The *Intended Consequences Initiative*:
A Proactive Move Toward Expert Medical Supervision
Of Medical Cannabis Patients in PA

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Introduction

The Pennsylvania Medical Marijuana Act of 2016 is modeled after similar pioneering legislation in several others states, learning from and improving upon the processes and experiences of 23 states which preceded PA in approving medical cannabis. Clearly the intention of the lawmakers is to provide cannabis as a supervised medical treatment for patients with severe medical conditions which cannabis has been found to alleviate. Yet evidence from other states with similar legislative models indicates that the growth of the medical cannabis industry does not typically reflect the medical intent of the legislation.

The PA Medical Marijuana Act specifies 16 specific Serious Medical Conditions (cancer, epilepsy, MS, etc.), as well as terminal illness. In PA, as in most other states, the list of specific conditions has a catch-all category appended to it -- severe chronic or intractable pain -- which is left to the discretion of recommending physicians to validate. The PA law also requires continued supervision of a cannabis patient by the recommending doctor. The reality in other states is that only a small minority of patients using medical cannabis are those with the specific Serious Medical Conditions, and few of those patients use cannabis under the supervision of a specialist who is treating their qualifying disease condition.

This paper explores the role of clinical practitioners in the supervision of cannabis treatment, and proposes strategic directions to create a more serious medicalized culture for cannabis use in PA, to steer the state toward Intended Consequences.

Across the Country

Law professor Gerald Caplan documents the shortcomings in the medicalization of cannabis in a paper entitled “Medical Marijuana: A Study of Unintended Consequences.”[1] Caplan’s research demonstrates the disconnect between the intended consequences of medical marijuana laws versus the way in which legalized cannabis has played out in other states. As Caplan elucidates, most of the medical cannabis patients in other states are obtaining the drug through the catch-all category, e.g. chronic pain (as opposed to a specific qualifying condition). This creates a loophole for the proliferation of legalized “recreational” use, which is ostensibly the dominant pattern in other states. Caplan describes recommending cannabis as a new kind of

[1] Gerald Caplan, “Medical Marijuana, A Study of Unintended Consequences,” 43 *McGeorge Law Review* 127 (2011), http://www.mcgeorge.edu/Documents/Publications/06_Caplan_FINAL.pdf

medical specialty, in which a small number of doctors devote their practice to providing referrals for medical cannabis to new patients--essentially a Dr. Feel Good service. He provides these examples of a Cannabis-Express-style medical culture:

- Time Magazine reported that at the start of 2010, “Colorado health department records show that only 2% of registered patients had cancer; 1% had HIV/AIDS. There were 94% who suffered "severe pain"--a catchall condition that can be entirely subjective and difficult for a doctor to measure or verify. Statewide, more than 70% of doctor recommendations were written by fewer than 15 physicians.”[2]

- In Oregon, fewer than ten percent of the roughly 35,000 patients holding cards suffered from cancer, multiple sclerosis, glaucoma, or the other specific debilitating conditions cited in the legislation. Ninety percent of registered cardholders cited chronic pain as their qualifying debilitating disease.

- In Michigan, two years after medical cannabis was legalized, 55 doctors certified 45,000 patients, with the great majority of recommendations issued for severe or chronic pain.

- Nevada’s percentages are nearly identical.

- Montana’s are slightly lower, with seventy-one percent of all medical marijuana users suffering from chronic pain.

Caplan also points out that the age and gender distribution of cannabis patients in other legalized states closely reflects the demographics of recreational users. And the cultural ambience, with “budtenders” and “ganjapreneurs,” has a public face more akin to Cheech & Chong than to the Surgeon General. Clearly the medical cannabis industry is dominated by recreational users, with little participation by the patients who are the intended consumers or by the doctors who are treating their qualifying conditions. Caplan puts it succinctly: “Evidence of excessive prescribing by physicians can perhaps be inferred from the marketing of marijuana. There is something odd about physicians recommending medication such as Gold Dust, Mango Hash, Frazzleberry, Chemdawg Kief, Blue Dream, Grape Wreck, Qrazy Train, Violator Kush, Burkle, Cheese Melt, and Green Crack Silly Putty. Such names would seem to hold no special appeal for one experiencing nausea following surgery, chemotherapy, or the like. Instead, they suggest that the dispensary, like the doctor, may have the recreational user in mind.”

In California in 2014, State senators tried (and failed) to pass an intended consequences bill to close some of the loopholes that allow for the excessive prescribing for recreational users. The proposed legislation would have restricted cannabis prescriptions to a patient’s primary care physician or a referral from that doctor, to hinder doctors who do little more than prescribe marijuana to new patients. Chris Boyd, president of the California State Police Chiefs Association noted, “The voters' intent on that initiative was for those who really need medical

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[2] Andrew Ferguson, “The United States of Amerijuana,” *Time Magazine*, Nov. 22, 2010, http://www.time.com/time/nation/article/0,8599,2030768-2,00.html

marijuana, the sick and the dying. That is not what has played out."[3] After 18 years of a recreational medical cannabis culture in California, it is rather late in the game to effectively legislate reforms, but in newly-legalized states there is the opportunity to address these issues up front.

Why are so few patients with Serious Medical Conditions using cannabis in other states? Why are so few doctors recommending it, especially the specialists who treat the qualifying conditions? Let's take a brief look at the prevailing medical science factors and legal factors that inhibit widespread adoption of cannabis as a treatment option in states where it is sanctioned.

Cannabis Science

It may seem risky for a clinician to endorse a drug which lacks solid clinical testing, not to mention a drug which is banned by the US government. Marijuana occupies a unique status in modern medicine: it is a CSA Schedule 1 drug, which classification defines it as having no medicinal value. Marijuana research has been subjected to even more stringent regulations than other Schedule 1 drugs, which has largely blocked the ability of medical scientists to explore the basic science.

Yet the emerging body of medical cannabis research provides consistent evidence of many therapeutic actions, which calls into question the Schedule 1 assertion of no medicinal value. It is an enticing new topic for medical scientists, especially because over a million patients are already using it legally across the US! Not to mention many millions more using it off the radar.

Medical research in cannabis is proceeding in a very different way than the typical R&D process for pharmaceutical drugs, and the existing knowledge base in cannabis science is still in its infancy. Never before has a regulated drug been introduced to the public without a lengthy process of basic research, resulting in a systematic and comprehensive study of safety and efficacy. The pharmaceutical research system comprises an experimental program with cross-study correlation throughout the life process of the clinical investigation. This body of knowledge is the basis for determining standardized treatment protocols and dosages, warnings, and contraindications.

Cannabis science has no such standardized experimental umbrella. In one sense, the field is still in a basic science phase, investigating the endocannabinoid system as a physiological function, and exploring various therapeutic methods of action for many disease conditions. Drug research typically begins with in vitro and animal studies until enough evidence is amassed to justify in vivo experimentation. Yet cannabis first became accessible legally in California just around the same time as the discovery of the existence of the endocannabinoid system, when cannabis was barely on the medical science radar. So the doctors who were the early prescribers

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[3] Laura Olson, "Medical marijuana bill limits who can prescribe pot," *Orange County Register*, March 3, 2014, http://www.ocregister.com/articles/marijuana-603995-medical-state.html

were essentially doing in vivo experimentation with their patients, with little scientific evidence to guide their use of the new treatment.

Cannabis is now receiving enormous attention in the medical science world because it is becoming more accessible to scientists, has many promising therapeutic indications, and is being sanctioned as a therapeutic drug in many states, which alone impels the need for research. It is fascinating to watch the medical process unfold: cannabis is a bad-boy drug that has been forced into the medical arena, while cannabis science is somewhat crippled by the lack of a big-money umbrella that would provide for standardized research and testing, as well as the legal and regulatory quagmire that surrounds cannabis testing. Yet this grassroots medical experiment has gained so much momentum that the scientific community cannot ignore it, so they are scrambling to provide science backup.

Perceived Obstacles for Physicians

The chaotic nature of cannabis investigation and clinical application makes cannabis science a wild card in medical science at this moment. Many doctors and medical organizations take the stance that cannabis science is yet unproven, therefore it has no legitimacy and its safety has not yet been validated.

Most doctors lack a strong (or any) educational background in cannabis science and the physiology of the endocannabinoid system, so they have no substantive basis for opting in or out with medical cannabis. And at a higher level, most medical associations and healthcare organizations are similarly unequipped to make informed policy decisions about medical cannabis to guide clinical practice. The Dr. Feel Good cultural atmosphere further promotes a frivolous perception of cannabis among the medical science community, with the perception that endorsing cannabis may detract from professional credibility.

Physicians who are affiliated with HMOs may worry about their HMO relationship if they recommend cannabis to patients, even those with legally-approved conditions, if the HMO has not clarified guidelines for their doctors. In 2001, attorneys for Kaiser Permanente reviewed the risk of federal prosecution for doctors recommending medical cannabis in Colorado, and advised that doctors are free to recommend cannabis for their patients in accordance with state regulations. Yet in 2010, Mother Jones magazine published an article entitled "How to Get a Pot Card (Without Really Trying),"[4]which indicates that Kaiser Permanente doctors in California are reluctant to prescribe marijuana. The author Josh Harkinson describes his personal experiment to determine whether he could get a medical marijuana card for a "vague undocumented medical problem" and whether his wife could get a card for her severe arthritis. Harkinson was worried that he may be too healthy to qualify, but he sailed through the process at a "medical marijuana evaluation center" in San Francisco, where he presented with chronic pain, joint pain, and insomnia, and was given a card with no physical exam or review of his medical records. In the meantime, his wife, suffering from incapacitating arthritis, approached the Kaiser Permanente

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[4] Josh Harkinson, "How to Get a Pot Card (Without Really Trying), *Mother Jones*, October 11 2010, http://www.motherjones.com/politics/2010/10/california-medical-marijuana-pot-card

rheumatologist who was treating her condition, who claimed to have no authority over medical marijuana and referred her to a Kaiser GP. The GP ultimately refused her request, explaining "I very rarely write letters for medical marijuana, and then it's only for advanced cancer. I am not willing to write a letter for a relatively healthy 34-year-old for medical marijuana."

The Kaiser Permanente webpage on Medical Marijuana outlines risks of cannabis, with a very brief summary of why some medical experts endorse cannabis for relief of pain and nausea for cancer and AIDS patients, and muscle spasticity for MS. They provide no substantive directives for Kaiser Permanente doctors or patients, stating that “If you use medical marijuana to treat an approved medical condition, the federal government might not prosecute you. But there's no guarantee. If you think you might want to try medical marijuana, talk to your doctor. You can also call your state department of health or health services to learn more about the laws in your state.” This perspective provides very little guidance or assurance for doctors and patients; instead it appears to ignore the need for definitive medical oversight.

The professional risks are not well defined for physicians recommending a Schedule 1 drug that is legal at the State level but prohibited at the Federal level, so doctors may shy away from cannabis even if they are convinced of its potential efficacy. One thing seems clear: that legalized medical use of cannabis has reached a critical mass across the US, and the current regulatory policies at the Federal level are so far out of sync with the reality of state-legal cannabis use that policy reform is certainly on the horizon. As the regulatory landscape shifts toward increased sanctions at the Federal level, doctors and medical organizations will be able to work with cannabis treatments without fear of government prosecution.

The Brookings Institute published a 2015 paper entitled “Ending the U.S. government’s war on medical marijuana research,”[5] which elaborates on the need for setting public policies on cannabis research to address the current legal and scientific quagmire surrounding legalized medical use of a Schedule 1 drug. The authors John Hudak and Grace Wallack contend that “the bipolar nature of federal marijuana policy is not just confounding, but creates risks to public health and public safety,” because patients using cannabis legally have little medical support. As Hudak and Wallack point out, “in the context of medical marijuana, there is no excuse for the dearth of scientific information and no one is more to blame for that shortcoming than the United States government.“

For practicing clinicians, the medicinal value of cannabis is still an unanswered question. Yet many thousands of seriously ill patients in PA will be eligible to use cannabis next year, and some will choose to use it with or without the participation of their doctors. In this way, the lack of physician involvement is itself a public health and safety risk.

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[5] John Hudak and Grace Wallack, “Ending the U.S. government’s war on medical marijuana research,” Center for Effective Public Management at Brookings, October 2015. http://www.brookings.edu/~/media/research/files/papers/2015/10/20-war-on-marijuana-research-hudak-wallack/ending-the-us-governments-war-on-medical-marijuana-research.pdf

Strategic Directions to Promote Intended Consequences

Just as the federal government bears responsibility for enabling scientific research on cannabis, so doctors and medical organizations hold the key to providing supervised cannabis treatment in legalized states. Elin Kondrad and Alfred Reid summarize a survey of family doctors in Colorado in their article "Colorado Family Physicians' Attitudes Toward Medical Marijuana."[6] Kondrad and Reid conclude that the "gulf between physicians who are providing medical marijuana recommendations as a substantial portion of their practice and primary care providers who are far more likely to have a continuity relationship with a patient suggests that a continuity relationship influences provider behavior related to medical marijuana and may lead to more judicious recommendation of medical marijuana."

Pennsylvania is just now in the beginning phase of setting the direction for the emerging cannabis industry here. This is a golden opportunity to set a ground-breaking precedent in rolling out a medical cannabis program which gets this drug to the patients who need it most, with expert supervision from the specialists who are managing their care. The PA legislation opens the door to a whole spectrum of potential outcomes, ranging from a proliferation of Cannabis-Express docs to a climate of science-based medical application.

The *Intended Consequences Initiative* intends to help PA steer our medical cannabis industry in the direction of optimal therapeutic efficacy for seriously ill patients. Clinical policy making by doctors and health organizations is a conscious act that takes into consideration all dimensions of this complex situation: evidence from medical science, legal and professional risks associated with the US Prohibition, and the fact that many of their patients will be using cannabis courtesy of Dr. Feel Good. In the absence of well-considered policies in place in the organizations that employ and support physicians, individual doctors have little guidance in clinical use of cannabis. And even independent doctors need to establish their own clinical policies on cannabis.

Strategic directions for Intended Consequences include:

- An early outreach program for physicians and for organizations that provide professional oversight, i.e. medical associations, medical schools, and health care systems, to promote the need to establish clinical policies for medical cannabis. Elements include the development of overview educational materials for up-to-date cannabis medical science, plus discussion of business and legal considerations for cannabis recommenders.

- Coordination with the State Department of Health to help medical organizations assess legal risks associated with cannabis medicine. The ambiguous legality of medical cannabis may deter doctors from participating, but an understanding of the State's efforts to protect physicians and their governing organizations may help doctors to feel safer to

[6] Elin Kondrad and Alfred Reid, "Colorado family physicians' attitudes toward medical marijuana,". *J Am Board Fam Med*. 26 (2013), 52-60, http://www.jabfm.org/content/26/1/52.long

opt in. We propose to work with the State Department of Health to provide the medical community with expert State-sanctioned guidance on legal risks.

- Study the process of policy making in health care organizations by launching a pilot case with one organization that is willing to explore the issue and establish a directive for their doctors. It doesn't matter whether their recommendation is to allow or encourage or discourage or prohibit cannabis recommendation among their physicians; we can learn about how to guide the policy-making process, to then assist other organizations in making informed choices about their position.

- PA will require a 4-hour training course for physicians who register to recommend cannabis. Examination of similar curricula developed for doctors in other states points to much room for improvement in the quality and usability of the educational materials. It is essential to compile a curriculum that specifies best practices for physicians based on a basic understanding of current cannabis science, coupled with the clinical experience of doctors in other states who have cultivated their understanding of cannabis medicine through extensive experience with the specific qualifying conditions.

- Physician training may be enhanced by providing advanced cannabis education in specialized areas, such as a seminar designed specifically for oncologists, focusing on basic science of cannabis as an oncology treatment and expert protocols for working with cannabis cancer patients.

- The *Intended Consequences Initiative* will assemble a network of subject matter experts, consisting of cannabis medical scientists and experienced cannabis physicians at the leading edge of clinical practice. These experts will assist in providing presentations for early outreach programs, CME-accredited course curricula, and one-on-one mentoring with new cannabis docs, to facilitate a high level of support for policy making and medical education.

Conclusion

The first step toward Intended Consequences in PA is awareness of the trends in other states toward unintended consequences. The PA Department of Health is in the process of establishing policies and procedures to implement the Medical Marijuana Act. Now is the time to explore the avenues for moving toward a medically-sound cannabis industry in PA, within the confines of the legislation. Decisive clinical policy making within the medical community, in coordination with the Department of Health, is a key component of an Intended Consequences effort, and may provide a model for steering other states in this direction.