The Legalization of Marijuana: Implications for Regulation and Practice

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Today, marijuana—both medical and recreational—is legal in several states despite the absence of scientific evidence regarding its safety and efficacy. This article reviews questions about the long-term impact of marijuana use on health care and public safety, including the effects of abuse and dependence. The article also addresses the regulatory implications of legalized marijuana and makes recommendations for best practices for primary care providers.

In recent years, public policy has moved towards loosening restrictions on medical marijuana. After the current administration indicated in 2009 that medical marijuana prosecution would have a low priority as long as users and providers conformed to state laws, medical marijuana use has sharply accelerated. Since 2009, a variety of public health and safety trends and statistics have been published, raising questions about the long-term impact of marijuana use on health care, regulation, and public safety.

By 2013, several states had changed their laws to allow not just the medicinal use of marijuana but recreational use as well. As regulators develop standards of care and policies regarding marijuana use in their states, they need to look closely at the implications of liberal state and federal marijuana laws, the lack of evidence-based research on the efficacy of marijuana, and the responsibility primary care providers (PCPs) have to their patients.

Until the late 1930s, physicians in the United States routinely prescribed marijuana. Not until 1970 did the law forbid all use. In 1975, the Food and Drug Administration (FDA) established the Compassionate Use Program allowing marijuana use for patients suffering from cancer, glaucoma, and multiple sclerosis. The program was not based on research, just the recognition that glaucoma was the leading cause of blindness in the world and that patients with terminal or refractory diseases were enduring enormous suffering. In the 1990s, members of the American Academy of Ophthalmology's Committee on Drugs noted that no scientific evidence showed marijuana was safe and effective in the treatment of glaucoma. Then, the Institute of Medicine stated that marijuana caused too many adverse effects—primarily cognitive adverse effects—to be used for lifelong glaucoma treatment, especially since several FDA-approved drugs were already available (Gundersen, 2015).

In 2003, the Controlled Substance Act classified marijuana as a Schedule I drug, that is, a drug with a high potential for abuse and no safe medical use (Gundersen, 2010). Previously, in 1986, a synthetic form of oral tetrahydrocannabinol (THC), the main psychoactive substance in marijuana, had been introduced. This synthetic drug, dronabinol (Marinol), was classified as a Schedule II drug, that is, a drug with high abuse potential but a current acceptable medical use, making it accessible to patients in need and for research purposes (Gundersen, 2010).

Medical Marijuana Use

In most states where marijuana has become legal (see Table 1), ballot initiatives have been used to amend state constitutions, allowing marijuana to be recommended for specific disabling conditions (Nussbaum, Boyer, & Kondrad, 2011). Generally, public health departments are responsible for implementing and administering the medical marijuana registry program. Debilitating conditions qualifying for the use of marijuana include glaucoma, cachexia, cancer, HIV and AIDS, seizures, severe pain, severe nausea, persistent muscle spasms and spasticity and, in some states, posttraumatic stress disorder. Typically, a patient wishing to use marijuana legally for medicinal purposes must be evaluated by a PCP, who then makes a recommendation if the patient suffers from one or more qualifying conditions. In most states, an application is submitted to the health department. If it is approved, the patient is issued a medical marijuana card, which generally expires after 1 year, when another evaluation is required for continued use. Objectively measured qualifying conditions, such as cachexia, glaucoma, HIV/AIDs, and cancer, account for only a small percentage of the cards issued. Severe pain, a highly subjective condition, is the most commonly diagnosed condition for patients who receive medical marijuana cards (Gundersen, 2010, 2015).

Across the country, a small number of PCPs make the majority of recommendations for medical marijuana. For some, their entire practice is making recommendations for medical marijuana only. Thus, patients may not be adequately informed about alternative remedies, including evidence-based treatments with known safety and efficacy. When only one treatment

is offered in exchange for compensation, the PCP's fiduciary responsibility to patients may be compromised. The patient's interest must be paramount, and PCPs should review all available treatments based on the patient's medical and psychological needs (*Witherell v. Weimer,* 1981).

The recreational use of medicinal marijuana, the financial exploitation of medicinal marijuana, and the rise in the number of diagnoses of severe pain despite the lack of scientific evidence are causes for concern. In Colorado, an overwhelming number of medical marijuana cards have been issued for chronic pain—many for young people—which strongly suggests recreational use (Gundersen, 2010, 2015). Effective public health policy depends on accurate health reporting and scientific analysis, neither of which is possible when patients or the PCPs who treat them distort health care decision making for their own advantage (Gundersen, 2010, 2015).

In some states such as Colorado, legislation was introduced to tighten the rules and regulations governing the medical marijuana industry thus reducing the abuses of PCPs making medical marijuana recommendations without adequate evaluation or follow-up monitoring (Nussbaum et al., 2011). Specifically, a PCP must obtain a clinical history and perform an adequate physical examination to arrive at an accurate diagnosis. The PCP must maintain a chart on the patient and reassess the qualifying condition over time to determine whether the patient has improved with the recommended treatment. In addition, PCPs making marijuana recommendations must have unrestricted medical and Drug Enforcement Administration licensure, and regulatory boards have the authority to examine the care provided to patients who have marijuana recommendations. Conflicts of interest are addressed by not allowing PCPs to be employed by or profit from dispensaries. Two PCPs must independently examine a patient younger than age 21 and concur about the diagnosis and appropriateness of marijuana treatment.

Evidence and Efficacy Data

Research on the use of marijuana for medical purposes is lacking, partly because marijuana is classified as a Schedule I drug, making it all but impossible to conduct the randomized, double-blind, placebo-controlled studies necessary to assess efficacy and safety. Although the Institute of Medicine's 2003 authoritative report identifies potential benefits of marijuana related to its anti-inflammatory, antiemetic, antispasmodic, and analgesic properties and its ability to lower intraocular pressure (Joy, Watson, & Benson, 2003), the studies thus far have been retrospective, with small numbers of subjects. Differing cannabinoid concentrations, differing exclusion criteria, and confounding variables limit the reliability of early study outcomes (Institute of Medicine, 2015; Nussbaum et al., 2011; Volkow, Baler, Compton, & Weiss, 2014; Wallace et al., 2007).

TABLE 1

Timeline for Legalization of Marijuana by State

The following timeline shows individual states and the District of Columbia that have liberalized marijuana laws through decriminalization and legalization of recreational marijuana and medical marijuana.

- 1996: California
- 1998: Alaska, Oregon, Washington
- 1999: Maine
- 2000: Colorado, Hawaii, Nevada
- 2004: Montana
- 2006: Rhode Island
- 2007: New Mexico, Vermont
- 2008: Michigan
- 2010: Arizona, New Jersey
- 2011: Delaware, Washington, District of Columbia
- 2012: Connecticut, Massachusetts
- 2013: New Hampshire, Illinois
- 2014: Maryland, Minnesota

A few families have legally obtained cannabidiol tinctures for children who suffer from intractable epilepsy, specifically Dravet syndrome, and some have had promising results. In one study of 19 children with epilepsy, two had complete remissions from seizures. Another eight had a significant decrease in seizures, and six had a decrease of 25% to 60% in their symptoms (Volkow et al., 2014). Though promising, the small sample size does not provide the efficacy and safety data the FDA demands before introducing a new drug to the public.

Marijuana purchased from dispensaries has not been formally investigated for safety and efficacy. No standardizations for therapeutic dosing have been established. Marijuana is dispensed in unknown, varying strengths and is not monitored for purity. Unlike medications approved by the FDA, no postmarketing surveillance is conducted to track unforeseen adverse effects. Despite being a Schedule I drug, marijuana has bypassed the prescription drug monitoring program in many states (Gundersen, 2015).

Additionally, the potency of THC obtained through interdiction seizures has increased from approximately 3% in the 1980s to 12% or higher in 2014 (Rocky Mountain High Intensity Drug Trafficking Area [RMHIDTA], 2014). As a result, the marijuana available today may be more hazardous than earlier studies reflect. Whereas an average-size marijuana joint contains 10% to 15% THC, butane hashish oil—a concoction of hashish oil infused with butane—can contain up to 90% THC.

The Colorado Department of Public Health and Environment has now established a Medical Marijuana Scientific Advisory Council to gather new scientific evidence about marijuana. Experienced researchers have been awarded grants for the purpose of more clearly defining the risks and benefits of marijuana use.