Document #1315 **CMA Legal Counsel**
The Compassionate Use Act of 1996: The Medical Marijuana Initiative **January 2011**

"The Compassionate Use Act of 1996" (CUA), was passed by a vote of the people on November 5, 1996, and became effective on November 6, 1996. (Health & Safety Code §11362.5.) In addition, on October 12, 2003, the governor signed S.B. 420 into law, which established the Medical Marijuana Program (MMP). The MMP, codified at Health & Safety Code §§11362.7-11362.83, seeks to implement the CUA by, among other things, clarifying the scope of its application, facilitating the prompt identification of qualified patients/caregivers, and promoting uniform and consistent application of the Act among the counties across the state. This document contains a discussion of the questions most likely to be asked about those laws.

BASIC PROVISIONS OF THE COMPASSIONATE USE ACT (CUA)

1. What did California law formerly prohibit?

Under former state law, a patient was prohibited from obtaining, possessing, or cultivating, cannabis for any purpose, including medical treatment purposes. *The same continues to be true under federal law.* Under federal law, cannabis is currently classified as a Schedule I drug, which means that it has no generally recognized medical use. On June 6, 2005, the United States Supreme Court ruled that the federal Controlled Substances Act is valid even as applied to the intrastate, noncommercial cultivation, possession and use of cannabis for personal medical use on the advice of a physician. (*Gonzales v. Raich* (2005) 545 U.S. 1, 162 L.Ed.2d 1, 125 S.Ct. 2195.) The court's ruling maintains the existing federal prohibition against possession, cultivation, and distribution of cannabis. The ruling has no direct impact on California's current law (CUA and MMP), nor does it narrow or otherwise negatively affect the Ninth Circuit's ruling in *Conant v. Walters*, which stated that physicians have a First Amendment right to discuss treatment options with their patients, including treatment with medicinal cannabis (*see* discussion below).

The federal Department of Justice in October 2009 issued guidelines for prosecuting attorneys in states having "medical marijuana" laws. For more information about these guidelines, *see* Question 15 below.

2. What does the CUA allow patients to do?

The CUA provides that the state criminal law prohibitions against cultivation and possession of cannabis do not apply to a seriously ill patient (and his or her "primary caregiver") who possesses or cultivates cannabis for (the patient's) personal medical treatment, with the oral or written recommendation or approval of a physician. The California Attorney General has opined that the term "marijuana" in the CUA applies to concentrated cannabis or hashish. (Ops.Cal.Atty.Gen. No. 03-411 (2003).) In addition, the MMP clarifies that a patient or designated primary caregiver may **transport or process** cannabis for the patient's personal medical use. A primary caregiver may also administer medicinal cannabis to a patient. (Health & Safety Code §11362.765.)

The MMP establishes a ***voluntary***, ***fee-based*** identification card program which enables patients and primary caregivers to offer affirmative proof of their status if they are challenged by state or local law enforcement personnel. The Legislative Counsel of California has opined that **requiring** qualified patients to participate in the ID card program would constitute an unconstitutional amendment of the CUA.

(Legislative Counsel of California, "Medical Marijuana: Identification Program (S.B. 420)" #16771 (Aug. 20, 2003).) A patient must submit certain information to the county health department. If the information is complete and accurate, the county will issue a photo identification card to the patient and, if applicable, a separate photo ID card to the patient's designated primary caregiver. The county will submit the cardholder's unique user ID number, and the card's expiration date, to the State Department of Health Services. The Department in turn will maintain 24-hour, toll-free telephone number to enable state and local law enforcement officers to verify the validity of the ID card. The card is valid for one year and can be renewed. (Health & Safety Code §§11362.71-76.)

3. Which medical conditions are covered by the CUA and the MMP?

The CUA applies to patients with cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, and migraine. In addition, it applies to "any other illness for which marijuana provides relief." The MMP clarifies the concept of a "serious medical condition," which can qualify a patient to obtain an ID card and use medicinal cannabis upon a physician's recommendation: AIDS, anorexia, arthritis, cachexia, cancer, chronic pain, glaucoma, migraine, persistent muscle spasms (including those associated with MS), seizures (including those associated with epilepsy), and severe nausea. Furthermore, the concept includes *any other chronic or persistent medical symptom that either 1) substantially limits the ability of the person to conduct one or more major life activities as defined in the ADA*; *or 2) if not alleviated, may cause serious harm to the patient's safety or physical or mental health.* (Health & Safety Code §11362.7(h).) Further information can be obtained from the State of California at the following website: www.cdph.ca.gov/programs/MMP/Pages/CompassionateUseact.aspx.

4. Must a patient have tried all other conventional treatments before I can consider recommending medicinal cannabis?

No. Nothing in the CUA or the MMP requires a physician to determine that a patient has failed (or would fail) on all other conventional medicines before the physician may recommend or approve the use of medicinal cannabis. For the perspective of the Medical Board on this issue, *see* Question 11.

5. Are minors covered by the CUA?

The CUA does not exclude minors. Moreover, the MMP clarifies that minors are covered by the CUA and can obtain identity cards with the consent of their parents or guardians. (Health & Safety Code §11362.715.) However, a physician should proceed cautiously. The physician should ensure that 1) the parents or guardians are fully informed about the risks and benefits of medicinal cannabis and give their consent to such treatment; 2) the minor has a serious medical condition; and 3) all conventional treatments have been tried unsuccessfully, or considered and rejected (e.g., because of probable unacceptable side effects), before recommending the use of medicinal cannabis. The physician may wish to warn the parents or guardian that child protective agencies in the past have attempted to take action against parents/guardians who have provided medicinal cannabis to their child. Careful documentation in the medical record is particularly essential. For the perspective of the Medical Board on this issue, *see* Question11 .

6. How can a patient establish that he or she qualifies for a card under the MMP?

A patient must provide "written documentation" by the attending physician in the patient's medical records stating that the person has been diagnosed with a serious medical condition and that the medical use of cannabis is appropriate. In addition, the patient must provide his/her name; proof of county residency; the name, office address, office telephone number, and California medical license number of his/her attending physician; the name and duties of his/her primary caregiver; and a government-issued photo ID card (of the patient and the primary caregiver, if any). (Health & Safety Code §11362.715.) "Written documentation" means accurate reproductions of the relevant portions of the patient's medical record. (Health & Safety

Code §11362.7(i).) *See* Questions30 33-, below. In Washington, the state supreme court has ruled that a recommendation from a California physician was not sufficient to qualify a patient residing in Washington under that state's medicinal cannabis law. (*State of Washington v. Tracy* (Wash. 2006) 158 Wash.2d 683, 147 P.3d 559.

7. What happens if a patient does not wish to participate in the ID card system but has the bona fide recommendation of a physician to use medicinal cannabis?

If a qualified patient chooses **not** to obtain a card, he or she will still be entitled to the protections of the CUA. Furthermore, many of the provisions of the MMP apply equally to patients and designated caregivers, whether or not they possess ID cards.

8. Does the CUA protect a patient from being arrested if he or she has a physician's recommendation?

No. The CUA does not absolutely immunize a patient from the possibility of arrest. A patient might still be arrested if, for example, law enforcement officers believe that the patient is not cultivating cannabis for his or her personal medical use. Instead it means that a patient or caregiver has a *limited* immunity from prosecution under state law. In People v. Mower (2002) 28 Cal.4th 457, 122 Cal.Rptr.2d 326, the California Supreme Court ruled that pursuant to the CUA the patient may raise his or her status as a patient or caregiver 1) as a basis for moving to set aside an indictment or information before trial on the ground of the absence of reasonable or probable cause to believe that his or she is guilty; or 2) as an affirmative defense at trial. The court further ruled that the patient/defendant has the burden of proof to establish the facts of his or her status. However, he or she need only raise a reasonable doubt as to his or her guilt, rather than having to prove his or her status by a preponderance of the evidence. (The latter evidentiary standard would require a greater degree of proof.)

The MMP is intended to protect patients with ID cards against improper arrest. The law prohibits state or local law enforcement officers from refusing to accept an ID card unless the officer has **reasonable cause to believe** that the information in the card is false or fraudulent or the card is being used fraudulently. (Health & Safety Code §1362.78.) Hence, the MMP should help to ensure that a patient or primary caregiver is not arrested in the absence of good evidence that he/she is violating the provisions of the CUA and/or the MMP.

The California Court of Appeals for the Fourth Appellate District recently ruled that, if a patient is arrested and is thereafter found to be in lawful possession of marijuana under the CUA and/or the MMP, the police must return the marijuana to him or her. The court opined that law enforcement officers would not be subject to federal sanctions, since they would be acting pursuant to their official duties in complying with the trial court's order to return the marijuana to the patient, and were therefore entitled to immunity under 21 U.S.C. §885(d). City of Garden Grove v. Superior Court (Kha) (2007) 157 Cal.App.4th 355, 68 Cal.Rptr.3d 656. *See also, State v. Kama* (2002)178 Ore.App. 561; 39 P.3d 866. However, a different outcome may result if a person possesses more marijuana than is permitted under state law, Chavez v. Superior Court (2004) 123 Cal.App.4th 104; 20 Cal.Rptr.3d 21.

9. When should a patient seek a physician's advice about medicinal cannabis?

As with all medications, it would be best if a patient were to seek the physician's advice and approval before beginning to use cannabis. There may be "exigent circumstances" in which a physician's approval/ recommendation may be contemporaneous with, or subsequent to, a patient's possession (although prior to actual usage). (People v. Trippet (1997) 56 Cal.App.4th 1532, 1548 n. 13, 66 Cal.Rptr.2d 559.) However, an appellate court ruled that the Act did not apply to a patient who was self-medicating with cannabis, who had not consulted a physician for several years before his arrest, and who did not seek a physician's

approval for his cannabis use until three months after his arrest. (People v. Rigo (1999) 69 Cal.App.4th 409, 81 Cal.Rptr.2d 624.) In refusing to apply the Act's protections, the court stressed that "Medical marijuana should be prescribed [by a physician] for specific relief for clearly defined medical problems."

MEDICAL BOARD ISSUES

10. What does the CUA allow physicians to do?

The language of the CUA provides that physicians cannot be "punished or denied any right or privilege" for having recommended cannabis to a patient for medical purposes. Therefore, it should be impermissible for a state governmental entity to punish a physician either criminally or civilly under *state law, or to subject the physician to loss of license or other administrative sanction*, **solely** on the basis of having made an oral or written recommendation for the medical use of cannabis (at least for a serious medical condition).

Unlike patients, whose possession and/or cultivation of cannabis would be illegal but for the CUA, a physician's discussion and, if appropriate, recommendation, of the use of medicinal cannabis, **in accordance with standard physician office practices**, does not, in the absence of other factors, violate either state law or the professional standard of practice. Therefore, in the unlikely event that a physician were criminally prosecuted under state law, solely on the basis of having recommended the use of medicinal cannabis, it is unclear whether the physician would enjoy the limited immunity established in Mower, or a broader immunity against arrest. However, since immunity from arrest is exceptional, the limited Mower immunity would probably apply. In a subsequent administrative proceeding initiated by the Board, the administrative law judge did, indeed, apply a limited immunity.

11. Does this mean that the Medical Board cannot take any action against me because I have recommended cannabis to a patient?

No. The Medical Board should not attempt to punish a physician **solely** on the basis of the fact that the physician approved the use of medicinal cannabis. However, if the Medical Board believes that the physician's conduct has not met the applicable standard of care, the Medical Board may seek to impose disciplinary action against the physician. When the CUA was first enacted, the Medical Board issued a statement stating that a physician who recommends the use of medicinal cannabis should have arrived at that decision in accordance with accepted standards of medical responsibility. On May 7, 2004, the Board adopted an informational statement to give further guidance to physicians who may recommend the use of medicinal cannabis to their patients. The statement stressed that physicians would not be subject to investigation or disciplinary action if they arrive at the decision to recommend medicinal cannabis in accordance with accepted standards of medical responsibility that "any reasonable and prudent physician would follow when recommending or approving any other medication or prescription drug treatment." The statement described these standards as follows:

- History and good faith examination of the patient;
- Development of a treatment plan with objectives;
- Provision of informed consent, including discussion of side effects;
- Periodic review of the treatment's efficacy;
- Consultation, as necessary; and
- Proper record keeping that supports the decision to recommend the use of cannabis.

The statement also provides information on a number of specific issues. The statement:

- Acknowledges that a patient need not have failed on all other medications in order for a physician to recommend or approve the use of medicinal cannabis.

- Cautions physicians to determine that the use of medicinal cannabis will not mask an acute or treatable progressive condition that could lead to a worsening of that condition.

- Clarifies that physicians may recommend or approve medicinal cannabis for conditions other than those specifically set forth in the CUA and, in doing so, the physician may rely upon 1) the results of clinical trials, if available; 2) medical literature and reports; 3) the experience of that physician or other physicians; or 4) credible patient reports. The risk-benefit ratio must be as good, or better, than other medications that could be used for that patient.

- Notes that a physician who is not the patient's primary treating physician may still recommend medicinal cannabis for the patient's symptoms. However, the physician must either consult with the patient's treating physician or obtain the patient's prior medical records that confirm the patient's diagnosis and treatment history.

- Warns that recommendations must be limited to the time necessary to monitor the patient. Periodic reviews must occur at least annually or more frequently as warranted.

- Recognizes that a physician may recommend the use of medicinal cannabis for a minor, but the parents or guardians must be fully informed of the risks and benefits and consent to that use.

The full statement is available at www.medbd.ca.gov/Medical_Marijuana.html.

Accordingly, if the Medical Board believes that a physician has failed adequately to follow proper practice standards when recommending the use of medicinal cannabis, the Medical Board may initiate an investigation against the physician or even revoke the physician's license. *See*, e.g., Medical Board of California, In the Matter of the Accusation and Petition to Revoke Probation Against: Hany Assad, M.D. http://publicdocs.mbc.ca.gov/pdl/mbc.aspx (license revocation).

However, the First Amendment constrains the Board's discretion to investigate a physician. By extension of a decision from the U.S. Court of Appeals for the Ninth Circuit, *Conant v. Walters*, the Board should not be able to initiate such an investigation solely on the basis of a recommendation given within a *bona fide* physician-patient relationship unless the Board in good faith believes that it has substantial evidence of criminal conduct or conduct that fails to meet appropriate standards of care. *See* discussion below. Although this ruling applies specifically to the federal government, the constitutional principles articulated therein would apply equally to actions taken, or sanctions imposed, by state or local governmental entities. In its 2004 statement, the Board stressed that the mere receipt of a complaint that a physician is recommending medicinal cannabis will **not** trigger an investigation "absent additional information that the physician is not adhering to accepted medical standards."

12. What if I give my patient a written recommendation to use medicinal cannabis, and someone complains to the Medical Board? Does the mere fact that I made such a written recommendation allow the Board to act upon the complaint and seek to obtain my patient's medical records?

No. In Bearman v. Superior Court (2004) 117 Cal.App.4th 463, 11 Cal.Rptr.3d 644, the California Court of Appeal for the Second Appellate District ruled that the mere fact that a physician has issued a written recommendation for a significant medical condition does not empower the Board to obtain the patient's

medical records, as part of the Board's effort to investigate the physician's practices. Under the California constitutional right of privacy, the Board cannot delve into a patient's private medical information merely because it wants assurance that the law has not been violated or a physician is not negligent. The Board must provide sufficient "competent evidence" to enable a court to determine that "good cause" exists to order the records disclosed. The mere fact that a physician has written a recommendation constitutes neither.

The Court of Appeal further stressed that the patient does not waive his or her constitutional right of privacy merely by disclosing that recommendation to a law enforcement officer for the purpose of establishing the patient's right to possess and/or cultivate cannabis pursuant to the Compassionate Use Act. Such waiver does not occur, even if the physician states, in the written document, the medical condition for which he or she is recommending medicinal cannabis. Under Bearman, then, the Board effectively cannot initiate an investigation based only on a complaint or other information which merely states that the physician has made a recommendation for the use of medicinal cannabis—**since the Board cannot obtain patient medical information to support that investigation**. The Board's 2004 statement appears to confirm this principle.

HEALTH INSURANCE/EMPLOYMENT ISSUES

13. Must a health insurer reimburse a patient for the physician's services in examining and evaluating the patient and making a recommendation and/or for the cost of obtaining medicinal cannabis?

The MMP does not require a government, private or any other health insurance provider or health care service plan to be liable for any claim for reimbursement for the use of medicinal cannabis. (Health & Safety Code §11362.785(d).) The CUA is silent on the issue. It is probable that the courts would interpret the CUA in a manner consistent with the MMP. Thus, the issue of reimbursement will depend on the scope of the patient's health plan. In August 2006, the Director of the California Department of Health Services determined that the cost of medicinal cannabis, which a qualified patient regularly purchased from her primary caregiver, constituted a *bona fide* medical expense that should be deducted from her income for the purpose of determining her share of cost under the Medi-Cal Personal Care Services Program. (*In the Matter of Sylvia Price* (Sept. 25, 2006) CDHS 2003106214.)

However, welfare recipients in California can no longer use state-issued debit cards at cannabis dispensaries, since they are deemed to be "inconsistent with the intent" of the program. On November 2, 2010, Governor Schwarzenegger sent a letter to county welfare directors announcing that ATMs and point-of-sale card readers in such businesses will be removed from the network that accepts California's Electronic Benefits Transfer cards. (http://articles.latimes.com/2010/nov/02/local/la-me-ebt-cards-20101102.)

14. Must I allow my employees to use medicinal cannabis in my workplace?

The MMP does not require any accommodation of the use of medicinal cannabis on the property or premises of any place of employment or during the hours of employment. (Health & Safety Code §11362.785(a).) Again, the CUA is silent on the issue. In Ross v. Ragingwire Telecommunications (2008) 442 Cal.4th 920, 70 Cal.Rptr.3d 382, the California Supreme Court concluded that an employer did not violate either the Fair Employment and Housing Act (FEHA) or public policy (as expressed in the CUA) by discharging a recent employee who failed a pre-employment drug test because of his use (outside of the workplace/working hours) of medicinal cannabis. The court determined that nothing in the text or history of the CUA suggested that the voters intended for the initiative to address the respective right and obligations of employers and employees.

For more information on drug testing, *see* CMA ON-CALL document #0525, "Physician Obligations Regarding Drug or Alcohol Testing."

FEDERAL CONTROLLED SUBSTANCE ACT

15. I'm sure that my practices will meet the standard of care, but I don't want to run afoul of federal law. What should I do or avoid in order to keep from violating the federal Controlled Substances Act?

Physicians who intentionally make certain oral or written statements, or take other action, for the purpose of assisting patients to obtain cannabis in violation of federal law, may be subject to serious liability under federal law. The Ninth Circuit has affirmed that the First Amendment protects physicians' right to recommend or advise that their patients use medicinal cannabis so long as the physicians do not aid and abet, or conspire with, their patients to violate the federal drug laws. (*Conant v. Walters* (9th Cir. 2002) 309 F.3d 629.)

On October 19, 2009, the U.S. Department of Justice issued guidelines to federal prosecutors in States that have enacted laws authorizing the medical use of cannabis. The DOJ stressed that it is committed to making "efficient and rational use of its limited investigative and prosecutorial resources" and that the "disruption of illegal drug manufacturing and trafficking networks continues to be a core priority." The guidelines advise against prosecutions of individuals whose actions "are in clear and unambiguous compliance with existing state laws" governing the medical use of marijuana, such as patients with cancer or other serious illnesses who use cannabis "as part of a recommended treatment regimen," or those caregivers in "clear and unambiguous compliance with existing state law. " However, prosecution of "commercial enterprises that unlawfully market and sell marijuana for profit" continues to be an enforcement priority. The Department warned that "claims of compliance with state or local law may mask operations inconsistent with the terms, conditions, or purposes of those laws." Furthermore, federal prosecutors are not expected to charge, prove, or otherwise establish any state law violations, and compliance with state law does not create a legal defense to a violation of the Controlled Substances Act. *See* http://blogs.usdoj.gov/blog/archives/192.

Following the issuance of the DOJ guidelines, the Office of National Drug Control Policy issued a statement stressing that the DOJ guidelines should not be read as the federal government's tacit approval of the medicinal use of cannabis.

See www.whitehousedrugpolicy.gov/news/press09/marijuana_legalization.pdf. The Drug Enforcement Administration issued a similar statement. (www.justice.gov/dea/pubs/pressrel/pr102209.html.) The federal Department of Transportation also issued a statement clarifying that the DOJ's guidelines do not impact the DOT's drug testing program, www.fmcsa.dot.gov/documents/Medical-Marijuana-Notice.pdf. *See also* the DEA Position on Marijuana, www.whitehousedrugpolicy.gov/statelocal/California_listing.html.

It is possible that the DOJ guidelines will reduce the likelihood that physicians could be at risk of liability under federal law for aiding and abetting a patient in obtaining cannabis. However, the scope and impact of the DOJ guidelines are at present uncertain. Therefore, it is still extremely important for physicians to understand the difference between permissible and impermissible recommendations. This document explains that difference below.

PHYSICIANS' ABILITY TO RECOMMEND THE USE OF CANNABIS

16. I understand that physicians can be punished for recommending cannabis to their patients. How can this be true?

Federal law establishes a clear prohibition against knowingly or intentionally distributing, dispensing, or possessing cannabis. *See* 21 U.S.C. §§841-44. A person who aids and abets another in violating federal law, 18 U.S.C. §2, or engages in a conspiracy to purchase, cultivate, or possess marijuana, 21 U.S.C. §846, can be punished to the same extent as the individual who actually commits the crime. The penalty for a first-time violation of these provisions in the case of less than 50 kilograms of cannabis is imprisonment for a term of up to five (5) years, a fine of up to $250,000, or both. The penalty for a violation committed after a prior drug conviction is imprisonment for a term of up to ten (10) years, a fine of $500,000, or both. (21 U.S.C. §841(b)(1)(D).) But *see* Question15 above.

Other federal sanctions are also possible. If a physician were to aid and abet or conspire in a violation of federal law, the federal government might revoke the physician's DEA registration through an administrative procedure. This would seriously hinder the physician's ability to provide proper medical care to his or her patients. Physicians should also be aware that a felony conviction relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance results in mandatory exclusion from the Medicare and Medi-Cal programs. (42 U.S.C. §1320a-7(a)(4).)

17. Why has there been so much confusion over whether or to what extent a physician may "recommend" to a patient the medical use of cannabis?

Before the enactment of the CUA, a physician could discuss with, and recommend to, a patient the medical use of cannabis, but any recommendation did not, as either a legal or practical matter, assist the patient in obtaining cannabis. After the CUA, however, a patient who can demonstrate a physician's recommendation can lawfully (under state law) possess and/or cultivate cannabis for his or her personal medical use. *Furthermore, as a practical matter, a patient with a physician's recommendation can obtain medicinal cannabis at a cannabis dispensary or some other source.* A few cannabis dispensaries were in existence before the enactment of the CUA, but their numbers and public visibility increased after the law was passed.

As a result, the federal government has argued that, now, a "recommendation" has the same effect as a prescription because it enables a patient to obtain and possess cannabis; therefore, those physicians who intentionally provide recommendations, only for the purpose of assisting patients in obtaining and possessing cannabis, may be guilty of aiding and abetting a federal crime.

Unfortunately, the terms "recommend" and "recommendation" can refer to a wide variety of discussions and actions. Because of this uncertainty, a number of physicians, who were uncertain whether and to what extent they could converse with their patients about cannabis, brought a lawsuit against the federal government, asking a federal court to determine what types of discussions and recommendations were protected by the First Amendment freedom of speech.

The courts have now definitively ruled in favor of the physicians as discussed below. (*Conant v. Walters* (9th Cir. 2002) 309 F.3d 629, affirming *Conant v. McCaffrey* (N.D.Cal. Sept. 7, 2000) 2000 WL 1281174. *See also Conant v. McCaffrey* (N.D.Cal. 1997) 172 F.R.D. 681).)

18. What do these rulings allow physicians to do? Can I provide my patients with information and advice about cannabis if I think that might help them make decisions about their medical care?

In *Conant*, the court made the following rulings:

Physicians licensed in California may discuss and recommend the medical use of cannabis to patients suffering from severe nausea (commonly associated with HIV/AIDS and cancer), wasting syndrome (commonly associated with HIV/AIDS), increased intraocular pressure (commonly associated with glaucoma), seizures or muscle spasms associated with a chronic, debilitating condition (commonly associated with epilepsy, multiple sclerosis, and paraplegia/quadriplegia/hemiplegia), and/or severe, chronic pain (commonly associated with diagnosed paraplegia/quadriplegia/hemiplegia, HIV/AIDS, metastasized cancers, and cervical disk disease). *It is important to note that the court's ruling does not explicitly extend to physicians recommending cannabis to patients with other diseases or conditions.* Physicians who recommend the use of cannabis to other types of patients may still be protected by the First Amendment, but the availability of such constitutional protection is not certain.

A physician's recommendation must be made in the context of a bona fide physician-patient and must be based on the physician's best medical judgment.

Physicians have a legitimate need to discuss with, and to recommend to, their patients all medically acceptable forms of treatment. If a physician could not communicate his or her opinion that cannabis is the best therapy or at least should be tried, the physician-patient relationship would be seriously impaired.

A physician's recommendation may not necessarily lead to a violation of the federal drug laws. Patients may use such a recommendation to urge the government to change those laws, i.e., to petition the government for a redress of grievance or a change in policy. Furthermore, a recommendation may enable a patient to gain admittance to a federally approved research program; to obtain cannabis in a foreign country where such access is not prohibited; or to establish that the patient's use of cannabis is "medically necessary."[1]

Physicians may issue writings [in addition to normal documentation in the patient's medical record] that memorialize their recommendations, if the patient may need such a writing for the above purposes. However, if these purposes do not apply, a physician "should proceed more cautiously." If the physician concludes that the "sole use and reason" for the writing would be simply to obtain cannabis in violation of federal law, the writing would probably not be entitled to First Amendment protection. **Therefore, a physician should document in his or her records the reason for each recommendation and the reason for each written certification.**

Some patients may use recommendations to obtain cannabis from cannabis dispensaries in violation of the federal law. However, if a physician issues a sincere recommendation based on his or her best medical judgment, then he or she has not violated federal law, even if the physician foresees that the recommendation could be used to facilitate a federal crime. The Ninth Circuit affirmed that the mere fact that a physician anticipates that a patient will use the recommendation to obtain marijuana "does not translate into aiding and abetting or conspiracy." Nevertheless, the court cautioned that, "[i]f, in making the recommendation, the physician intends for the patient to use it as the means for obtaining marijuana, as a prescription is used as a means for a patient to obtain a controlled substance, then a

[1]This last use may no longer be valid after the Supreme Court's decision in *United States v. Oakland Cannabis Buyers' Cooperative* (2001) 532 U.S. 483, 149 L.Ed.2d 722, establishing that medical necessity does not constitute an exception to the federal Controlled Substances Act, , at least with regard to the distribution of medicinal cannabis. On remand, the Ninth Circuit rejected Raich's remaining challenges to the Controlled Substances Act. *See Raich v. Gonzales* (9th Cir. 2007) 500 F.3d 850. However, on August 20, 2008, a federal district court refused to dismiss a lawsuit brought by the city of Santa Cruz and the Wo/Men's Alliance for Medical Marijuana, which asserts that the federal government has sought to nullify California' medical marijuana laws, thereby violating the 10th Amendment. (*Santa Cruz v. Mukasey* (N.D.Cal. 2008) No. C 03-01802 JF (not for citation).) WAMM recently dropped its lawsuit, citing the Obama administration's new policy. The settlement allows WAMM to reinstate its lawsuit if the government changes its policy.

physician would be guilty of aiding and abetting the violation of federal law." The court explained that a physician would aid and abet "by acting with the specific intent to provide a patient with the means to acquire marijuana." In addition, "a conspiracy would require that a doctor have knowledge that a patient intends to acquire marijuana, agree to help the patient acquire marijuana, and intend to help the patient acquire marijuana."

Bad faith recommendations are not entitled to protection. Thus, physicians who issue insincere recommendations without a medical basis and with the knowledge and intention that the recommendation would be used illegally to obtain cannabis would be subject to DEA revocation or other federal sanctions. If the patient asks a physician how to obtain cannabis, the physician (if he or she chooses to address the subject) should advise the patient that cannabis is prohibited under the present federal drug laws and inform the patient about the availability of cannabis under federal research programs or foreign laws (if the physician possesses information about such programs or laws). However, federal law would prohibit a patient from bringing cannabis or a cannabis-based medicine across the U.S. border.

In 2007, a physician brought First Amendment and equal protection challenges based upon the alleged undercover investigation of his medical practice. The physician contended that the DEA and various state and federal officials had conducted a retaliatory investigation of his practice in response to his statements concerning medical marijuana. The federal trial court denied the defendants' motions to dismiss and for summary judgment with respect to the First Amendment and equal protection claims, applying "strict scrutiny" to the challenged governmental actions. At trial, the physician must provide evidence to support his claim that the government should have employed alternate methods to achieve their stated purpose of obtaining a physician recommendation in order to investigate a medical marijuana dispensary. (*Denney v. DEA* (E.D. Cal. 2007) 508 F.Supp.2d 815.)

19. Does this mean that I can actually suggest that my patient use medicinal cannabis? Can I use the word "recommend"?

Under the *Conant* court's ruling, a physician should be able to conduct in good faith a traditional physician-patient conversation in the physician's office as follows:

The physician may describe the relevant scientific literature and provide the patient with information about the possible health risks and therapeutic benefits of cannabis for use in the patient's condition (including informing the patient that those potential risks and benefits have not, for many indications, been fully tested in, or even fully identified by, properly-controlled clinical trials). The physician can attempt to answer the patient's medical questions.

The physician may describe (without identifying information) anecdotal evidence concerning medicinal cannabis use by other patients with the same or similar condition.

The physician may provide his or her professional opinion concerning the possible balance of risks and benefits in the patient's particular case, including, if appropriate, a specific recommendation that the patient use medicinal cannabis for medical purposes. A physician might say, "For you, cannabis might be worth a try," "I recommend that you use cannabis," "In your case, the benefits of using cannabis appear to outweigh the risks." There are no "magic words" that a physician must use or avoid in order to inform a patient that the physician believes cannabis may be a medically-appropriate treatment for that patient.

In many cases, a patient may already have discovered that cannabis provides relief from his/her symptoms and may be seeking the physician's agreement that the use of medicinal cannabis is appropriate in the patient's case. Without a physician's concurrence, the patient's use of cannabis remains illegal under state law. In such a case, a physician is probably providing an "approval," rather than a "recommendation." In

People v. Jones (2003) 112 Cal.App.4th 341, 4 Cal.Rptr.3d 916, the Court of Appeal stated that the word "approval" "connotes a less formal act than a 'recommendation'." The court indicated that the word "recommendation" suggests that the physician has raised the issue of medicinal cannabis and presented it to the patient as a potentially appropriate treatment, whereas the word "approval" suggests that the patient has raised the issue, and the physician has "expressed a favorable opinion" of the use of medicinal cannabis for that patient. It should be noted that, while a physician's approval would have prospective effect, it may not "retroactively" authorize a patient's prior use of cannabis (which is relevant if a patient is being prosecuted for such use). *See* Question 9 above.

CMA also urges physicians to advise their patients that, notwithstanding the CUA, the cultivation, possession and use of cannabis, even for medical purposes, is illegal under federal law. *See Gonzales v. Raich* Question 1, above. But see Question 15 above. Generally, physicians are not required to be familiar with, nor warn patients about, the legal consequences of a patient's health care treatment decision. However, there has been much controversy and confusion about the legality of the therapeutic use of cannabis, and many patients may think that, if their physician believes cannabis on balance may be beneficial for them, they can cultivate, obtain, and use cannabis *without risk of any punishment*. They may not understand that they could still be subject to prosecution or other sanctions under federal law. (For example, a U.S. Customs Inspector wrote to a physician, urging the physician to advise patients that they may be subject to severe penalties for transporting even a small amount of cannabis.) Therefore, if the physician engages in a conversation with a patient, such as that described above, the physician should ensure that the patient understands what legal risks exist for the patient under federal law. The physician should further make it clear that he or she cannot take any action for the purpose of enabling the patient to obtain or possess cannabis.

20. What is a "*bona fide*" physician-patient relationship? May I discuss and advise a patient about medicinal cannabis if I am not the patient's primary treating physician?

Many physicians do not believe that they are sufficiently well informed about the risks and benefits of medicinal cannabis to be able accurately to counsel their patients. Therefore, patients may seek such information and advice from other physicians who feel confident in their ability to address these issues, but who will not be responsible for the ongoing care of the patient's medical condition(s). It is possible that a bona fide physician-patient relationship may be established in such a situation if the physician engages in the same activities ordinarily undertaken by a specialist, for example, by:

- Conducting a good faith examination of, and obtains a medical history from, the patient before discussing and advising the patient about cannabis;
- Ensuring that the patient has a serious medical condition;
- Documenting the results of that exam/history and discussion in the patient's medical record, including the basis for the physician's conclusion that cannabis might be therapeutic;
- Consulting with the patient's primary care physician and/or obtaining a copy of the portion of the patient's medical record relating to the condition for which the physician has recommended the use of cannabis, e.g., which establishes the patient's diagnosis and previous care and treatment;
- Referring a patient to a specialist where appropriate; and
- Providing follow-up assessment at regular intervals including, but not limited to, telephonic communication with the patient, in order to ascertain the safety and effectiveness of cannabis on the patient's condition and overall health. In order to ensure such contact, the physician may limit the duration of the recommendation.[2]

In light of the Medical Board's 2004 statement (*see* Question 11), it would appear that such practices constitute a *bona fide* physician-patient relationship. Nevertheless, a physician who seeks to provide information and advice in such a situation should consult his or her legal counsel.

MEDICAL NECESSITY

21. I have read a lot about a case involving "medical necessity." What does the idea mean, and does it allow cannabis dispensaries to distribute medicinal cannabis to certain patients?

A number of years ago, the federal government filed six (6) civil suits against cannabis dispensaries in Northern California, arguing that the dispensaries were violating federal law, which prohibits the sale, manufacture or distribution of cannabis. Those suits were consolidated before a single federal judge. A federal district court issued a preliminary injunction to close the operations. (*United States v. Cannabis Cultivators Club* (N.D.Cal. 1998) 5 F.Supp.2d 1086.) The court thereafter refused to modify its injunction to permit the Oakland Cannabis Buyers Cooperative to distribute medicinal cannabis to patients demonstrating "medical necessity." The case was appealed and ultimately reached the U.S. Supreme Court.

In May 2001, the U.S. Supreme Court ruled against the Cooperative. The court ruled that there is no "medical necessity" exception to the Controlled Substances Act's (CSA) prohibition against manufacturing and distributing cannabis. (*United States v. Oakland Cannabis Buyers' Cooperative* (2001) 532 U.S. 483, 149 L.Ed.2d 722.) The court concluded that a necessity exception for cannabis is "at odds" with the terms of the CSA, the provisions of which leave "no doubt" that the defense is unavailable. Cannabis's placement in Schedule I of the CSA "reflects a determination" that cannabis has no medical benefits worthy of an exception and cannot be used outside the confines of a government-approved research project.

On remand, the defendants in the OCBC case, and the parties in a related case involving a Santa Cruz medicinal cannabis cooperative (WAMM), contended that the federal constitution protects *patients' rights* to use and obtain medicinal cannabis, at least when all conventional treatments have failed, and that the Controlled Substances Act cannot validly be applied to noncommercial intrastate activity. As noted above in Question 1, the Supreme Court in *Gonzales v. Raich* rejected the Commerce Clause argument, and, on remand, the Ninth Circuit rejected the remaining arguments.

22. Do the U.S. Supreme Court's rulings in *OCBC* or *Raich* affect the CUA?

In neither case did the U.S. Supreme Court rule on the validity of the CUA, nor do its holdings implicitly nullify that law.

DISCUSSING RISKS AND BENEFITS

23. How can I learn more about the risks and benefits of medicinal cannabis? Where can I get more information?

There have been few properly controlled clinical trials investigating the safety and efficacy of medicinal cannabis, although information is growing. The Center for Medicinal Cannabis Research (CMCR) at the University of California San Diego has funded a number of Phase 2 clinical trials using smoked cannabis. For the results of this research, *see* www.cmcr.ucsd.edu. Several CMCR-funded studies have been

[2] In People v. Windus (2008) 165 Cal.App.4th 634, 81 Cal.Rptr.3d 227, the California Court of Appeal for the Second District ruled that the CUA does not itself require a patient periodically to renew a physician's recommendation. However, the Medical Board has determined that proper medical practice does require a physician to conduct regular follow-up assessments.

published, demonstrating statistically-significant improvements in several pain conditions. Abrams, DI, et al., "Cannabis in Painful HIV-associated Sensory Neuropathy: a Randomized, Placebo-controlled Clinical Trial," *Neurology* 68(7):515-21 (2007) (painful HIV-related peripheral neuropathy); Wilsey, B, et al., "A Randomized, Placebo-Controlled, Crossover Trial of Cannabis Cigarettes in Neuropathic Pain," The Journal of Pain 9(6):56-21 (2008) (neuropathic pain); Ellis, RJ, et al., "Smoked Medicinal Cannabis for Neuropathic Pain in HIV: A Randomized, Crossover Clinical Trial," Neuropsychopharmacology 1-9 (2008) (painful HIV-related neuropathy). *See also*, Wallace, M, et al., "Dose-dependent Effects of Smoked Cannabis on Capsaicin-induced Pain and Hyperalgesia in Healthy Volunteers," Anesthesiology 107785-96 (2007) (dose-dependent effects in an experimental pain model). For an analysis of the significance of these studies, *see* Barthwell, A., "Early Findings in Controlled Studies of Herbal Cannabis: A Review,"Journal of Global Drug Policy and Practice (2010) Vol. 4, issues 1 & 2. (http://globaldrugpolicy.org/4/1/1.php, http://globaldrugpolicy.org/.)

In addition, a UK pharmaceutical company has completed ten Phase 3 double blind, randomized, placebo-controlled clinical trials. These trials, involving patients with multiple sclerosis, neuropathic pain, or cancer pain, investigated the safety and efficacy of a cannabis-derived pharmaceutical product, comprised of specific cannabinoid ratios and delivered as an oromucosal spray. The results demonstrated statistically significant benefit in a range of symptoms, including neuropathic pain, spasticity, and sleep disturbance. The product was shown to have an excellent safety profile, and most patients were able to titrate (adjust) their dose in order to achieve improvements in their symptoms without incurring notable psychoactive side effects that would interfere with day-to-day living. The company's first product, Sativex®, is approved in the U.K., Spain, Canada, and New Zealand for the adjunctive treatment of spasticity in multiple sclerosis (MS). It is also approved in Canada for the adjunctive treatment of neuropathic pain in MS and for the adjunctive treatment in patients with advanced cancer whose pain is not being adequately controlled by strong opioids. The company completed a Phase II/III dose-ranging trial in cancer pain under an FDA IND in November 2009 and began a Phase III study late in 2010.

The extent of information about the various forms of unstandardized herbal cannabis is still limited. Therefore, physicians should be cautious when undertaking to discuss the risks and benefits of medicinal cannabis use. A physician may be at risk of malpractice liability if a patient suffers an adverse effect, of which the physician was unaware, that would likely have been identified if such testing had taken place. Little is known about potential health risks, particularly of long-term use of smoked cannabis. Furthermore, certain patient populations may be at greater risk of adverse side effects, such as patients with psychiatric illness. It is also uncertain whether cannabis may interact with various prescription medications.

Finally, because cannabis is not a regulated pharmaceutical, the crude herbal form may contain impurities or contaminants that could be harmful, particularly to patients with immunodeficiency problems. The Los Angeles City Attorney's office recently conducted an undercover purchase of several cannabis samples from dispensaries. Two of the three samples were contaminated with bifenthrin, a pesticide. One sample had 170 times the allowable amount for herbs. (Mem. P&A in Support of Plaintiff's Application for Temporary Restraining Order, Order to Show Cause Re Preliminary Injunction and Preliminary Injunction, *People v. Hemp Factory V et al.*, No. BC 424881 (Cal. Sup. Ct. Oct. 30, 2009); Los Angeles City Attorney, "City Attorney Explains Medical Marijuana Issue on NBC," http://lacityorgatty.blogspot.com/2009/10/city-attorney-explains-medical.html (accessed Dec. 30, 2009).) Herbal cannabis, depending on how it is cultivated, harvested, and stored, is also susceptible to fungal and other microbial contamination. In the Netherlands and Canada, where the governments each license one cultivator to produce "medical grade" cannabis for distribution to qualified patients, the herbal material must be irradiated to reduce microbial levels. *See*, e.g., Hazekamp, A., "An Evaluation of the Quality of Medicinal Grade Cannabis in the Netherlands," *Cannabinoids* 2006; 1(1):1-9. Physicians should warn patients about these potential risks when appropriate.

The following books and articles also provide extensive sources of information about the risks and benefits of the medical use of cannabis:

- Institute of Medicine, National Academy of Sciences, *Marijuana as Medicine: Assessing the Science Base* (1999).

- McCarberg, BH, "Cannabinoids: Their Role in Pain and Palliation," *Journal of Pain & Palliative Care Pharmacotherapy.* 21(3):19-28 (2007).

- McCarberg, BH, and Barkin, RL, "The Future of Cannabinoids as Analgesic Agents: A Pharmacologic, Pharmacokinetic, and Pharmacodynamic Overview," *American Journal of Therapeutics* 14(5): 475-483 (2007).

- Russo, EB, "The Role of Cannabis and Cannabinoids in Pain Management," in Cole, BE, and Boswell, M., eds., *Weiner's Pain Management: A Practical Guide for Clinicians* 7th ed. Boca Raton, FL: CRC Press, p. 823-844 (2006).

- Russo, EB, "The Solution to the Medicinal Cannabis Problem," in: Schatman ME, ed., *Ethical Issues in Chronic Pain Management*. Boca Raton, FL: Taylor & Francis. p 165-194 (2006).

- Russo, EB, and Guy GW, "A Tale of Two Cannabinoids: the Therapeutic Rationale for Combining Tetrahydrocannabinol and Cannabidiol," *Medical Hypotheses* 66(2):234-246 (2006).

- Mechoulam R., ed., *Cannabinoids as Therapeutics*, Basel, Switzerland: Birkhauser Verlag (2005).

- Grinspoon, L and Bakalar, J., *Marijuana: The Forbidden Medicine* (1997).

- Mathre, M.L., ed., *Cannabis in Medical Practice: A Legal, Historical and Pharmacological Overview of the Therapeutic Use of Marijuana* (1997).

- *Cannabis and Cannabinoids: Pharmacology, Toxicology, and Therapeutic Potential*, eds. F. Grotenherman and E.B. Russo, Binghamton, NY: Haworth Press (2002).

- Iversen, L.L., *The Science of Marijuana* (2000)

- Guy, G., Whittle, B.A., and Robson, P.J, eds. *The Medicinal Uses of Cannabis and Cannabinoids* (2004).

- Diplock, J., Cohen, I., and Plecas, D., "A Review of the Research on the Risks and Harms Associated to the Use of Marijuana," *Journal of Global Drug Policy and Practice*, www.globaldrugpolicy.org/3/2/3.php.

24. Is cannabis more potent now than it was 30 years ago?

The levels of THC and other cannabinoids in cannabis and cannabis products distributed by dispensaries are uncertain. However, the University of Mississippi has been analyzing the THC levels of seized cannabis for over 30 years. In that period of time, those levels (for domestic cannabis seizures) have increased from an average of 1.7% to 13%.

See www.whitehousedrugpolicy.gov/publications/pdf/mpmp_report_104.pdf. Individual samples have reached as high as 37%. By contrast, the levels of CBD (cannabidiol), a non-psychoactive cannabinoid,

have become negligible. CBD was present in ancient cannabis and is believed to dampen many of the effects of THC, including its psychoactive effect. The use of high THC/low CBD cannabis, particularly by patients who are cannabis-inexperienced, may result in a higher incidence of CNS-related side effects.

PROFESSIONAL LIABILITY COVERAGE

25. What if a patient uses herbal cannabis on my recommendation and suffers some adverse health event as a result? If I am sued, will my professional liability insurance cover me?

Different malpractice carriers have different policies. Some refuse to insure for harms resulting from medications, including cannabis, that are not approved by the FDA. *See* Mead, A.P., "Cannabis-Based Medicines: What Does the Future Hold?" *Physician Insurer* (Nov. 2006). A physician should discuss the issue with his/her liability carrier.

OBTAINING CANNABIS/PERMISSIBLE QUANTITIES

26. How are patients or caregivers supposed to obtain cannabis?

The CUA was intended to authorize a patient or a patient's "designated primary caregiver" to cultivate and possess cannabis for the patient's medical use. A "primary caregiver" is the individual designated by the patient who has consistently assumed responsibility for the patient's housing, health, or safety. The MMP clarifies the conditions under which an individual may serve as a designated primary caregiver for one or more patients (whether or not the patients have ID cards). *See* Health & Safety Code §11362.7(d). Furthermore, the law specifically states that the caregiver may receive compensation for actual expenses, including reasonable compensation incurred for services provided to a patient to enable that person to use medicinal cannabis. (Health & Safety Code §11362.765(c).)

Even with a valid recommendation from a physician, many patients (and caregivers) were arrested on the charge that they were cultivating more cannabis than was needed for the patient's personal medical needs and hence were cultivating for purposes of sale. The MMP attempts to address that problem by providing that a patient or primary caregiver may possess eight ounces of dried cannabis, and in addition, six (6) mature or twelve (12) immature plants, per patient. However, if a patient has a physician's statement that this quantity does not meet the patient's medical needs, the patient or primary caregiver may possess a larger amount consistent with those medical needs. (Health & Safety Code §11362.77.) Several counties have also previously established specific limits on the number of plants and the quantity of plant material that an individual patient may possess. The MMP allows cities and counties to retain or enact guidelines permitting patients and caregivers to exceed these amounts. (*Id*.)

In People v. Kelly (2010) 47 Cal.4th 1008,103 Cal.Rptr.3d 733, the California Supreme Court struck down Section 11362.77 as applied to patients who qualify for the protections of the CUA (by having a physician's recommendation to use cannabis for medical purposes) but who have not chosen to obtain an ID card under the MPP. The court ruled that Section 11362.77, as so applied, constituted an invalid amendment of the CUA because it burdened a patient's right under the CUA to possess and/or cultivate as much cannabis as is reasonable for the patient's personal medical use. The court determined that Section 11362.77 falls short of "matching" the rights established by the CUA. First, subdivision (b) (which allows a patient to possess a larger amount of cannabis than allowed in (a) if a physician recommends that the allotment does not meet the person's medical needs) does not apply to plant cultivation limits; second, it could be difficult for a patient to obtain a physician's recommendation that the patient needed to use and possess more cannabis than allowed. Hence, a patient who "qualifies" to use cannabis for medical purposes under the CUA may, if arrested, present evidence in court that the amount he/she possessed and/or cultivated was reasonable in light of his/her medical needs. That evidence may include, but does not require, a physician's

recommendation or testimony regarding the quantity of cannabis appropriate for that patient. Patients who choose to obtain ID cards are still subject to Section 11362.77.

Many patients are too ill to cultivate their own marijuana, and many caregivers lack the skill or location for such cultivation. However, the CUA did not authorize any individual or entity (such as cannabis dispensaries) to sell, or even give, cannabis to a patient or caregiver, even with a physician's written or oral recommendation. After the CUA was initially passed, the operators of some dispensaries were designated by hundreds of patients as the patients' "primary caregiver."

However, under the CUA, a cannabis dispensary may not qualify as a "primary caregiver" under the law. (People ex rel Lungren v. Peron (1997) 59 Cal.App.4th 1383; 70 Cal.Rptr.2d 20.) In Peron, the court stressed that the state criminal statutes prohibiting both the selling and the giving away of cannabis were not affected by the CUA. However, the Peron case involved a dispensary that was open to the public, i.e., to any individual qualified under the initiative, that charged for the cannabis (albeit on an allegedly nonprofit basis), and that potentially served as only one of several sources of supply for any patient who chose to purchase cannabis there. *See also* People v. Galambos (2002) 104 Cal.App.4th 1147, 128 Cal.Rptr. 844 (neither defense of medical necessity nor limited immunity of the CUA can be claimed by an individual who purported to cultivate cannabis for medicinal cannabis dispensary). The Peron court stressed that the language of the CUA does **not** preclude a primary caregiver from serving more than one patient, and indeed the MMP explicitly allows more than one patient to designate the same caregiver, if the patients and caregiver reside in the same county. However, the California Supreme Court ruled that a person whose "caregiving" consists principally of supplying cannabis and instructing on its use, and who otherwise only sporadically takes some patients to medical appointments, cannot qualify as a "primary caregiver" under the CUA. (People v. Mentch (2008) 45 Cal.4th 274, 85 Cal.Rptr.3d 480.) The court concluded that a primary caregiver must prove at a minimum that he/she 1) consistently provided caregiving, 2) independent of any assistance in taking medical marijuana, 3) at or before the time he/she assumed responsibility for assisting with medical marijuana. A primary caregiver must be the principal, lead, or central person responsible for rendering assistance in the provision of daily life necessities.

The MMP recognizes that patients and caregivers may associate in order collectively or cooperatively to cultivate medicinal cannabis. (Health & Safety Code §11362.775.) In August 2008, the California Attorney General's office issued "Guidelines for the Security and Non-diversion of Marijuana Grown for Medical Use."

See http://ag.ca.gov/cms_attachments/press/pdfs/n1601_medicalmarijuanaguidelines.pdf.

The AG's Guidelines stressed that a "cooperative" must file articles of incorporation with the state and conduct its business for the mutual benefit of its members. It must follow strict rules on organization, articles, elections, and distribution of earnings, and must report individual transactions from individual members each year. A "collective," while not defined under California law, should be an organization that merely facilitates the collaborative efforts of patient and caregiver members. Neither collectives nor cooperatives should purchase cannabis from, or sell to, non-members. The Guidelines also set forth suggested practices to ensure that these entities operate in compliance with state and local law and ensure security and non-diversion of cannabis to illicit markets. Mere retail storefront dispensaries are illegal.

California appellate courts have also addressed these issues. In People v. Hochanadel (2009) 176 Cal.App.4th 997, 98 Cal.Rptr.3d 347, the California Court of Appeal ruled that the MMP's authorization of collective and cooperative cultivation projects did not unconstitutionally amend the CUA (an initiative can only be amended by another initiative). However, the court stressed that storefront dispensaries that "merely provide walk-in customers with medical marijuana [do] not possess the type of 'consistent'

relationship necessary to achieve primary caregiver status" and that any such projects must not be conducted on a for-profit basis.

The MMP may allow certain members of a legitimate collective to bring a civil suit following seizure of their cannabis. In County of Butte v. Superior Court (Williams) (2009) 175 Cal.App.4th 729, 96 Cal.Rptr.3d 421, the Court of Appeal for the Third District ruled that the MMP did not merely provide a defense in a criminal prosecution but in addition enabled a patient (whose residence was being used in such a collective) to bring a civil action alleging unlawful seizure of the cannabis being cultivated by the collective. The Butte County case involved a small number of patients who joined together to form a collective, who contributed "comparable amounts of money, property and labor," and who conducted the cultivation at the home of one of the patients. A deputy had ordered Williams (the plaintiff) to destroy all but 12 of 41 cannabis plants, despite the fact that Williams produced copies of physician recommendations for himself and the other 6 members of the collective. The Court of Appeal ruled that the plaintiff should be allowed to argue in a civil action that the deputy lacked probable cause to order the plaintiff to destroy the cannabis plants and that such lack of probable cause led to a violation of his constitutional right of due process under the state constitution. The Court of Appeal did not rule on whether or not the collective could lawfully cultivate that number of plants, nor whether the county's policy of allowing collective cultivation only if each member actively participates in the actual cultivation; that would be determined at trial. On September 23, 2009, the California Supreme Court denied review.

In addition, many cities and counties in California have issued bans or moratoria on the establishment of dispensaries, believing that such dispensaries are not authorized under state law and/or create unacceptable risks to public health and safety. In City of Claremont v. Kruse, the Court of Appeal for the Second Appellate District ruled that neither the CUA nor the MMP precludes a city from taking local action to ban dispensaries. (City of Claremont v. Kruse (2009) 177 Cal.App.4th 1153, 100 Cal.Rptr.3d 1.) *See* Riverside County, "Medical Marijuana: History and Current Complications," (white paper) (Sept. 2006); ONDCP, California City and County Listing of Illegal Store Front Ordinances, www.whitehousedrugpolicy.gov/statelocal/California_listing.html. A.B. 2650, adding Health & Safety Code §11362.768, provides that a cannabis dispensary may not be located within 600 feet of a K-12 school, except as allowed by a local ordinance enacted prior to January 1, 2011. A.B. 2650 further states that its provisions do not prohibit local jurisdictions from adopting ordinances or policies that further restrict the location of such dispensaries. Many cities have enacted measures that place additional taxes on medical marijuana sales. See, e.g., Albany ($25 per square foot on all business improvements occupied by the dispensary), Berkeley (2.5%), La Puente (10%), Oakland (5%), Richmond (5%), Sacramento (up to 4%), San Jose (10%), Stockton (2.5%), Rancho Cordova ($600 per square foot of cultivation with a maximum of 25 square feet allowed).

The California Chiefs of Police have issued a white paper on the subject of dispensaries, www.californiapolicechiefs.org/nav_files/marijuana_files/files/MarijuanaDispensariesWhitePaper_042209.pdf.

A trial court in Los Angeles County recently issued a preliminary injunction ordering a cannabis dispensary to cease selling cannabis, ruling that California law does not authorize collectives to sell cannabis, but only to grow it and recoup reasonable costs. In addition, the court stated that sales of cannabis would trigger the requirements of the California Sherman Food and Drug Act's requirements properly to label drugs (i.e., substances intended for medical use). The Los Angeles City Attorney's office had performed undercover purchases of cannabis and, upon testing the material, had determined had it contained extremely high levels of pesticides, including one that is banned in the U.S. The court further enjoined the dispensary from selling or distributing cannabis that was so contaminated. (*People v. Hemp Factory V,* (Jan. 2010) (Sup. Ct. Central Dist.) BC 424881.)

27. How can a patient know how much medicinal cannabis to take?

Because medicinal cannabis in its unrefined herbal form is not consistent and standardized like conventional pharmaceutical products, both physicians and patients are often uncertain about how the patient should use the substance. Physicians are placed in a difficult position if a patient inquires how much medicinal cannabis the patient should take to obtain therapeutic relief, while avoiding undesirable side effects. Patients may also ask how the cannabis should be administered. Physicians should warn patients of the potential risks of pulmonary harm that could result from smoking, particularly if the patient is using medicinal cannabis for a chronic condition. Furthermore, physicians should be able to inform patients about the existence of alternative, non-smoked delivery forms, such as vaporizers, baked goods, teas, etc. Since the federal government has taken the position that physicians may not lawfully prescribe cannabis for medical use, physicians should be cautious when advising a patient about such issues. If the physician's advice becomes too specific, e.g., how to prepare a tea, how much to drink and at what time of day, where vaporizers can be purchased, it could be construed as a prescription, a form of incitement, or a type of aiding and abetting. But *see* Question 15 above. Furthermore, many physicians do not have the knowledge to be able to give patients guidance in such matters. Physicians could refer patients to Internet and print resources (*see* partial list above) that can provide a wide spectrum of information about medicinal cannabis. *See* Carter GT, Weydt P, Kyashna-Tocha M, Abrams DI, "Medicinal Cannabis: Rational Guidelines for Dosing," *IDrugs* 7(5):464-70 (2004).

A city or county may have specific guidelines governing the amounts of cannabis that patients may lawfully possess and cultivate. *See* Question 26 above. *A physician should be free to opine that the allowable amount of cannabis does not appear to meet a particular patient's medical needs, if the physician has a reasonable basis for such an opinion. However, CMA does not advise physicians to* ***specify*** *the amount of cannabis that* ***would*** *be consistent with the patient's needs.* CMA believes that a physician may lawfully record the patient's reports of his or her extent of cannabis use and his or her description of symptom relief, or lack thereof.

28. What if a patient asks me how he or she can obtain cannabis?

Physicians should **not** provide a patient with the name and address of a cannabis dispensary or other type of cannabis distributor. While physicians may be sympathetic to a patient who cannot otherwise obtain medicinal cannabis, physicians may risk serious sanctions if they direct a patient to a specific cannabis source. But *see* the Department of Justice recent guidelines, Question 15 above. Physicians should inform a patient that the physician cannot affirmatively assist the patient in obtaining cannabis.

MEDICAL RECORD DOCUMENTATION

29. May I record my conversation with the patient in the patient's medical record?

Most certainly. As with all physician-patient discussions, a conversation about medicinal cannabis should be documented in the medical record, in accordance with the physician's normal charting practices. Such recordation will ensure that this, like all information that relates to the patient's health care, will be available for the future reference of the physician or other health care providers. In addition, if a patient should use cannabis and suffer an untoward side effect (or be prosecuted under federal law), the physician can demonstrate that he or she warned the patient of that possibility.

30. What should I do if a patient asks for a copy of his or her medical record?

A patient has a right under state law to obtain a copy of his or her medical record. Since a separate statutory scheme requires physicians to provide patients with their medical records on request, the physician-patient conversation described above should not be construed as deliberately assisting the patient

to obtain cannabis, even if the patient, on his or her own, decides to take the medical record to a cannabis dispensary, and even if the physician is aware that the patient may do so. However, a physician might be subject to sanctions if there is clear evidence that the physician is conspiring in the patient's plan. Therefore, physicians should *not* state that the physician is making the recordation in order to enable the patient to obtain cannabis from a dispensary, nor should the physician actively encourage a patient to request a copy of the medical record for that purpose. When providing the patient with a copy of his or her medical record, the physician again should follow his or her normal practice. Typically, when copying medical records for any purpose, physicians should provide a complete medical record, i.e., one that contains the entire patient's medical information, or at least all that is relevant to the condition at issue.

RESPONDING TO PATIENT REQUESTS FOR TESTIMONY

31. What do I do if a patient is prosecuted under state law for possessing or cultivating, and I am subpoenaed to testify about the office conversation in order to establish the patient's right to a limited immunity under the CUA?

A physician may be required by subpoena to testify in court, or to provide a sworn written statement, to describe the information and advice that he or she provided a patient. The district court's earlier ruling in the *Conant* case indicates that a physician cannot be punished for providing such testimony or statement under compulsion of law. Under the court's later September 7 ruling, it would seem a physician cannot be sanctioned for providing such oral or written testimony *voluntarily*, i.e., without a subpoena, although this is not completely free from doubt. The Ninth Circuit did not explicitly address this issue.

RESPONDING TO LAW ENFORCEMENT REQUESTS

32. I understand that local police in some areas have contacted physicians directly in order to determine whether or not patients have recommendations from those physicians for the medical use of cannabis. How should I deal with their requests?

Physicians must be extremely cautious in this situation. The California Confidentiality of Medical Information Act severely limits the circumstances under which physicians may disclose patient medical information to a third party, including the police. In short, physicians may discuss or testify about such information only pursuant to 1) a written consent from the patient which meets the formal requirements of the Act, including identification of the specific medical information that can be disclosed; or 2) a court order, or (if patient office records are being sought) search warrant. (If the records are sought by search warrants, they can only be released to a special master. (Penal Code §1524(c).) A "special master" is an attorney who is a member in good standing of the California State Bar who has been selected by the court from a list maintained by the State Bar. The special master must accompany the person serving the warrant and must inform the person upon whom the warrant is being served of the specific items being sought and that the party being served will have an opportunity to produce the items requested. If the physician being served states that certain items should not be disclosed, those items shall be sealed by the special master and taken to court for a hearing. The physician must be informed of the date, time, and place of the hearing, which ordinarily must be held within three days. (Gordon v. Superior Court (1997) 55 Cal.App.4th 1546, 65 Cal.Rptr.2d 53.)

Even if the physician is required (by court order or search warrant) or permitted (by patient authorization) to testify about or discuss the existence of a recommendation with the police, the physician would be well advised to reveal as little as necessary about the patient's actual medical condition. There are a number of state and federal laws that provide heightened protection to drug and alcohol abuse treatment records, AIDS test results, and certain mental health information. In addition, the California constitutional right of privacy protects patient medical information whenever the patient would have had a "legitimate

expectation under the circumstances" that certain information would remain private. Although the application of the constitutional protection is sometimes uncertain, its prohibitions apply to the conduct of private actors (like physicians), and its breach can result in serious damage liability. Therefore, physicians should reveal no more patient information than is essential to serve the legitimate purposes of the inquiring party.

Thus, again, even if there is a patient consent or a court order, CMA encourages physicians only to reveal whether or not 1) the patient has a serious medical condition (but not the nature of the condition) and 2) the physician has recommended or approved the patient's medicinal use of cannabis. This should be sufficient to enable the police to determine whether the patient is acting in accordance with the intent of the CUA. If a patient registry and ID card program is operating within the city/county, the police should be able to confirm the legitimacy of an ID card without directly contacting the physician.

Physicians who testify or have such discussions with the police should have nothing to fear from the federal government. By confirming to the police that the physician approved the patient's use of medicinal cannabis, the physician is merely providing evidence that is relevant to the criminal proceeding involving the patient.

RESPONDING TO PATIENT REQUESTS FOR COMPLETION OF FORMS

33. Patients have asked me to sign and/or complete different types of forms that relate to the patient's use of cannabis for medical reasons. Can I provide a patient with such a form?

As indicated above, physicians should avoid providing a patient with any writing whose **sole** purpose is to enable the patient to obtain cannabis at a cannabis dispensary or some other source. Under no circumstances should a physician sign a form that contains a logo or letterhead of a cannabis dispensary or that mentions a cannabis dispensary in the body of the letter.

Furthermore, even if there is no mention of a cannabis dispensary, a physician must be cautious. As the *Conant* rulings state, a writing is not protected if the physician's purpose in providing the writing is to enable the patient to obtain cannabis in violation of federal law. If the only credible answer to the question "Why did you give this writing to the patient?" is "To enable the patient to obtain cannabis," then the physician may be subject to liability under federal law. It must be remembered that whether or not a physician is merely attempting to help a patient obtain cannabis is a question of fact, and the physician's subjective intent and knowledge must be determined on the facts of each case. The actual wording on a form may not be the only factor that is taken into account in making this determination.

The *Conant* rulings did not specifically address the situation of the physician who gives a patient a letter of recommendation for the purpose of enabling the patient to reduce the likelihood of arrest, or, if arrested, to exercise his or her rights under Mower (*see* Question 8). An argument can be made that a recommendation letter which is provided for "defensive" purposes should be protected. However, others have argued that, since such a letter intends to enable a patient to cultivate and/or possess/retain cannabis, it therefore still constitutes aiding and abetting a violation of federal law. It should be noted that the *Conant* district court did state that a physician could be subject to punishment for aiding and abetting the *cultivation or possession* of cannabis.

It appears that, ostensibly pursuant to the MMP, the California Department of Health Services has developed a physician form entitled "Written Documentation of Patient's Medical Records." The form asks for the physician's name and certain professional information and for the patient's name and diagnosis. The patient must be "under the medical care and supervision" of that diagnosing physician. It also asks the physician to sign a statement confirming that the patient has been diagnosed with the above medical

condition(s) and that the "use of medical marijuana is appropriate." (www.cdph.ca.gov/pubsforms/forms/CtrldForms/cdph9044.pdf.)

The MMP was carefully crafted to minimize the potential liability risks to physicians under federal law. The MMP clearly states that the requirement of "written documentation" from the attending physician means "accurate reproduction of the relevant portions of the patient's medical records," which the patient has a legal right to request. (Health & Safety Code §11362.7(i).) CMA believes that it would be more prudent for physicians to decline to sign the state form, instead providing a patient (upon the patient's request) with a copy of the relevant portion of the patient's medical record, which the patient can submit along with his/her application for an ID card. An argument can be made that by filling out the state form, the physician is merely assisting the patient (and the State) in ensuring that a qualified patient is not subject to improper arrest by state or local law enforcement. Such a "defensive" purpose may not put a physician in violation of federal law. However, among the "legitimate" reasons listed by *Conant* as justifying a physician in giving a patient a recommendation, the patient's "avoiding arrest" was not one of them

ACTIONS TO AVOID

34. Are there any other types of actions that I should avoid?

A physician should avoid the following:

a) Providing cannabis to a patient;

b) Describing to a patient how the patient may obtain cannabis, for example, by giving the name and address of a cannabis distributor;

c) Communicating with a cannabis distributor, such as a cannabis dispensary, to confirm a recommendation made to a patient in an office dialogue;

d) Offering a specific patient ***individualized*** advice concerning appropriate dosage timing, amount, and route of administration.

Whether a particular recommendation or action is permissible will depend on the surrounding circumstances. Again, physicians cannot intentionally take an action for the purpose of enabling a patient to obtain cannabis or otherwise to violate the federal drug laws. There will be a gray area between the clearly permissible and clearly impermissible categories of action. Physicians will need to use their own judgment in assessing the level of risk involved in particular conduct.

POTENTIAL LIABILITY TO THIRD PARTIES

35. What if one of my patients gets involved in some sort of an accident as a result of using cannabis for medical purposes?

The Initiative does not a) supersede legislation prohibiting persons from engaging in endangering conduct; nor b) condone the diversion of cannabis for non-medical purposes. Therefore, if a patient using cannabis drives an automobile and injures another individual in an accident, the patient's physician could in theory be sued by the injured party (and/or by an injured patient him or herself) claiming that the physician, who had discussed the potential health risks and therapeutic benefits of cannabis with the patient, had not adequately warned the patient not to engage in such endangering activity while impaired.

If a physician chooses to discuss with a patient the risks and benefits of cannabis, the physician should be sure to warn the patient not to engage in dangerous activities, such as driving, operating large machinery,

etc., if impaired by cannabis (or any other medication or substance) and should scrupulously document the conversation in the patient's medical record. In addition, if the physician knows or has reason to believe that the patient will not heed the physician's advice, the physician may be well-advised to warn the patient's family, or other individuals who are likely to occupy an automobile with the patient, about the patient's potentially impaired driving ability. Physicians should be aware that a failure to warn may result in the physician's being liable to the patient if the patient is injured, as well as to third parties who are injured by the patient.

For recent articles on this issue, *see* Ramaekers, J.G., et al., *Cognition and Motor Control as a Function of Delta-9-THC Concentration in Serum and Oral Fluid: Limits of Impairment*, www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T63-4K1G57Y-1&_user=10&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=14f4a3bf1fd7d0a8220c0f8624d45177 (Elsevier); Smiley, A., *Marijuana: On-Road and Driving Simulator Studies*, pp. 173-88, in The Health Effects of Cannabis, eds. H. Kalant, et al., Toronto: Center for Addiction and Mental Health (1998); Sexton, B.F. et al., *The Influence of Cannabis on Driving*, Transport Research Laboratory Limited, Berkshire, UK (2002), www.trl.co.uk/online_store/reports_publications/trl_reports/cat_road_user_safety/report_the_influence_of_cannabis_on_driving.htm; Bates, M. and Blakeley, A.T., *Role of Cannabis in Motor Vehicle Crashes*, Epidemiologic Reviews 21: 222-232 (1999); EMCDDA, "Cannabis Use and Driving: Implications for Public Health and Transport Policy, " www.emcdda.europa.eu/themes/driving.

AMA POLICY

36. Didn't the AMA recently change its policy in this area?

As a result of several proposed resolutions, the AMA's Council on Science and Public Health (CSAPH) prepared recommendations and a report on the subject of the medicinal use of cannabis. That report was adopted by the House of Delegates. One recommendation states that "marijuana's status as a federal Schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines and alternate delivery methods." This recommendation did not support the use of crude herbal cannabis by patients. The report emphasized: "This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product." (www.ama-assn.org/ama1/pub/upload/mm/443/csaph-report3-i09.pdf.) The full text of the report is expected to be published in the near future.

At its 2010 Interim Meeting, the AMA House of Delegates voted to amend current policy by urging the creation of a "special" schedule for cannabis (rather than moving cannabis to Schedule II), for the purpose of facilitating clinical research. (www.ama-assn.org/assets/meeting/2010i/i-10-annotated-k.pdf.)

37. What would rescheduling accomplish?

Rescheduling herbal cannabis would not make cannabis available to patients by prescription. Only a specific FDA-approved product can be prescribed directly to patients. Therefore, each cannabis-derived product would have to go through the FDA approval process. Placing cannabis in Schedule II could make it easier for individual physician-researchers to conduct research, since they would be able to conduct such research (as a "coincident activity") if they already had registrations (licenses) to prescribe Schedule II substances, such as OxyContin. However, the results of the research would have to meet the quality, safety, and efficacy standards of the FDA in order to obtain marketing approval as a prescription medication.

CMA POLICY

38. What is CMA's position on the medical use of cannabis?

Physician-patient dialogue: CMA opposes any governmental threats against physicians arising from discussion of medicinal cannabis in the context of an established physician-patient relationship. Therefore, CMA strongly supports the principles articulated by the federal court in the *Conant* case described above.

Opposition to prosecution of patients: CMA opposes the criminal prosecution of patients who possess or use smoked herbal cannabis for medical reasons upon the recommendation of a physician.

Therapeutic use: CMA has consistently maintained its position that cannabis should be available for therapeutic use as a Schedule II drug only if there are properly controlled studies proving that it is efficacious. CMA believes that seriously ill patients should not be offered a therapy whose efficacy may be illusory and which in some cases may actually worsen the patient's medical condition. Therefore, CMA has opposed the "medicalization" of cannabis unless and until there is objective proof that such use is scientifically justifiable.

Medical necessity: At the same time, however, CMA believes that, if a physician concludes that there are no standard therapies available that will sufficiently relieve the suffering of a seriously ill patient, and cannabis is the only treatment that can provide such relief, the patient should be able to seek out, and obtain access to, that treatment without interference from the federal government. Therefore, CMA filed an amicus brief with both the Ninth Circuit and the U.S. Supreme Court in *United States v. Oakland Cannabis Buyers Cooperative* and *Gonzales v. Raich*, discussed above, supporting the concept of medical necessity.

Research encouraged: CMA continues to support scientifically rigorous research, including all FDA-approved Phase II and Phase III clinical trials and to examine the current science concerning the therapeutic role of cannabinoid-based pharmaceuticals. To this point, CMA has supported efforts to remove cannabis from Schedule I in order to allow greater access for research, limited prescriptive access and appropriate oversight of the supply for the protection of patients and society. In addition, CMA has supported efforts to create, and to obtain federal government approval for, a reliable and high-quality source of cannabis within California for the purposes of (1) facilitating research; and (2) providing controlled distribution (of cannabis) to appropriate patients, upon recommendation of their physician, through pharmacies or other closely regulated sources. However, CMA believes that it should re-examine the need for continued research on smoked herbal cannabis in light of recent research on its benefits and harm and the long-term prospect of smoked herbal cannabis as a medicine.

Medical Board scrutiny: In March 2003, CMA's House of Delegates concluded that CMA should urge the Medical Board to revise its guidelines concerning medicinal cannabis so that the guidelines include the requirement for a good faith exam with diagnosis, treatment and follow up recommendations, and more fully clarify and affirm the legitimate role of physicians in recommending cannabis to appropriate patients. CMA also believes that the Medical Board should apply clinically appropriate standards of care to all physicians, and should **not** apply a higher standard of care or to require a higher degree of evidence in cases where medicinal cannabis is involved. As a result of this policy, CMA worked with the Medical Board to develop an appropriate informational document concerning medicinal cannabis, as discussed in Question 11.

CURRENT RESEARCH AND THE POSITION OF THE FDA

CMA supported a piece of legislation, S.B. 847, authored by Senator Vasconcellos, which established the Cannabis Research Act. This legislation authorized the University of California to implement a three-year research program (the California Cannabis Research Program) to ascertain the general medical safety and

efficacy of cannabis and, if it is found to be therapeutically valuable, to establish guidelines for its appropriate administration and use. *See* Health & Safety Code §11362.9. Three million dollars were appropriated for the first three years of the program. As a result, the Center for Medicinal Cannabis Research (CMCR), whose administrative offices are based at the University of California in San Diego, has awarded a number of research grants. For more information, you may wish to call the Center at (619) 543-5024 or view its website at www.cmcr.ucsd.edu. Under subsequent legislation, CMCR was established as a permanent research center within the University of California.

In addition, GW Pharmaceuticals, a British pharmaceutical company founded for the purpose of developing cannabis-derived pharmaceutical products, has been conducting controlled clinical trials in the UK for the past ten years. GW is focusing on symptoms of cancer pain, neuropathic dysfunction, and neuropathic pain. The company's first product, Sativex®, is approved in the U.K., Spain, Canada, and New Zealand for the adjunctive treatment of spasticity in multiple sclerosis (MS). It is also approved in Canada for the adjunctive treatment of neuropathic pain in MS and for the adjunctive treatment in patients with advanced cancer whose pain is not being adequately controlled by strong opioids. The company completed a Phase II/III dose-ranging trial in cancer pain under an FDA IND in November 2009 and began a Phase III study late in 2010. For more information about GW's research program, *see* www.gwpharm.com.

In 2004, the Food and Drug Administration (FDA) issued a guidance document entitled "Botanical Drug Products," in which it acknowledged that modern pharmaceutical products can be developed from botanical materials and set forth the elements of that development path. Food and Drug Administration, "Botanical Drug Products," www.fda.gov/OHRMS/DOCKETS/98fr/04-13031.htm. In April 2006, the FDA released an interagency statement stating that recent voter initiatives or legislative actions making smoked cannabis available for medical use are "inconsistent with efforts to ensure that medications undergo the rigorous scientific scrutiny of the FDA approval process and are proven safe and effect under the standards of the FD&C Act." The Statement concluded that "[e]fforts that seek to bypass the FDA drug approval process would not serve the interest of public health because they might expose patients to unsafe and ineffective drug products." Food and Drug Administration, "Inter-Agency Advisory Regarding Claims That Smoked Marijuana is a Medicine," www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108643.htm.

Currently, the University of Mississippi (pursuant to a contract with the National Institute on Drug Abuse) provides the sole source of research-grade herbal cannabis in the US. The University of Massachusetts Amherst (Prof. Lyle Craker) is seeking to obtain from the DEA a bulk manufacturing license in order to cultivate and supply cannabis for FDA-approved research projects. An Administrative Law Judge has recommended to the DEA that the application be granted. *In the Matter of Lyle E. Craker, Ph.D., Docket No. 05-16, Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of Administrative Law Judg*e (Feb. 12, 2007). The ALJ's recommendation was rejected by the DEA Deputy Administrator. (Drug Enforcement Administration, Lyle E. Craker, Denial of Application, 74 Fed.Reg. 2101 (Jan. 14, 2009).) The denial has been appealed to the U.S. Court of Appeals.

Two cannabinoid pharmaceutical products are presently on the US market. Cesamet® (nabilone) and Marinol® (dronabinol). Both are approved for nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional treatments. Marinol® is also approved for appetite loss associated with weight loss in people who have acquired immunodeficiency syndrome (AIDS). Cesamet®, a synthetic analogue of tetrahydrocannabinol (THC) is in Schedule II of the Controlled Substances Act, and Marinol® is in Schedule III. THC in any other form remains in Schedule I (as does marijuana), although the DEA has recently issued a Notice of Proposed Rulemaking (NPRM) proposing to transfer certain generic dronabinol products to Schedule III. DOJ, DEA, "Listing of Approved Drug Products Containing Dronabinol in Schedule III," 75 Fed. Reg. 67054 (Nov. 1, 2010).

39. I have heard that cannabis may be legalized in California for recreational use. Is this true?

In 2010, California Assembly Member Tom Ammiano introduced two bills which would have allowed the commercial cultivation, distribution and retail sale of cannabis. An initiative appeared on the November 2010 ballot. It would also have legalized the possession of one ounce of cannabis (and the cultivation of a five by five square foot area of land) by adults for personal use, as well as permitting cities and counties to allow the commercialization of cannabis within their jurisdiction. The initiative failed by a vote of 54% to 46%. Representative Ammiano may reintroduce legislation in the next legislative session.

The CMA House of Delegates recently adopted policy recommending that CMA consider the criminalization of marijuana to be a failed public health policy and that CMA encourage and participate in debate and education regarding the health aspects of changing current policy regarding cannabis use. On September 30, 2010, Gov. Arnold Schwarzenegger signed into law SB 1449 (amending Health & Safety Code §11357 and Vehicle Code §23222), which downgrades the penalty for possession of less than one ounce of marijuana from a misdemeanor to a civil infraction. The use of cannabis remains illegal under federal law.

40. What is "Spice"? Is it more harmful than cannabis?

A number of synthetic cannabinoids have been developed over the past 30 years for research purposes to investigate the endocannabinoid receptor system in non-human studies. Although these compounds have THC-like properties, they are much more potent than THC, and none is being studied as a possible medication in human/clinical trials. Products containing these synthetic cannabinoids are marketed as "legal" alternatives to cannabis and are being sold over the internet and in tobacco and smoke shops, drug paraphernalia shops, and convenience stores. Brands such as “Spice,” “K2,” “Blaze,” and “Red X Dawn” are labeled as incense to mask their intended purpose. These compounds, alone or spiked on plant material, have the potential to be extremely harmful due to their method of manufacture and high pharmacological potency. Since 2009, DEA has received an increasing number of reports from poison centers, hospitals and law enforcement regarding these products. Fifteen states have already taken action to control one or more of these chemicals. Health warning have been issued by numerous state public health departments and poison control centers describing the adverse health effects associated with these compounds, including agitation, anxiety, vomiting, tachycardia, elevated blood pressure, seizures, hallucinations, and non-responsiveness.

The DEA has recently acted on an emergency basis to place five such compounds in Schedule I. DOJ, DEA, "Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids into Schedule I," 75 Fed. Reg. 71636 (Nov. 24, 2010). This action will make possessing and selling these chemicals or the products that contain them illegal in the U.S. for at least one year while the DEA and the United States Department of Health and Human Services (DHHS) further study whether these chemicals and products should be permanently controlled.

We hope this information is helpful to you. CMA is unable to provide specific legal advice to each of its more than 30,000 members. For a legal opinion concerning a specific situation, consult your personal attorney.

For information on other legal issues, use CMA ON-CALL, or refer to CMA's *California Physician's Legal Handbook*. This book contains legal information on a variety of subjects of everyday importance to practicing physicians. Written by CMA's Legal Department, the book is available on a fully searchable CD-ROM, or in a seven-volume, softbound format. To order your copy, call (800) 882-1262 or visit CMA's Bookstore at www.cmanet.org.