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Document # 1315 **CMA Legal Counsel**

The Compassionate Use Act of 1996 **January 2004**
The Medical Marijuana Initiative

Proposition 215, "The Compassionate Use Act of 1996," 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. S.B. 420, codified at Health & Safety Code §§11362.7-11362.83, seeks to implement Proposition 215 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 PROPOSITION 215

1. What did California law formerly prohibit? [1]

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. However, on December 16, 2003, the U.S. Court of Appeals for the Ninth Circuit concluded that the federal Controlled Substances Act is likely unconstitutional as applied to the intrastate, noncommercial cultivation, possession and use of cannabis for personal medical use on the advice of a physician. The court reasoned that medicinal cannabis, when cultivated locally for personal consumption, does not appear to have any "direct or obvious" effect on interstate commerce, thereby depriving Congress of jurisdiction to regulate such activity under the Commerce Clause of the federal constitution. The Court remanded the case to the district court for entry of a preliminary injunction against the federal government. The ruling may be appealed to the U.S. Supreme Court, but at the time of this writing, the cultivation and use of medicinal cannabis under such circumstances would seem to be lawful under **both** state and federal law. (*Raich v. Ashcroft* 2003 WL 22962231.)

2. What does Proposition 215 allow patients to do?

Proposition 215 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.[2] In addition, S.B. 420 clarifies that a patient or designated primary caregiver

[1] It is possible that the federal government will seek a stay of the preliminary injunction once it has issued. However, it is unlikely that any such effort would be successful.

[2] The California Attorney General has recently opined that the term "marijuana" in Proposition 215 applies to concentrated cannabis or hashish. (Ops.Cal.Atty.Gen. No. 03-411 (2003)).

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.)

S.B. 420 establishes a ***voluntary***,[3] ***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. 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 Proposition 215 and S.B. 420?

Proposition 215 applies to patients with cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine. **In addition**, it applies to "any other illness for which marijuana provides relief." S.B. 420 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).)

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

No. Nothing in Proposition 215 or S.B. 420 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.

5. Are minors covered by Proposition 215?

Proposition 215 does not exclude minors. Moreover, S.B. 420 clarifies that minors are covered by Proposition 215 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.

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[3] The Legislative Counsel of California has opined that **requiring** qualified patients to participate in the ID card program would constitute an unconstitutional amendment of Proposition 215. (Legislative Counsel of California, "Medical Marijuana: Identification Program (SB 420)" #16771 (Aug. 20, 2003).)

6. How can a patient establish that he or she qualifies for a card under S.B. 420?

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).)

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 Proposition 215. Furthermore, many of the provisions of S.B. 420 apply equally to patients and designated caregivers, whether or not they possess ID cards.* S.B. 420 does not supersede local programs, so long as they are consistent with its provisions. (Health & Safety Code §11362.83.)

8. Does Proposition 215 protect a patient from being arrested if he or she has a physician's recommendation?

No. Proposition 215 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 Proposition 215 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.)

Hopefully, S.B. 420 will be effective in protecting patients with ID cards against improper arrest. The new 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, S.B. 420 should help to ensure that a patient or primary caregiver is not be arrested in the absence of good evidence that he/she is violating the provisions of Proposition 215 and/or S.B. 420.

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."

10. What does Proposition 215 allow physicians to do?

The language of Proposition 215 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,*[4] *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).

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 Proposition 215 was first enacted, the Medical Board issued a statement stated that a physician who recommends the use of medicinal cannabis should have arrived at that decision in accordance with accepted standards of medical responsibility:

- History and physical 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; and
- Proper record keeping that supports the decision to recommend the use of cannabis.

Therefore, if, for example, the Medical Board believes that the physician failed adequately to evaluate one or more patients before recommending the use of medicinal cannabis, the Medical Board may initiate an investigation against the physician. However, by extension of a decision from the US Court of Appeals for the Ninth Circuit, *Conant v. Walters*, the Board should not be able to initiate an investigation against a physician 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 of conduct that fails to meet conventional 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 January 2003, the Medical Board's Division of Medical Quality invited the California Medical Association to join with the Board in drafting a set of guidelines to assist physicians wishing to participate in the implementation of Proposition 215. The guidelines intend to set forth principles that would outline the appropriate standard of care in this area. A proposed draft of such guidelines is currently under development.

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[4] Unlike patients, whose possession and/or cultivation of cannabis would be illegal but for Proposition 215, 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. It is also unclear how the *Mower* immunity would be applied in an administrative proceeding initiated by the Medical Board.

12. 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?

S.B. 420 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).) Proposition 215 is silent on the issue. It is probable that the courts would interpret Proposition 215 in a manner consistent with S.B. 420. Thus, the issue of reimbursement will depend on the scope of the patient's health plan.

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

S.B. 420 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, Proposition 215 is silent on the issue, but it is probable that the courts will interpret Proposition 215 in a manner consistent with S.B. 420. The use of drug testing in the workplace is more complicated. A physician should seek legal advice before discharging or disciplining an employee who 1) has an ID card/ physician's recommendation; 2) does not appear to be impaired, and 3) does not use medicinal cannabis in the workplace or during working hours. For more information on drug testing, *see* CMA ON-CALL document #0525, "Physician Obligations Regarding Drug or Alcohol Testing."

FEDERAL CONTROLLED SUBSTANCE ACT

14. 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) 329 F.3d 629.) It is extremely important for physicians to understand the difference between permissible and impermissible recommendations. This document explains that difference below. The following discussion applies **only** to situations wherein the underlying conduct, e.g., distributing, obtaining or using cannabis, would itself violate federal law. If, under the decision described above, the underlying conduct is **not illegal** under the Controlled Substances Act, a physician cannot be subject to aiding or abetting or conspiracy liability.

PHYSICIANS' ABILITY TO RECOMMEND THE USE OF CANNABIS

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

The ruling discussed above applies only to the intrastate, noncommercial cultivation, possession and use of cannabis for personal medical purposes on the advice of a physician.[5] It may **not** apply if a patient were

[5] An argument can be made that such a transaction may not be commercial, i.e., the dispensary may be operated as a nonprofit entity, or that, even if commercial, the intrastate cultivation and distribution of medicinal cannabis does not have a substantial affect on interstate commerce. However, the *Raich* case did not explicitly address this situation.

to purchase cannabis from a cannabis dispensary or other source. In many cases, patients' only source of medicinal cannabis may be such a dispensary. The following discussion will be relevant to such situations.

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 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 years, a fine of $500,000, or both. (21 U.S.C. §841(b)(1)(D).)

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).)

16. 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 Proposition 215, 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 Proposition 215, 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, even though it may not be specifically authorized by the law, a patient with a physician's recommendation can obtain medicinal cannabis at a cannabis dispensary ("buyers' club") or some other source.*[6]

As a result, the federal government argues 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) 229 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).)

[6] A few cannabis dispensaries were in existence before the enactment of Proposition 215, but their numbers and public visibility increased after the laws was passed.

17. 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.*[7]
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> 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.
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> 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.
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> 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."[8]
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> 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.**
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> Some patients may use recommendations to obtain cannabis from cannabis clubs 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

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[7] 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.

[8] This last use is no longer valid after the Supreme Court's decision in *U.S. 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.

marijuana, as a prescription is used as a means for a patient to obtain a controlled substance, then a physician would be guilty of aiding and abetting the violation of federal law."[9]

Bad faith recommendations are not entitled to protection. Thus, physicians who issue insincere recommendations without a medical basis and with knowledge that the recommendation would be used illegally to obtain cannabis would be subject to DEA revocation. 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).

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

Under the 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.

CMA also urges physicians to advise their patients that, notwithstanding Proposition 215, the cultivation, possession and use of cannabis, even for medical purposes, is illegal under federal law.[10] But see *Raich v. Ashcroft*, above. 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.

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[9] 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."

[10] 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 recently 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.

19. 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?

The federal government's threats have frightened and deterred many physicians from being willing to discuss and advise their patients about medicinal cannabis. Furthermore, 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 both knowledgeable and 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.

There can be no assurance that the Medical Board or the Drug Enforcement Administration would conclude that such practices constitute a *bona fide* physician-patient relationship. A physician who seeks to provide information and advice in such a situation should consult his or her legal counsel.

MEDICAL NECESSITY

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

Several years ago, the federal government filed six civil suits against buyers' clubs in Northern California, arguing that the clubs were violating federal law, which prohibits the sale, manufacture or distribution of cannabis. Those suits were consolidated before a single federal judge. On May 13, 1998, that judge issued a preliminary injunction to close the clubs. (*U.S. 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."

On appeal, the U.S. Court of Appeals for the Ninth Circuit reversed, ruling that, notwithstanding the fact that cannabis is a Schedule I drug under the federal Controlled Substances Act (CSA) (and therefore deemed to be without medical use), there exists a medical necessity defense to a violation of the Act. The Court found that "medical necessity" could be shown for persons 1) with serious medical conditions; 2) for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; 3)

who will suffer serious harm if they are denied cannabis; 4) and for whom there is no legal alternative to cannabis for the effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects. The Court of Appeals instructed the trial court to reconsider the clubs' request for a modification of the injunction to exempt distribution to persons for whom cannabis is a medical necessity. (*U.S. v. Oakland Cannabis Buyers' Cooperative (OCBC)* (9th Cir. 1999) 190 F.3d 1109.)

On remand, the trial court applied the doctrine of medical necessity, as articulated by the Ninth Circuit, and ruled that OCBC could distribute the cannabis to patients meeting the above criteria. On November 27, 2000, the U.S. Supreme Court granted review (certiorari).

On May 14, 2001, in an 8-0 opinion, Justice Breyer abstaining, 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. (*U.S. 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.

Furthermore, the Court emphasized in dictum that nothing in its analysis, or in the statute, suggests that there should be **any** distinction drawn between the prohibitions against manufacturing and distributing and the other prohibitions of the CSA. Therefore, although the three concurring justices disagreed, five members of the Court believe that a medical necessity exception would similarly not apply in a prosecution against a health care provider for dispensing or against a patient for possession/personal use.

However, the Supreme Court did not address the constitutional issues that might be implicated by the application of the Controlled Substances Act to distribution of cannabis by a dispensary such as OCBC to patients meeting medical necessity criteria. On remand, the defendants in the OCBC case 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. The district court rejected these arguments, and the case, as well as another related case involving a Santa Cruz medicinal cannabis cooperative, have been appealed to the Ninth Circuit. As noted above, another panel of the Ninth Circuit in the *Raich* case recently accepted the Commerce Clause argument, at least with regard to patients who cultivate and use cannabis for personal medical purposes. Rulings in the other two cases are expected in the near future.

21. Does the U.S. Supreme Court's ruling affect Proposition 215?

The U.S. Supreme Court did not explicitly rule on the validity of Proposition 215, nor does its holding implicitly nullify that law. Proposition 215 merely abrogates the state law prohibitions against possession and cultivation of cannabis for seriously ill patients (and their primary caregivers) who have the recommendation or approval of their physicians to use cannabis medicinally. Such possession and cultivation have always been prohibited by the CSA. Had the Court recognized a medical necessity exception to the CSA in the above case, a **small number** of patients would have been able to obtain and use cannabis lawfully under federal law (and cannabis clubs could have distributed to such patients). However, Proposition 215 does **not** require patients to demonstrate medical necessity; indeed, a patient (with the physician's recommendation) may use cannabis for "any condition for which cannabis may provide relief." Obviously, Proposition 215 allows a much larger number of patients to use cannabis medicinally than would the concept of medical necessity.

DISCUSSING RISKS AND BENEFITS

22. 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 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, and many of these are currently underway. In addition, a UK pharmaceutical company has just completed four Phase 3 double blind, randomized, placebo-controlled clinical trials. These trials, involving patients with multiple sclerosis and/or neuropathic pain, investigated the efficacy of a standardized whole plant extract delivered as an oromucosal spray. The results demonstrated statistically significant benefit in a range of symptoms, including neuropathic pain, spasticity, and sleep disturbance. The extracts were shown to have an excellent safety profile, and most patients were able to titrate their dose in order to achieve improvements in their symptoms without incurring unwanted side effects that would interfere with day-to-day living. The company anticipates that its first product, Sativex, will be available by prescription in the UK in the first half of 2004.

However, the extent of such information 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. Physicians should warn patients about these potential risks when appropriate.

There are a number of websites that provide sources of information about the risks and benefits of the medical use of cannabis. They include:

- Dr. Lester Grinspoon, **www.rxmarijuana.com**
- Center for Medicinal Cannabis Research (CMCR), **www.cmcr.ucsd.edu**
- GW Pharmaceuticals, PLC, **www.gwpharm.com** (includes information about research into nonsmoked standardized cannabis extracts).
- International Association for Cannabis as Medicine, **www.acmed.org**
- Marijuana Policy Project (MPP), **www.mpp.org**
- Multidisciplinary Association for Psychedelic Studies (MAPS), **www.maps.org**
- Drug Reform Coordination Network, **www.drcnet.org**
- Media Awareness Project (MAP), **www.map.org**
- Alliance for Cannabis Therapeutics, **www.marijuana-as-medicine.org**

The following books and articles also provide extensive sources of information:

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

- 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).

- Zimmer, L., and J. Morgan, *Marijuana Myths: Marijuana Facts* (1997)

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

- Russo, E.B., "Role of Cannabis and Cannabinoids in Pain Management," in *Pain Management: A Practical Guide for Clinicians*, ch.31, pp. 357-75, ed. R.S. Weiner. Boca Raton, FL: CRC Press.

- Whittle, B.A., Guy, G.W., and Robson, P.J., *Prospects for New Cannabis-based Prescription Medicines*, Journal of Cannabis Therapeutics 2 (3-4): 183-205 (2001).

- Grotenhermen, F., *Harm Reduction Associated with Inhalation and Oral Administration of Cannabis and THC*, J. of Cannabis Therapeutics (3-4):133-152 (2001).

- Russo, E.B.(ed.), Journal of Cannabis Therapeutics (Haworth Press)

OBTAINING CANNABIS/PERMISSIBLE QUANTITIES

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

Proposition 215 was intended to authorize a patient or a patient's "designated primary caregiver" to cultivate and possess cannabis for the patients' 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. S.B. 420 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. S.B. 420 attempts to address that problem by providing that a patient or primary caregiver may possess eight ounces of dried cannabis, and in addition, six mature or 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. S.B. 420 allows cities and counties to retain or enact guidelines permitting patients and caregivers to exceed these amounts. (*Id.)*

Many patients are too ill to cultivate their own marijuana, and many caregivers lack the skill or location for such cultivation. However, Proposition 215 did not authorize any individual or entity (such as cannabis buyers' clubs or dispensaries) to sell, or even give, cannabis to a patient or caregiver, even with a physician's written or oral recommendation. After Proposition 215 was initially passed, the operators of some dispensaries were designated by hundreds of patients as the patients' "primary caregiver."

However, a California appellate court stated that 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 Proposition 215. 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 Proposition 215 can be claimed by an individual who purported to cultivate cannabis for medicinal cannabis dispensary). However, the Peron court stressed that the language of Proposition 215 does **not** preclude a primary caregiver from serving more than one patient, and indeed S.B. 420 explicitly allows more than one patient to designate the same caregiver, if the patients and caregiver reside in the same county. Moreover, the statute recognizes that patients and caregivers may associate in order collectively or cooperatively to cultivate medicinal cannabis. (Health & Safety Code §11362.775.)

Therefore, it is possible that a dispensary that is founded for the purpose of distributing medicinal cannabis solely to its members, and that is run as a true cooperative, may qualify for the protections of the initiative. If patients and caregivers cannot cultivate medicinal cannabis—through individual or cooperative cultivation-- then patients in California (and in other states that authorize the possession and cultivation of cannabis for medical purposes) may resort to the black market, with its attendant risks of violence, exposure to more dangerous drugs, and injury from contaminated or otherwise impure products.

24. 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, nonsmoked 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. 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.

Recently, the city of Oakland revised its guidelines governing the amounts of cannabis that patients may lawfully possess and cultivate. Those guidelines state that patients may exceed those limits if they have a physician's statement indicating that the amounts allowed by the guidelines do not meet the patient's medical needs. Such a statement allows a patient to cultivate/use an amount of cannabis "consistent with those needs." *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. The Oakland guidelines further provide that patients are encouraged to record their actual usage with their physicians and to match their "garden yield" with that documented usage. Again, a physician should be free to record a patient's description of his or her actual usage. However, for the reasons stated in this document, CMA does not encourage physicians to provide specific recommendations of daily usage levels.

25. 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 club 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. Physicians should inform a patient that the physician cannot affirmatively assist the patient in obtaining cannabis.

MEDICAL RECORD DOCUMENTATION

26. 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.

27. 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 buyers' club, 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 all the patient's medical information, or at least all that is relevant to the condition at issue.

RESPONDING TO PATIENT REQUESTS FOR TESTIMONY

28. 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 Proposition 215?

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

29. 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?[11]

Physicians must be extremely cautious in this situation. The Confidentiality of Medical Information Act, Civil Code §§56 *et seq*., 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.)[12]

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 Proposition 215.

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.

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[11] In one recent case, federal law enforcement personnel seized the patient records of a physician who had provided recommendations to approximately 6,000 patients. The physician, who allegedly has a medical condition that is covered by Proposition 215, was also cultivating 32 cannabis plants.

[12] 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.)

RESPONDING TO PATIENT REQUESTS FOR COMPLETION OF FORMS

30. 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 can be subject to punishment for aiding and abetting the *cultivation or possession* of cannabis. The Ninth Circuit's recent decision in the *Raich* case, described above, indicates that a patient's cultivation/possession of cannabis for noncommercial, personal medical use, where the cannabis has been cultivated within the state, may not be illegal under federal law. Hence, in such a case, a recommendation letter provided for defensive purposes should certainly enjoy the protections afforded by the *Conant* ruling.

Physicians should, in any event, avoid making any written statements which "warrant" or "certify" that a particular patient is "in compliance" with the law. It has come to our attention that certain individuals/organizations may be distributing forms which contain such statements. The physician has no way of knowing whether a particular patient, who possesses or cultivates cannabis, is actually "in compliance with" the law. For example, a patient may be cultivating cannabis for purposes of sale, in addition to his or her personal medical use. The California law does not authorize such activity.

COUNTY CERTIFICATION PROGRAMS

31. I have heard that some cities and counties have "certification" programs in which governmental officials will provide a patient with evidence (such as an identity card) that the patient is using cannabis for medical purposes within the protection of Proposition 215. Should I cooperate with county officials in these programs?

It is impossible to provide an answer that will apply to each and every such certification program. As indicated above, S.B. 420 permits local jurisdictions to maintain or establish their own ID card or other type of certification programs.

Physicians must carefully examine any local governmental certification program to ensure that the program's stated purpose is not to enable a patient to obtain cannabis from some source, but rather to

enable a patient to avoid arrest or conviction under the law. Even in such cases, the treating physician should avoid direct discussion with third parties (including county officials) confirming that the physician has recommended or approved a patient's use of medicinal cannabis. However, a physician can probably safely confirm with county officials that an individual is a patient of the physician's and perhaps also confirm the patient's diagnosis, assuming the patient has provided the physician with the appropriate written authorization for such disclosure. Certainly, the patient has a right to obtain copies of his or her medical records documenting the physician-patient discussion and to submit that documentation to governmental officials in order to obtain a certification card. The physician can confirm the authenticity of such medical records.

ACTIONS TO AVOID

32. 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

33. 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 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/1024/reports.asp?url=477.htm**; Bates, M. and Blakeley, A.T., *Role of Cannabis in Motor Vehicle Crashes*, Epidemiologic Reviews 21: 222-232 (1999).

CMA POLICY

34. 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.

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 US Supreme Court in *U.S. v. Oakland Cannabis Buyers Cooperative*, discussed above, supporting the concept of medical necessity, as well as in the other cases raising this issue before the Ninth Circuit.

Research encouraged: CMA believes that carefully designed, controlled clinical trials of the effectiveness of inhaled cannabis for medical uses should be encouraged. CMA urged the federal government to give expeditious consideration to a cannabis research proposal submitted by Donald Abrams, M.D., and to provide him with any technical assistance necessary to enable him to implement his proposal. Dr. Abrams' proposal was approved and funded with one million dollars from the National Institutes of Health. (Russell, *SF. Study of Cannabis, AIDS Patients is Approved*, San Francisco Chronicle (Oct. 9, 1997) p. 1.)

Dr. Abrams reported the results of this study in the summer of 2000. The data indicated that cannabinoids, both oral and smoked, did not adversely affect the HIV RNA levels of patients who were being treated with protease inhibitors; furthermore, patients using both cannabis and dronabinol (synthetic tetrahydrocannabinol) had greater caloric intake and gained significantly more weight than the controls.

CMA also sent a letter in the fall of 1999 to the Director Barry McCaffrey (the drug "czar") at the Office of National Drug Control Policy, expressing CMA's support for research into pharmaceutical-quality cannabis plant extracts that can be administered by alternative, i.e., non-smoked, delivery services. Such research is being conducted in the United Kingdom. For more information on this research, see **www.gwpharm.com**.

Currently CMA supports 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 supports 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.

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 marijuana 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 is currently working with the Medical Board to develop appropriate practice guidelines concerning medicinal cannabis.

CURRENT RESEARCH

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 recent 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 pharmaceutical-quality, prescribable, non-smoked cannabis-based medicines, has been conducting controlled clinical trials in the UK for the past four years. GW is focusing on symptoms of neuropathic dysfunction and neuropathic pain. GW hopes to obtain marketing approval in the UK for its first prescription product, Sativex, sometime in the first half of 2004. For more information about GW's research program, *see* **www.gwpharm.com.**

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 everday importance to practicing physicians. Written by CMA's Legal Department, the book is available on a fully searchable CD-ROM, or in a six-volume, softbound format. To order your copy, call (800) 882-1262 or visit CMA's Bookstore at www.cmanet.org.