA-approved marijuana to be prescribed—may be the safest course of action.

Table 2

What Does the DOJ Say?

Authority	Effect
Ogden Memorandum	Emphasized a laissez-faire attitude toward enforcing federal marijuana laws in the face of "clear and unambiguous compliance" with state marijuana laws[23]
Cole Memorandum I	Attempted to backpedal from the Ogden Memorandum and illuminated the long-standing position that "[t]he Department of Justice is committed to the enforcement of the Controlled Substances Act in all States"[24]
Cole Memorandum II	Ranked marijuana infractions—as long as offenders are nonetheless compliant with state law—near the bottom of the priority list[25]

Tangential Consequences

Notably, tangential effects brought on by the state and federal tension warrant additional remarks. Because medical marijuana has fallen into a "legal-but-not-entirely-legal status,"[26] the minutia of day-to-day regulation is largely anarchic, causing quasi-legitimacy and unforeseen outcomes.[27]

One of these consequences particularly pertinent to health care professionals turns on what a "qualifying diagnosis" and "physician's recommendation" means.[28] Though most states require these elements, the terms are often defined loosely. For example, "severe pain" as a qualifying, underlying ailment—an incredibly difficult value to quantify—constitutes the majority condition for all medical marijuana applicants in the United States.[29] In fact, in Colorado, Oregon, and Nevada, more than 90% of all registered medical marijuana users qualify due to "chronic pain."[30]

On top of this, consider the actual practice of a recommendation. In 2010, "more than 70% of doctors' recommendations [in Colorado] were written by fewer than 15 physicians."[31] And most recommendations take place under the following circumstances: (1) no prior relationship exists between the patient and physician; (2) the recommender is not a specialist in treating the underlying condition; and (3) no follow-up appointments are scheduled.[32]

What this means for physicians and physicians' counsel is that the Wild Wild West's version of "doctor" looks nothing like a typical physician-patient relationship. And that potentially gives rise to the following areas of risks: (1) licensing issues;[33] (2) ethical duties;[34] and (3) negligence-styled, standard-of-care lawsuits.[35] To be sure, a physician should not take lightly a recommendation for a patient to use medical marijuana.

Compliance Among the Maze

Finally, when the proverbial rubber meets the road, counsel should consider how to draft hospital policy in order to strike a reasonable balance between state and federal laws. As Figure A illustrates, more than a few policies must be analyzed. On the one hand, patients' rights (e.g., constitutionally-based autonomy in medical decision making[36]) should be considered, but on the other, hospitals have a duty to comply with regulations, some tied to purse strings, promulgated by the Centers for Medicare and Medicaid Services (CMS), The Joint Commission, and other regulatory and accrediting bodies (e.g., CMS requires drugs and biologicals to be administered pursuant to both federal and state laws[37]). For these competing interests, blanket prohibition is likely the safest course of action—federally, non-FDA-approved marijuana is still a Schedule I substance, permitting its use would be a violation of the CSA. But, as the below questions and answers entertain, what should a hospital do if a patient brings their own medical marijuana into the hospital? The answer may not be as straightforward as you think.

When advising health professionals, the middle ground – i.e., only permitting FDA-approved marijuana to be prescribed – may be the safest course of action.

Bringing Your Own Marijuana: Q & A

Angel Raich—yes, the Angel Raich from *Gonzales v. Raich*[38] (holding that Congress may regulate local cultivation and use of medical marijuana)—was asked to leave the University of San Francisco Medical Center in 2012 on account of her refusal to adhere to the hospital's no smoking policy.[39] Though Ms. Raich possessed her own medical marijuana and was assumedly within the strictures of the Compassionate Use Act, the non-FDA approved drug nonetheless violated the CSA. What is more, although it appears that Ms. Raich did not present under Emergency Medical Treatment and Labor Act-themed circumstances, this possibility would not be implausible, in which case the hospital may have been required to screen, stabilize, or transfer Ms. Raich despite her medical marijuana use.[40] Moreover, if a hospital decides to confiscate (and perhaps return) a patient's medical marijuana, a preemption issue could surface, implicating aiding and abetting charges.[41]

These nuances amount to the suggestion that hospitals, perhaps in the form of a punt, simply "prohibit" medical marijuana. The following statement would suffice: Medical marijuana (including non-FDA approved marijuana, oil-based marijuana, or non-approved substances derived from marijuana) is not permitted for use in or by patients during their inpatient admission to or treatment within any hospital facility. Even still, such sweeping prohibition begs a further question: what about non-FDA-approved products used during clinical trials?

Clinical Trials: Q & A

Suppose a patient engaging in a clinical trial finds themselves at a third-party hospital not taking part in the study. Further assume that the patient will remain in the third-party hospital for several days and would like to continue with their alternative treatment—i.e., continue using non-FDA-approved medical marijuana. This scenario potentially disrupts hospital policy, state law, and federal law.

Hospitals should permit the patient's continued use of non-FDA approved marijuana depending on whether the clinical study has approval under 21 U.S.C. § 823(f). Section 823(f) allows a Schedule I substance to be dispensed by a practitioner[42] for research purposes if the research is approved by the Secretary and not denied by the Attorney General (AG). The AG will only deny the research if it is not consistent with the "public interest."[43] This means that as long as there is ongoing, government-approved research, the substance will be statutorily exempted from the CSA, like that of FDA-approved medical marijuana.[44] Therefore, if the participant-patient is able to prove participation in the study, hospitals should consider allowing the patient to continue treatment.

Figure A

Conclusion

State legalization of medical marijuana engenders a host of issues for those working in the health care sector. From difficult questions of preemption to the competing interests of patients and federal law, legal counsel should have a firm understanding of the science behind medical marijuana, the key federal laws at issue, and the particular state laws affecting patients and physicians prior to providing advice. Looking into these issues now should assist counsel for hospitals and physicians to sculpt better, across-the-board answers to questions that will inevitably arise.

From difficult questions of preemption to the competing interests of patients and federal law, legal counsel should have a firm understanding of the science behind medical marijuana, the key federal laws at issue, and the particular state laws affecting patients and physicians prior to providing advice.

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Endnotes

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