

Stakeholders to Address Pharmaceutical, Legal Implications of Medical Marijuana

Marijuana has been called by many names – pot, grass, weed, ganja – and in 13 states, it is also called medicine. For more than a decade, consumer groups and lobbyists have pushed states to legalize the use of marijuana for medical purposes, propounding its usefulness in relieving symptoms associated with various ailments. While 13 states have decriminalized its use for certain medical conditions, and 13 more are exploring the possibility, marijuana remains illegal under federal law. This complex legal framework poses a precarious situation for patients and the practice of pharmacy alike.

Members of the boards of pharmacy and other stakeholders will address the pharmaceutical and legal issues surrounding the use of marijuana for medical purposes during the NABP 2009 Symposium, to be held December 3-4 in Tucson, AZ. (More information on these sessions is provided on page 194.)

The following states have already legalized medical marijuana: Alaska (1998), California (1996), Colorado (2000), Hawaii (2000), Maine (1999), Michigan (2008), Montana (2004), Nevada (2000), New Mexico (2007), Oregon (1998), Rhode Island (2006), Vermont (2004), and Washington (1998). Laws in these states generally allow the use of medical marijuana upon a practitioner's recommenda-

tion to treat symptoms associated with "serious, chronic, or debilitating medical conditions," according to an article published in the May 2007 issue of the *American Journal of Health-System Pharmacy*. As described in the article, "Medical Marijuana and the Developing Role of the Pharmacist," such conditions include the following indications:

- severe nausea and vomiting associated with cancer chemotherapy or other causes,
- weight loss associated with debilitating illness, including HIV and cancer,
- spasticity stemming from neurologic conditions such as multiple sclerosis,
- severe pain, and
- glaucoma.

At the federal level, however, marijuana is listed

in Schedule I of the federal Controlled Substances Act (CSA). Drug Enforcement Administration (DEA) and Food and Drug Administration (FDA) continue to support that placement because they say marijuana meets the three criteria for placement in Schedule I under the CSA: a high potential for abuse, a lack of currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

While research has established the potential medicinal value of the active ingredients, or cannabinoids, found in marijuana, FDA and DEA maintain that the evidence is not sufficient to support the approval of marijuana in its crude form (dried leaves and flowers, generally smoked) as a medicine. FDA issued an "Inter-Agency Advisory Regarding Claims That Smoked Marijuana Is a Medicine" in April 2006, concluding that no sound scientific studies have supported medical use of smoked marijuana for treatment in the US, and no animal or human data support the safety or efficacy of smoked marijuana for general medical use.

The physiological and psychoactive effects of marijuana, or *Cannabis sativa*, are attributed to its main active ingredient, delta-9-tetrahydrocannabinol (THC), the concentration of which determines the

potency and effect of the substance on the patient. The concentration of THC in marijuana varies greatly from plant to plant, and its common route of administration – smoking – also allows for considerable variability in the dose levels administered. Marijuana smoke also contains 50% to 70% more carcinogens than cigarette smoke, introducing other health risks.

For this reason, many of the scientists and researchers who proclaim the medicinal value of marijuana do not support the use of *smoked* marijuana as “medicine.” In its 1999 report “Marijuana and Medicine: Assessing the Science Base,” Institute of Medicine (IOM) states, “[s]cientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation; smoked marijuana, however, is a crude THC delivery system that also delivers harmful substances.”

The synthesis of the active ingredient into a form that can be tested for strength and purity, manufactured for dosing consistency, and administered via a more reliable route, on the other hand, has received greater acceptance in the medical community. “Defined substances, such as purified cannabinoid compounds, are preferable to plant products, which are of variable and uncertain com-

position,” the IOM report states. “Use of defined cannabinoids permits a more precise evaluation of their effects, whether in combination or alone. Medications that can maximize the desired effects of cannabinoids and minimize the undesired effects can very likely be identified.”

Such compounds have, in fact, been developed and approved for pharmacological use. The prescription drug Marinol® contains the active ingredient dronabinol, a synthetic form of THC. Like medical marijuana, this FDA-approved medication is used to treat nausea and vomiting caused by cancer chemotherapy, as well as to treat loss of appetite and weight loss in HIV patients.

As marijuana, in its crude form, is not an approved drug, it is not subject to the inspections, safeguards, and quality standards of the US pharmaceutical supply chain. Data regarding appropriate dose levels are not available to patients, nor are guidelines and warnings for use, and the concentration of THC from batch to batch is not consistent. This variability and uncertainty contribute to the reluctance toward legalizing marijuana as a medication.

According to FDA’s 2006 advisory, states’ measures to legalize medical marijuana are “inconsistent with efforts to ensure that medica-



tions undergo the rigorous scientific scrutiny of the FDA approval process and are proven safe and effective under the standards of the FD&C [Federal Food, Drug, and Cosmetic] Act.”

Consequently, patients must purchase marijuana from local cannabis dispensaries – not pharmacies – or grow their own, which raises further doubts about the safety and potency of the product. Most patients using medical marijuana have no contact with a pharmacist – or, if they do, it is because they are taking other prescription medications, and the pharmacist is generally not aware they are using marijuana in combination with these drugs. Thus, these patients rarely have the full (if any) benefit of pharmacist counseling.

Concerns for the lack of pharmacist guidance stem from marijuana-related adverse effects, interactions with a number of other medications, and exacerbation of certain disease states.

(continued on page 190)

Medical Marijuana

(continued from page 189)

Especially for their patients with certain concomitant medical conditions, pharmacists are encouraged to ask patients if they are using not only other prescription or over-the-counter medications, but also medical marijuana. In so doing, the pharmacist has the opportunity to educate patients on potential risks and contraindications of marijuana use.

As noted in the *American Journal of Health-System Pharmacy* article referenced

earlier, marijuana appears to interact with a variety of medications, including opioids, barbiturates, protease inhibitors, sildenafil, theophylline, antidepressants, anticholinergics, lithium, neuroleptic antipsychotics, anesthetic agents, and others. Opioids used in combination with marijuana, for instance, "can lead to cross-tolerance and mutual potentiation of effects," the article notes. The combination of marijuana with alcohol, benzodiazepines, or muscle relaxants can result in excessive depression of the central

nervous system. Evidence also suggests that marijuana can decrease the effectiveness of protease inhibitors and theophylline by increasing their clearance.

The article further notes that "marijuana may adversely affect patients with certain diseases, including immunosuppression, psychiatric disturbances, cardiac disease, respiratory disease, vertigo, cancer, pregnancy, and obesity." Additionally, marijuana may exacerbate certain psychiatric disorders.

In the current legal environment, actually recom-

mending marijuana, or assisting patients in obtaining it, falls outside the scope of pharmacy practice and could lead to disciplinary action. As in other areas of medication therapy management, however, the pharmacist may play a key role in advising patients in the management of their health and the safe use of their medications. The upcoming NABP Symposium will provide an opportunity for the boards of pharmacy and other stakeholders to further address the role of pharmacy in this issue. ®

Legal Briefs

(continued from page 185)

mine whether the findings of fact determined by the board are supported by a preponderance of the evidence. The licensee argued that the preponderance standard is the minimum standard that can be applied under the due process requirements of an administrative proceeding.

The court held that it did not need to reconcile the potential differing standards in that the

board findings were specifically noted to be under a preponderance standard (in some cases, in addition to the substantial evidence standard). The court held that this application of the more stringent preponderance standard satisfied the due process requirements and that it need not rule on the issue of whether a substantial evidence standard satisfied such requirements. Under that premise, the court addressed and found that the evidence, based upon the

board findings of wrongdoing, taking into consideration the credibility of the witnesses, supported a finding of guilt and justification of the sanctions. Accordingly, the court affirmed the lower court and upheld the findings and sanction imposed upon the licensee.

Boards of pharmacy are cautioned to know and understand the applicable burden of proof and ensure reference to such burden in their findings. In addition, the authority

to impose costs, disbursements and attorneys' fees may be critical to the ability of boards to effectively and efficiently operate, especially in these difficult financial times. As illustrated by this case, the lack of notice of the potential to impose such costs or expenses to the licensee dissuaded the board from pursuing such fees.

Frokjer v North Dakota Board of Dental Examiners, 764 N.W.2d 657 (ND 2009). ®

Search Engines

Online Advertising

(continued from page 187)

pharmacies. For this reason, NABP recommends patients use only VIPPS-accredited

Internet pharmacies when purchasing medication online.

A full listing of Recommended and Not Recommended sites, along with the Internet Drug Outlet Identification program

criteria and related patient information, is available in the Internet Pharmacies section of the NABP Website at www.nabp.net.

These efforts, as well as those of LegitScript and Knu|On, empower patients

to choose safely when purchasing medications online and educate otherwise law-abiding service providers on activities that enable these illegal and dangerous operations. ®