THE POTENTIAL MEDICAL LIABILITY FOR PHYSICIANS RECOMMENDING MARIJUANA AS A MEDICINE

Executive Summary

Physicians who are approached by patients for medical marijuana should be apprised of the accompanying potential medical liability. Companies writing medical malpractice insurance are carefully scrutinizing ways to limit their malpractice exposure because of escalating plaintiffs' settlements or judgments. One attempt to limit exposure is to exclude any claim arising from the use of a non-FDA approved medication.

Marijuana is a Schedule I drug in the Controlled Substances Act. By definition a Schedule I drug is considered to have a high potential for abuse, it lacks any currently accepted medical use in treatment, and it is unsafe even under medical supervision. However, a number of states have passed ballot initiatives permitting physicians to recommend crude marijuana as medicine.

There is substantial case law supporting the potential medical liability for a physician who recommends marijuana to patients. Courts have ruled that physicians have a duty to (1) render quality care, (2) be adept in the use of medical options, (3) provide a standard of care commensurate with accepted medical practice, (4) inform a patient of the risks and side-effects associated with a particular treatment, (5) not cause a patient injury or future harm, and (6) protect an unidentifiable, unknown third party who may be endangered by a patient under a medication.

Physicians who recommend marijuana would find it extremely difficult to demonstrate that they had "rendered quality care" or met the "standard of care" that other reasonably prudent, similarly trained and experienced physicians would consider. This is because the necessary scientific research regarding marijuana and its effectiveness, risks, benefits, dosages, interactions with other drugs, and impact on pre-existing conditions is not available, and because there are no quality controls in the manufacturing process.

Courts across the country have looked to drug companies' warnings and to the Physician's Desk Reference manual for direction in negligence cases. The medicinal use of marijuana does not appear in the Physician's Desk Reference, and there are no drug manufacturer warnings to accompany marijuana. In the absence of an adequate warning accompanying the product, it could be ruled unreasonably dangerous.

Historically, physicians rely upon the Federal Food and Drug Administration's (FDA) process for approving drugs to protect them from liability should a drug be unsafe. An Institute of Medicine study did suggest some potential therapeutic value in the individual chemical compounds that make up cannabis (marijuana), but clearly, the burden of proof has not been met, and the FDA has yet to approve marijuana. Recommending a non-FDA approved drug requires a major "leap of faith" for most jurors in a liability suit.
A different kind of damage claim is raised by physician errors that increase the likelihood of “future harm” to the plaintiff.

Some jurisdictions have allowed recovery for the increased risk of future harm or injury and also for the plaintiff’s anxiety that such a risk may materialize in the future. Clinical trials have shown that marijuana affects phases of the reproductive process, has more carcinogens than tobacco, is an addictive substance and is often a gateway drug to the use of cocaine, heroin and other psychoactive substances. The latent period between the start of smoking marijuana and the development of cancer, respiratory, heart or circulatory conditions is fraught with “future harm” implications. These potential implications closely follow the claims made by so many against the tobacco industry.

Risks associated with a particular treatment are perhaps the most important information that a physician can give to a patient for consideration. Generally, a physician functions as a learned intermediary between a drug manufacturer and the patient. This learned intermediary position is not possible when a physician recommends marijuana, because there is no drug manufacturer, no FDA approval, no standard chemical composition (potency and quality), no standard dosage, no safe delivery system, and no knowledge of marijuana’s interaction with other drugs or its impact on pre-existing conditions. Most marijuana used for medicine is grown in backyard gardens, hydroponic closets and large warehouses without any quality controls.

Several courts have held that a physician’s relationship with the patient was sufficient to impose a duty to protect unidentifiable, unknown third parties who are endangered by a patient. Similarly, courts have held that doctors who fail to warn their patients about the possible side effects of prescribed medicines can be held responsible if a patient suffers an adverse reaction and injures someone in a traffic accident. Smoking marijuana diminishes physical and mental abilities. A study conducted by the U.S. Department of Transportation, National Highway Traffic Safety Administration (NHTSA) concluded that smoking relatively low-moderate THC doses impairs driving. Frequently, marijuana is used in combination with alcohol. The NHTSA study found that the combination of alcohol (BAC 0.04) and a low-moderate THC produced “very severe effects on driving performance.”

On July 30, 2001, the Canadian government passed the Marihuana Medical Access Regulations that allows smoking marijuana for medical purposes. However, the Canadian Medical Association (CMA), the Canadian Medical Protective Association (CMPA), the Canadian Society for Addiction Medicine (CSAM), and the Physicians for a Smoke-Free Canada (PSC) all issued strong warnings against recommending crude marijuana as a medicine.

Dr. Henry Haddad, President of the Canadian Medical Association, wrote to the Minister of Health Canada regarding the Regulations, “As you know, physicians are not in a position to adequately counsel patients regarding the use of marijuana, nor do we have the necessary information regarding what constitutes the proper dosage, its interaction with other drugs, or its impact on other pre-existing medical conditions.”

This white paper discusses in detail these and other legal points. Extensive case law is cited to illustrate the substantial potential medical liability for physicians who recommend marijuana for patients and the resulting exposure for companies writing medical malpractice insurance.

Many leading insurance companies are adding exclusion clauses to their medical malpractice policies to disallow coverage for any claim arising from the recommendation of a non-FDA approved drug. These include Medical Liability Mutual Insurance Company, the nation’s leading writer of medical malpractice insurance, TIG Insurance and other leading writers of such coverage. If there were no insurance coverage, a physician would be exposed to paying defense costs and could be held personally liable for any judgment entered against him or her.
Medical Liability White Paper

Despite the fact that the Federal Food and Drug Administration (FDA) has not approved marijuana as a medicine that can be prescribed, a number of states have passed ballot initiatives permitting physicians to recommend crude marijuana as medicine for their patients. The ballot initiatives allow physicians to recommend this material for a wide variety of medical ailments, often without any documentation requirements.

With escalating plaintiffs' settlements or judgments, companies writing malpractice insurance are carefully scrutinizing ways to limit their risk to malpractice exposure. One alternative to limit exposure is to exclude any claim arising from the use of a non-FDA approved medication.

Marijuana is currently listed as a Schedule I drug under the Controlled Substances Act. As such, the Department of Health and Human Services has found there to be scientific and medical evidence that: (1) marijuana has a high potential for abuse, (2) marijuana has no currently accepted medical use in treatment in the United States, and (3) there is a lack of accepted evidence about the safety of using marijuana under medical supervision.

In 1999, an Institute of Medicine study "Marijuana and Medicine," did suggest potential therapeutic value found in some of the chemical compounds that make up cannabis (marijuana); these compounds are called cannabinoids. However, the effects of cannabinoids on the symptoms studied were generally modest, and in most cases, there were more effective medications. Importantly, the study noted risks associated with using plant products; a plant product has a variable and uncertain composition and requires a crude delivery system, which also delivers harmful substances. Clearly, the safety and efficacy of smoked marijuana has not been proven.

To recommend use of crude marijuana, smoked or ingested, as medicine to patients exposes a physician to serious ethical and legal questions. Courts have ruled that physicians have a duty to: (1) render quality care, (2) be adept in the use of medical options, (3) provide a standard of care commensurate with accepted medical practice, (4) inform a patient of the risks and side-effects associated with a particular treatment, (5) not cause a patient injury or future harm, and (6) protect an unidentifiable, unknown third party who may be endangered by a patient under a medication. This paper cites extensive case law to illustrate substantial potential medical liability for physicians who recommend marijuana to patients.

— MALPRACTICE —

Professional Negligence

U.S. case law upholds the medical liability issues that threaten physicians who recommend marijuana as a medicine.

"Malpractice is usually defined as unskilful practice resulting in injury to the patient, a failure to exercise the 'required degree of care, skill and diligence' under the circumstances." The term Professional Negligence is also used to describe the failure of a professional to conform to the appropriate standard of care.

— POINT OF LAW —

Standard of Care

In Hall v. Hilburn, 466 So.2d 856 (Miss. Sup. Ct. 1985), "The duty of care***takes two forms: (a) a duty to render a quality of care consonant with the level of medical and practical knowledge the physician may reasonably be expected to possess and the medical judgment he may be expected to exercise, and (b) a duty based upon the adept use of such medical facilities, services, equipment and options as are reasonably available ..." Because the necessary scientific research regarding marijuana and its effectiveness, risks, benefits, dosages, interactions with
other drugs, and impact on pre-existing conditions is not available, and because there are no quality controls in the manufacturing process, a physician cannot exercise a competent medical judgment. Further, the physician's "adept use of medical options" is suspect when there are other more effective drugs that have been approved by the FDA.

The standard of care applied in a tort suit or hospital peer review process does not normally derive from an external authority such as a government standard. In the medical profession, as in other professions, standards develop in a complicated way through the interaction of leaders within the profession, professional journals and meetings, and networks of colleagues. Neither, the FDA, the *National Institute of Health* (NIDA), the Department of Health and Human Services, nor state licensing boards have had much to do with shaping medical practice. Most clinical policies derive from a flow of reports in the literature, at meetings, and in peer discussions. Over a period of time, hundreds of separate comments come together to form a clinical policy. Even alternative medicines require medical and scientific literature to support their therapeutic use.

Different procedures (standards of care) exist in different regions and within the various states. However, with the advancement of computers and online databases, medicine has become more national in education and practice, the locality rule giving way to a national test for knowledge and skill. A physician relying on a contraindicated drug, an outdated surgical technique, or an inappropriate description of risk factors in getting a patient's informed consent, may be attacked by the plaintiff using the results of a computer search.

"The *American Medical Association* (AMA) adopted a policy in 1969 declaring that marijuana is a dangerous drug and as such is a public health concern," said AMA Immediate Past President, Richard F Corlin, M.D., adding that, "Although much has changed in American culture and in medical research since we made that statement 33 years ago, the AMA's view on marijuana use remains exactly the same - it is mind-altering, it can be addictive, and it can lead to destructive behavior. Marijuana use has serious and far-reaching health consequences that go far beyond the short-term high. It can cause mental health problems, such as increased anxiety, panic attacks, depression and lung damage. In addition, marijuana can lead to impaired judgment and, as a result, to risky behaviors such as dangerous driving, unprotected sex and increased delinquent behavior."

William M. Bennett, M.D., a nephrologist, clinical pharmacologist, and past president of the *American Society of Nephrology*, looked at the scientific research on cannabis and assessed whether there was any merit to the use of whole plant cannabis material as medicine. Dr. Bennett reviewed the most recent fifteen years of scientific literature on marijuana and was astonished at the tremendous amount of research that had been done, most of it revealing that cannabis was not a benign substance but rather one that was extremely complex, insidious, and dangerous.

(As of January 2001 the NIDA research center had catalogued more than 15,000 published studies.) Further, Dr. Bennett pointed out that there was no way to ascertain a safe and effective dose of marijuana because of the numerous compounds it contains, the potency of the compounds, their interaction with pharmaceutical drugs an individual might be taking, and whether or not the marijuana was contaminated with fungus, bacteria, or other chemicals. That is not to say that cannabis does not contain compounds that could be extracted or synthesized for medical use. But such compounds must be subject to FDA research protocols and approval.

Dr. Kenneth Green, Regent's Professor of Ophthalmology and the Director of Ophthalmic Research wrote, "All the 'old' arguments apply to marijuana, i.e., lack of standardization, the multiplicity of ingredients that vary with habitat, non-uniformity of response, unacceptable side effects (even in young, healthy volunteers, that would not necessarily be as mild in an older, glaucomatous population), requirements for continuous smoking on a daily basis for life that is counter to the smoking cessation efforts of many..."
Marijuana cannot be prescribed because the FDA has not approved it. Physicians may recommend marijuana but only in states that have passed citizen driven, not scientific driven, ballot initiatives. Historically, physicians rely upon the FDA's process for approving drugs to protect them from any liability exposure should a drug be unsafe. Recommending a non-FDA approved drug requires a major "leap of faith" for most jurors in a liability suit.

In the Illinois case of Lawson v. G.D. Searle & Co. (1976), 64 Ill.2d 543, 356, N.E.2d 779; 1 Ill.Dec. 497 (1976), a prescription drug may be deemed unreasonably dangerous because of the absence of an adequate warning accompanying the product, as the product may be "unavoidably unsafe" without such warning." There are no package insert instructions and warnings for marijuana.

Pharmaceutical instructions and warnings can be used to establish a standard of care. In 1993 Roxane Laboratories, Inc. issued an "Important Correction of Drug Information" to healthcare professionals for the drug Marinol® (dronabinol), containing a synthetic delta9-tetrahydrocannabinol (THC). THC is the major psychoactive ingredient in marijuana. The following warning was extensive and alarming. Likewise, the warning portends serious implications for the use of the natural THC drug—found in marijuana.

△ MARINOL is not indicated as first-line treatment for nausea and vomiting associated with cancer chemotherapy;

△ MARINOL is not indicated for the treatment of nausea and vomiting associated with cancer chemotherapy only in patients who have failed to respond adequately to conventional antiemetic treatments;

△ Because of the limitations of its indication, comparisons of MARINOL to conventional antiemetic products are inappropriate. MARINOL is not a therapeutic alternative to Compazine® (prochlorperazaine) or other conventional antiemetic treatments;
Patients taking MARINOL should remain under the supervision of a responsible adult during initial use and following dosage adjustments;

Patients using MARINOL should be advised of possible changes in mood and other adverse behavioral or disturbing psychotomimetic reactions and they should be instructed to report these changes to their healthcare provider;

MARINOL is a medication with a potential for abuse. Physicians and pharmacists should use the same care in prescribing and accounting for MARINOL as they would with morphine or other drugs controlled under Schedule II of the Controlled Substances Act. It is recommended that prescriptions be limited to the amount necessary for the period between clinic visits;

The risk/benefit ratio of MARINOL use should be carefully evaluated in the following types of patients for the reasons stated below:

- Patients with cardiac disorders, because of occasional hypotension, hypertension, syncope, or tachycardia;
- Patients with a history of substance abuse, including alcohol abuse or dependence;
- Patients with mania, depression, or schizophrenia because MARINOL may exacerbate these illnesses; these patients should undergo careful psychiatric monitoring during therapy; and
- Patients receiving concomitant therapy with sedatives, hypnotics, or other psychoactive drugs because of the potential for addictive or synergistic CNS effects.

This warning from Roxane Laboratories about Marinol® (dronabinol), the synthetic THC, puts physicians on notice that this drug has the potential for harm, that prescriptions must be controlled, dosages regulated and patients monitored.

Smoking crude marijuana exposes individuals to even greater harm than the synthetic THC, Marinol. According to testimony given by the Department of Justice, Drug Enforcement Administration, the mental and behavioral effects of marijuana can vary widely among individuals; but common responses, described by Wills (1998) and others (Adams and Martin 1996; Hollister 1986a, 1988a; Institute of Medicine 1982) include:

(1) Dizziness, nausea, tachycardia, facial flushing, dry mouth and tremor can occur initially

(2) Time distortions

(3) Illusions, delusions and hallucinations are rare except at high doses

(4) Impaired judgment, reduced coordination and ataxia, which can impede driving ability or lead to an increase in risk-taking behavior

(5) Emotional lability, incongruity of affect, dysphoria, disorganized thinking, inability to converse logically, agitation, paranoia, confusion, restlessness, anxiety, drowsiness and panic attacks may occur, especially in inexperienced users or in those who have taken a large dose

(6) Increased appetite and short-term memory impairment are common.13
POINT OF LAW —

Loss of a Chance Doctrine

The “Loss of a Chance” doctrine occurs when a physician is negligent in diagnosing a disease, and the resulting delay reduces the plaintiff’s chances of survival (even though the chance of survival was below fifty percent before the missed diagnosis), or when a strong argument can be made that the physician should be responsible for the value of the chance that the plaintiff lost, so long as the initial act of the physician was itself negligent. The majority of jurisdictions that have considered this “Loss of a Chance” theory have, in fact, adopted it. The leading case on this point is *Herskovits v. Group Health Cooperative*, 99 Wash.2d 609, 664 P.2d 474 (Wash. 1983), where the Washington State court considered the consequences of a physician’s missed diagnosis of lung cancer on the plaintiff’s future. The court found that the plaintiff’s chances of survival dropped from 39 percent to 25 percent, and that such a “Loss of a Chance” to survive was the proximate cause of his death.

Some individuals claim that marijuana can be used to treat a myriad of physical ailments. They often approach doctors with anecdotal stories of relief and cures provided by smoking marijuana. Based upon their anecdotal stories and a possible placebo effect, some patients may request to be treated with marijuana. This frequent scenario puts doctors in the position of accepting the patient’s self-diagnosis and possibly missing the correct diagnosis, thus delaying proper treatment and possibly putting themselves at risk of future legal action by the patient or his family.

In two states that passed ballot initiatives, Washington and Oregon, patients can seek medical marijuana for a number of ailments:

- Intractable pain, to mean pain unrelieved by standard medical treatments and medications
- Glaucoma, either acute or chronic
- Crohn’s Disease
- Hepatitis C
- Any disease, including anorexia, which results in nausea, vomiting, appetite loss, cramping, seizures, muscle spasms, and/or spasticity, when these symptoms are unrelieved by standard treatments.
- Cachexia
- Severe pain
- Severe nausea

There is no clinical research supporting marijuana as an effective treatment for any of the diseases listed. A physician risks negligence and “Loss of a Chance” by not treating a patient’s medical condition with the most effective medication.

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Aggravation (Exacerbation) of a Pre-existing Condition

An aggravation of a pre-existing ailment or condition has been held to be a separate element of compensable damages. “In *Balestr v. Terminal Freight Co-op. Ass’n*, 76 Ill.2d 451, 394 N.E.2d. 391, 31 Ill. Dec. 189 (1979), cert. denied, 444 U.S. 1018, 100 S.Ct. 671, 62 L.Ed.2d 648 (1980), it was held to be reversible error to refuse an instruction that the plaintiff’s right to recover damages for his or her injuries and disability is not barred or limited by the fact that they arose out of an aggravation of a pre-existing condition which made the plaintiff more susceptible to injury.”

Some who seek recommendations from physicians for marijuana treatment are human immunodeficiency virus (HIV) patients and cancer patients. This is cause for concern because marijuana use can compromise the immune system, particularly in those who have other health...
problems. The major psychoactive component of marijuana, delta-9 THC, has been shown in human and experimental animals to affect the immune system. Friedman et al. in Advances in Experimental and Medical Biology, Vol. 373, pp 103-113, 1996, present studies in mice given THC. These mice have reduced antibody formulation and abnormalities of other chemicals, which help the body fight viral and bacterial infection. When these mice are exposed to the bacteria, Legionella pneumophila, a rapid toxic shock-like death occurs – within one day.21

A. Sonia Buist, M.D., Professor of Medicine at OHSU School of Medicine, raised concern about giving marijuana to ill individuals. She stated, “Furthermore, I would maintain that its use (smoked marijuana) is contraindicated, because marijuana smoke is extremely irritating to the airways and may add additional pulmonary problems in these very susceptible individuals [AIDS patients]. Marijuana smoke is even more irritating to the airways than tobacco smoke and leads to severe inflammation, mucus secretion, and bronchitis.”

was diagnosed by her obstetrician as having had a missed abortion. He performed a dilation and curettage to remove the dead fetus from the plaintiff’s uterus. He used excess force, perforating her uterus and drawing part of her small intestine into her vagina. He then called on a general surgeon to assist. The surgeon repaired the damage by a bowel resection, removing a foot of the plaintiff’s intestine and connecting the two ends. The experts agreed that the plaintiff now faced a future risk of bowel obstruction, with one expert estimating the risk as ranging from eight (8) percent to sixteen (16) percent.

The court allowed two distinct damage claims. First, it held that the jury was properly instructed that *** it might award the plaintiff damages for her fear of the increased risk that she will someday suffer from a bowel obstruction. Second, it held that a plaintiff who has established a breach of duty that was a substantial factor in causing a present injury which has resulted in an increased risk of future harm, is entitled to compensation to the extent that the future harm is likely to occur. The court defined likely to occur as meaning merely an increased likelihood.25

Research has established that marijuana has the potential to cause reproductive problems and thus “future harm.” Gabriel G. Nahas, M.D., Ph.D., Department of Anesthesiology, NYU Medical Center, New York, NY, states, “The latest studies in molecular biology have demonstrated that THC, the active ingredient in marijuana, damages the earliest stage of reproductive function. Thus, marijuana is gametotoxic (toxic to embryos and sperm). It kills the reproductive cells of seven animal species, produces damage to the embryos and later to the fetus and develops. All of these destructive effects of marijuana on sperm cells, embryonic cells, or lymphocytes have now been related to the early production of ‘apoptosis,’ the programmed death of the cell.”25

As early as 1982, Surgeon General C. Everett Koop reported, “that marijuana decreased sperm count and activity, while interfering with ovulation and prenatal development.”16
Herbert Schuel, M.D., Department of Anatomy and Cell Biology, State University of New York, Buffalo, NY, reported on the reproductive risks at a 1998 international conference "Marihuana and Medicine" at New York University Medical Center. The Professor summarized his findings:

"THC is known to affect all phases of reproductive function studied thus far in humans and laboratory animals by inhibiting secretion of hormones by the pituitary glands; inhibiting ovulation; inhibiting sperm production and increasing the incidence of sperm with abnormal nuclei and acrosomes; inhibiting the motility of ejaculated sperm; affecting early embryonic development and implantation of the embryo into the lining of the uterus (uterine mucosa); and reducing the number pregnancies carried to term."[27]

Smoking marijuana is a harmful drug delivery system. Marijuana has more carcinogens than tobacco and poses a greater risk than tobacco. Smoking causes cancer and other deadly diseases. The smoke of crude marijuana contains 421 chemicals [Ed. Note, now over 450 have been identified.] Also contained in crude marijuana are toxic compounds such as carbon monoxide, acetaldehyde, naphthalene, phenol, cresol and more carcinogens than in tobacco. Crude marijuana can be contaminated with salmonella or with a fungus, Aspergillus fumigatus, which may cause severe pulmonary disease.[34]

The mode of inhaling a cannabis cigarette is very different than smoking a tobacco cigarette. Compared with tobacco smoking, cannabis smoking involves a two-thirds larger puff volume, a one-third larger inhaled volume, a four-fold longer breath hold time and a five-fold increase in blood carboxyhaemoglobin. The products of combustion from cannabis are thus retained to a much higher degree.[35] The latent period between the start of smoking marijuana and the development of cancer, respiratory, heart or circulatory conditions is fraught with "future harm" implications. These potential implications closely follow the claims made by so many against the tobacco industry.

Marijuana is an addictive substance, and the symptoms of marijuana withdrawal are clinically significant.[39] In 2001, there were 9,202 admissions in Cook County, Illinois, for marijuana treatment and 25,622 admissions for the entire state, according to the Illinois Department of Human Services.[31] Marijuana use presents a very real present and future harm. The Drug Abuse Warning Network (DAWN) reports on visits to the Emergency Department (ED) induced by, or related to, drug use with the episodes involving the use of an illegal drug or the use of a legal drug or other chemical substance for non-medical purposes.[37] From 2000-2001, Emergency Department episodes involving marijuana increased 15 percent, 96,426 to 110,512.[31] In 2001, 24 percent of episodes involving marijuana involved marijuana alone.[31]

Marijuana is often a gateway drug to the use of cocaine, heroin, and other psychoactive and addictive substances. In a study by Degenhardt L, et al., published in a 2001 issue of Drug and Alcohol Dependence, the authors reviewed numerous previous studies on the relationship between cannabis and the use of other drugs and concluded, "In particular, cannabis use and dependence were highly associated with increased risks of other substance dependence."[46] An Australian study, Escalation of Drug Use in Early-Onset Cannabis Users vs. Co-Twin Controls, found that a twin who had used cannabis by age 17 was 2.1 to 5.2 times more likely to use other drugs or be alcohol and drug dependent than their co-twin, who had not used marijuana.[36]
The risks of a specific treatment are perhaps the most important information for a patient to consider. Risks must be material to a patient’s decision-making in order to be disclosed. Courts often state that remote risks can be omitted, as can those commonly known by patients. Risks of drug side effects however are singled out for disclosure by some courts, even if the risk of a side effect is small. *Cunningham v. Charles Pfizer & Co.*, 1974 OK 146, 532 P.2d 1377, 1381 (Okl. 1974). (Duty to disclose “even though the chance of the adverse reaction occurring are statistically small.”).

Generally, a physician functions as a learned intermediary between a drug manufacturer and the patient. There is no learned intermediary position for a physician when recommending marijuana, because there is no drug manufacturer, no FDA approval, no standard chemical composition (potency and quality), no standard dosage, no safe delivery system, and no knowledge of marijuana’s interaction with other drugs or its impact on pre-existing conditions. Most marijuana used for medicine is grown in backyard gardens, hydroponic closets and large warehouses without any quality controls.

The concentration of delta 9-THC and other cannabinoids in marijuana varies greatly depending on growing conditions, parts of the plant collected (flowers, leaves, stems, etc), plant genetics, and processing after harvest (Adams and Martin, 1996; Agurell *et al.*, 1984; Mechoulam, 1973). Thus, there are many variables that can influence the strength, quality and purity of marijuana as a botanical substance. In the usual mixture of leaves and stems distributed as marijuana, the concentration of delta 9-THC ranges from 0.3 to 4.0 percent by weight. However, specially grown and selected marijuana can contain 15 percent or more delta 9-THC. Thus, a one-gram marijuana cigarette might contain as little as 3 milligrams or as much as 150 milligrams or more of delta 9-THC, among several other cannabinoids. As a consequence, the clinical pharmacology of pure delta 9-THC may not always be expected to have the same clinical pharmacology of smoked marijuana containing the same amount of delta 9-THC (Harvey, 1985). The lack of consistency of concentration of delta 9-THC in botanical marijuana from diverse sources makes the interpretation of clinical data very difficult.

There are no quality controls in the production of medical marijuana and no standard dosage of THC for “medical grade” marijuana. High tech growing operations increasingly produce higher potency plants. According to Dr. El-Sohly, Research Professor, University of Mississippi, National Center for Natural Products Research, “it is extremely difficult to determine the level of THC in a marijuana cigarette. The THC level is determined by chromatographic analysis (usually by gas chromatography or high performance liquid chromatography). The analysis is an instrumental analysis and has to be done in a laboratory authorized to handle controlled substances.”

There is no way in the growing process to maintain specific levels of THC. Dr. El-Sohly said, “The THC level from season to season depends on the environmental conditions, the time of harvest, and the parts of the plants harvested.”

In the states of Washington and Oregon, where ballot initiatives have established laws regarding the use of marijuana as a medicine, state statutes require physicians to advise their patients as to the “risks and benefits” of marijuana. No physician can possibly exercise the required degree of “care, skill, and diligence” when advising about a substance for which there are no quality controls in producing it, no established dosage, no safe delivery system, and no clinical research on its effectiveness, risks, benefits, and interactions with other drugs.
Third Party Endangered


In June of 2002, the Hawaii Supreme Court, in McKenzie v. Hawaii Permanente Medical Group, Inc., 98 Hawaii 296; 47 P.3d 1209 (2002) held that doctors who fail to warn their patients about the possible side effects of prescribed medicines can be held responsible if a patient suffers an adverse reaction and injures someone in a traffic accident. The ruling came from a civil lawsuit filed by Carole and Roger McKenzie on behalf of their daughter, who was 11-years old when she was struck by a car driven by Jerry Wilson (He filed a cross claim.). The suit contended that Kaiser Permanente Medical Group Inc. and one of its physicians, Dr. Robert Washecka, were negligent in prescribing a drug for Wilson that resulted in his fainting moments before his car hit the girl.

The Supreme Court's decision made clear that Hawaii doctors can be sued by third parties.

Smoking marijuana diminishes physical and mental abilities. A study conducted by the U.S. Department of Transportation, National Highway Traffic Safety Administration (NHTSA), “Marijuana, Alcohol and Actual Driving Performance,” concluded that smoking at relatively low-moderate THC doses impairs driving. The effects were dose-related and continued or increased for 2-1/2 hours after smoking. Frequently, marijuana is used in combination with alcohol. The NHTSA study found that the combination of alcohol (BAC 0.04) and a low-moderate THC produced “very severe effects on driving performance.” The 2001 DAWN Study of Emergency Department Visits substantiated the involvement of marijuana and alcohol, showing alcohol in combination with marijuana in 17 percent of the episodes.

Legal Rulings

The 9th U.S. Circuit Court of Appeals ruling that physicians may advise their patients about marijuana as a medicine without fear of criminal prosecution or losing their licenses does not address the civil liability, professional conduct, and competency issues facing physicians. In a paper titled, “Potential Physician Malpractice Liability Associated with Complementary and Integrative Medical Therapies” and published in the Annals of Internal Medicine, Attorney Michael H. Cohen and Dr. David M. Eisenberg write, “From a liability standpoint, by pursuing a therapy for which evidence indicates either inefficacy or serious risk, the physician is not only deviating from conventional standards of care but also causing patient injury; thus, the physician is probably liable.”
CANADIAN MEDICAL ASSOCIATION

Physicians cannot properly counsel patients about marijuana, and recommending marijuana places the physician in a precarious legal position.

On July 30, 2001, the Canadian government passed the Marihuana Medical Access Regulations that allows smoking marijuana for medical purposes. However, the Canadian Medical Association (CMA), the Canadian Medical Protective Association (CMPA), the Canadian Society for Addiction Medicine (CSAM), and the Physicians for a Smoke-Free Canada (PSC) all issued strong warnings against recommending crude marijuana as a medicine.

Dr. Henry Haddad, President of the Canadian Medical Association, wrote an open letter to the Honorable Allan Rock Q.C., Minister, Health Canada, “expressing serious concerns” about the federal government regulations. Dr. Haddad was adamant, stating, “As you know, physicians are not in a position to adequately counsel patients regarding the use of marijuana, nor do we have the necessary information regarding what constitutes the proper dosage, its interaction with other drugs, or its impact on other pre-existing medical conditions.”

He went on to say, “The Regulations as currently written are flawed: they may pose a threat to the health of patients, they have the potential to undermine the patient-physician relationship, and they place physicians in a precarious legal position.”

John E. Gray, MD, CCFP, FCFP, the Secretary-Treasurer/CEO of the Canadian Medical Protective Association, with 60,000 members, wrote a letter to the Honorable Allan Rock Q.C., Minister, Health Canada. Dr. Gray emphasized his concerns about the medical use of cannabis.

“The CMPA believes the medical declarations required under the Regulations place an unacceptable burden on member physicians to inform themselves as to the effectiveness of medical marijuana in each patient’s case, as well as the relative risks and benefits of the drug and what dosage would be appropriate.”

“This information is simply not available. In medicine, knowledge is typically derived from clinical trials, of which we understand there are very few for marijuana. Given the fact that many physicians would not have the necessary knowledge about the effectiveness, risks, or benefits of marijuana, we believe it is unreasonable to make physicians gatekeepers in this process.”

“As a mutual medical organization with the unique mandate of defending the professional integrity of doctors, we are critically aware of and concerned about the medico-legal difficulties that may face members who choose to follow Health Canada’s Marihuana Medical Access Regulations.”

CANADIAN SOCIETY OF ADDICTION MEDICINE

There is more risk than benefit in the use of cannabis for medicinal purposes.

An April 12, 2001, article from the Calgary Herald quoted Dr. Nady el-Guebaly, head of Foothills Hospital Addiction Centre in Calgary and a spokesman for the Canadian Society of Addiction Medicine (CSAM), as saying that the regulations “place most physicians in this country in a serious ethical quandary.” According to the article, the
Society's policy states that, "overall there is more risk than benefit in the use of cannabis products for medicinal purposes." The same article quotes Dr. Bill Campbell, president of CSAM and a Calgary family physician who treats addicts, "Although the government may wish to call its plans to regulate marijuana 'compassionate medicine,' it must not yet be considered as 'medical' – for smoking marijuana has not met the rigorous criteria required before a drug can be considered both safe and therapeutic."

**PHYSICIANS FOR A SMOKE-FREE CANADA**

*Smoking a marijuana joint is a harmful drug delivery system.*

Physicians for a Smoke-Free Canada (PSC) point out the government's reckless disregard for appropriate medical boundaries. Dr. Jim Walker, an Ottawa dermatologist and a member of PSC's executive board said, "The marijuana joint is a harmful drug delivery system, the proverbial dirty syringe."

In a PSC news release, the physicians state, "Marijuana produces more tar per weight of leaf burned than tobacco and a higher level of some cancer-causing substances, such as benzopyrene. Because marijuana smokers tend to inhale larger amounts of smoke, breathe it deeper into their lungs, and hold it in their lungs for longer periods than cigarette smokers, researchers conclude that lung tissue is exposed to harmful chemicals to a relatively greater extent."

Dr. Atul Kapur, an emergency medicine physician in Ottawa and president of PSC, said that especially those whose health is already compromised by disease should be advised against inhaling any form of smoke.

Dr. Walker pointed out the glaring inconsistencies between Health Canada's policies on marijuana and its policies regarding tobacco and pharmaceutical approvals. "Just as we applaud the strong new warning on cigarette packages, we are deeply disturbed by the absence of any requirement to inform patients or participants in clinical trials of the harmful consequences of smoking marijuana. In our opinion this is not only inconsistent, it reflects dubious scientific and medical ethics."*

**HEALTH CANADA**

*Canada's Health Minister is uncomfortable with sick people smoking marijuana.*

In August 2002, Canada's Health Minister, Anne McLellan, speaking at the annual Canadian Medical Association (CMA) meeting said that she was uncomfortable with sick people smoking marijuana and that Ottawa would not distribute marijuana for medicinal purposes until clinical trials could be completed. Ms. McLellan said that marijuana should be subject to the same standards as other prescription drugs and agreed it was hypocritical for her department to allow pot smoking while working to reduce tobacco smoking.

"I understand the issues that we in this room have and feel in relation to the lack of scientific evidence, possible liability issues, and the fact that the federal Department of Health does find itself in a slightly ironic position when I am responsible for the single largest campaign in the federal government – the anti-smoking campaign," she said.**

The Health Canada - Office of Cannabis Medical Access' web site cautions about the efficacy of smoked marijuana, "Evidence of the therapeutic value of smoked marihuana is heavily anecdotal. While there are anecdotal reports on the therapeutic value of smoked marihuana, scientific studies supporting the safety and efficacy of marihuana for therapeutic claims are inconclusive. Health Canada is also concerned about the health risks associated with the use of marihuana, especially in smoked form."**

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**CONCLUSION:**
Physicians Who Recommend
Marijuana May Find They Have
No Insurance Coverage
For Potential Resulting Claims

*Insurance companies are introducing
exclusions for non-FDA approved drugs.*

Whatever the liabilities that may inure to
physicians recommending marijuana, there is a
very real question as to whether or not such
liabilities would be covered under standard
medical malpractice or professional liability
insurance policies. Traditionally, such insurance
policies provide a defense for claims or lawsuits
against its insureds (physicians) and
indemnification for any settlements or judgments
within the policy limits. There is no guarantee
that these insurance policies will afford coverage
for the recommendation of an illegal, non-FDA
approved drug such as marijuana.

TIG Specialty Insurance recently revised its
physician policy form to include the following
new exclusion clause: “Non-FDA Approved
Medication or Device. Any claim that arises from
the design, manufacture, use, distribution,
promotion or sale of any non-FDA approved
medication, device, equipment or protocols.”

Medical Liability Mutual Insurance Company
(MLMIC), the nation’s number one writer of
medical malpractice insurance, has very similar
exclusionary language in its policies covering non-
FDA approved drugs. Other leading companies,
recognizing the potential liability, are adding
similar exclusionary language. Still, other
insurance companies have added specific
questions to their application process as to
whether the physician applicant has prescribed
or recommended non-FDA medication.

The points of law discussed in this paper and the
extensive case law cited in support of these points
would suggest that more insurance companies will
follow suit by adding similar exclusions to their
medical malpractice policies.

If there were no coverage, a physician would be
exposed to paying defense costs and could be held
personally liable for any judgment entered against
him or her.
NOTES


4 Health Law.

5 Health Law 265.

6 Health Law 240.


9 Green, Kenneth, Ph.D., D.Sc., Regent’s Professor of Ophthalmology, Professor of Physiology, Director of Ophthalmic Research, Department of Ophthalmology, letter to Sandra S. Bennett, Drug Watch Oregon, October 28, 1991.

10 Health Law. 243.


13 Dept. of Justice, Denial of Petition, 20042.


17 Health Law, 262.


22 A. Soni Buist, AM.D., Professor of Medicine, Head Pulmonary and Critical Care Medicine, OHSU School of Medicine, letter to Sandra S. Bennett, Drug Watch Oregon, 1991.

23 Health Law, 264.

24 Health Law, 264.


26 Nahas, Marijuana and Medicine

“Marijuana, Alcohol and Actual Driving Performance.” Dept. of Transportation


“I “Marijuana, Alcohol and Actual Driving Performance.” Dept. of Transportation


“I John E. Gray, MD, CCFP, FCPh, Secretary-Treasurer/CEO of Canadian Medical Protective Association, letter to The Honorable Allan Rock QC, Minister, Health Canada, November 8, 2001.


