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Expanding legal treatment options for medical marijuana in the State of Louisiana

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ABSTRACT

Background: The use of cannabis for 'medical' purposes has expanded throughout the USA. Despite the limited peer-reviewed medical research, medical marijuana therapy has been to treat chronic pain, stimulate appetite, treat nausea, and ameliorate muscle spasticity.
Challenge: In the state of Louisiana, this potential treatment is strictly controlled. The ability of the individual patient to receive this therapy is limited since any prescribing provider had to be both licensed by the state medical board and registered with the board to prescribe medical marijuana. Medical cannabis could be used only for limited medical disorders. The 'Medical Marijuana' HB819 bill authorizes the recommendation of medical marijuana for additional conditions and allows any state-licensed physician to recommend/prescribe medical marijuana.
Alternative options: The government may consider working with the state medical board to lessen its regulation allowing a collaborative effort to formalize protocols for safe prescribing of medical marijuana. A more liberal option would be to make it available to the consumer over the counter, while a state tracking mechanism is set in place to limit the amount purchased.
Conclusions: Two stakeholders pertaining to this new legislation to focus on are the Louisiana State government and healthcare providers. This law probably has the biggest impact on healthcare providers and their relationship to patients. This legislation may allow providers to have more 'freedom in medical marijuana treatment plans'. These benefits would be monitored using such criteria as cost, access to care, as well as patient and healthcare provider satisfaction.

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1. Policy introduction

The current status of medical marijuana use in Louisiana is limited. It is both limited in the scope of approved uses and also in its control. All medical marijuana use is controlled by the State Board of Medical Examiners. The list of suggested uses for medical marijuana is short and includes intractable pain, cancer, glaucoma, Parkinson's, HIV and AIDS, cachexia, seizures, epilepsy, spasticity, severe muscle spasms, Crohn's disease, muscular dystrophy, multiple sclerosis, post-traumatic stress disorder, and certain autism spectrum disorders [1–3]. Additionally, there are rules and regulations set by the Louisiana State Board of Medical Examiners (LSBME) that must be followed by the prescribing physicians. The Prescribing physicians must both be board certified by the LSBME and be registered to prescribe medical marijuana [4].

Legislation LA HB819 seeks to expand the use of medical marijuana to both 'cover' more diseases and provide more freedom to physicians. It seeks to cover the conditions already listed as well as diseases such as neurodegenerative diseases, traumatic brain injury, chronic pain, and any conditions requiring hospice or palliative care. This legislation also allows the physicians to use their judgement when treating patients and allows for them to prescribe medical marijuana to patients who they think would benefit from it even if that disease process is not specifically listed in the law. This law also removes the LSBME from the set of regulations. If passed, this law only requires that there be an established doctor-patient relationship with a physician who is licensed and in good standing with the LSBME and believes, in their clinical judgement, that treatment with medical marijuana would be beneficial to the patient.

This legislation would be sufficient to remove many of the barriers that prevent patients from getting medical marijuana and would decrease the bureaucracy that currently plagues the process by removing the LSBME directly from regulations by

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returning decision-making ability to the physician's medical judgement.

2. Relevant case law and application

2.1. California proposition 215, the medical marijuana initiative

Medical Use of Marijuana Initiative or the Compassionate Use Act [5,6], was added to the 5 November 5th 1996 general election ballot in California as an initiated state statute. It was later approved. It is estimated that California may have millions of residents, who are qualified medical cannabis users. Importantly, San Diego and San Bernardino counties attempted to challenge this law but lost in all California courts. Finally, they petitioned the Supreme Court, but the Fourth District Court of Appeal held that 'the purpose of the (federal law) is to combat recreational drug use, not to regulate a state's medical practices'.

The law sets a precedent of medical use of marijuana in other states (in this case California) and therefore makes the case for allowing the other states to allow their physicians to recommend cannabis to their patients. Importantly, it suggests that "physicians who recommend the use of marijuana for medical treatment may not be 'punished or denied any right or privilege'. Physicians, knowing that they will not be prosecuted by their local government, medical board or their local hospital, are more likely to prescribe medical marijuana for their selected patients. Physicians and other allied providers are already prescribing medications to 'alleviate pain and suffering'. This case law application would place medical marijuana next to other commonly prescribed medications. If doctors can prescribe morphine or tramadol, why not medical marijuana? One can argue that it 'doesn't make sense'.

2.2. Use of marijuana for medical treatment, code of district of Columbia

The District of Columbia allows 'a qualifying patient to possess and administer medical marijuana and 'have a signed, written physician's recommendation for the use of medical marijuana' [7]. This law sets a precedent to allow a physician to make a recommendation for medical cannabis, as long as there is a 'bona fide relationship with the qualifying patient' and his/her medical opinion/training allows for that decision. Importantly, the law expands beyond the medical problems and addresses dental problems as well, clarifying that [medical marijuana] may 'provide the qualifying patient with relief from a qualifying medical or dental condition'. Additionally, the law is mentioning the side effects of the other prior treatment as a possible indication for medical marijuana. Similarly to California Proposition 215 [6], the law offers substantial protections for physician and/or an authorized practitioners, by stating that they 'shall not be subject to any penalty, including arrest, prosecution, or disciplinary proceeding, or denial of any right or privilege, for advising a qualifying patient about the use of medical marijuana'.

3. Alternative approaches

3.1. Collaborative work with the state's medical board to reduce regulatory restrictions

Under the USA Constitution, states are authorized to establish laws and regulations to protect the health, safety and overall welfare of their citizens. To insulate the public from the unprofessional, inappropriate, unlawful or incompetent practice of medicine, each of the states and territories in the USA has formally adopted a Medical Practice Act, which outlines the requirements for the practice of medicine within their borders and authorizes a medical board to enforce the provisions of the Act. Although these laws are somewhat hardwired, the medical boards recognize that with evolving technology, expansion of scientific knowledge, and legislative interventions, there is a need for some flexibility with the interpretation of bylaws. Given these facts, with enough scientific evidence, a case can be made for the approval of medical marijuana prescriptions by medical providers. Be that as it may, there are still concerns for potential legal actions against a prescribing provider if a patient under the influence causes harm to another individual. A recommendation would be to delineate the difference between 'prescription' and 'recommendation' or 'certification'. Under the law, a provider is protected from legal actions if they recommend or certify that a patient has specific conditions and may benefit from the use of medical marijuana. The medical board could encourage all providers, as part of that their medical practice, to complete a recommendation or certification form during encounters with these patients.

3.2. Push for food and drug administration approval and over-the-counter availability

The Food and Drug Administration (FDA) is a federal agency whose primary effort is to enforce the Federal Food, Drug, and Cosmetic Act [8]. As part of its focus on drugs, the FDA recognizes the existence of patients with unmet medical needs and the need to develop therapies for these patient populations. Further, the FDA has established programs designed to expedite and facilitate the availability of

investigational therapies to patients who have persistent serious medical conditions after all approved, available therapies have been exhausted. Examples of these programs include Breakthrough Therapy, Accelerated Approval, Fast Track, and Priority Review [9]. These programs allow the FDA enough flexibility to support sound and scientifically-based research in novel drugs such as the use of medicinal marijuana. There is a plethora of scientific research that may suggest supports the efficacy and safety of some key components of marijuana [2,3,10–12]. Although the FDA is bound by federal laws and statutes, which include the criminalization of the use of marijuana, it can focus its approval efforts on these cannabis-derived compounds. The FDA, through the aforementioned programs, can work with pharmaceutical companies interested in further developing these components into safe, effective, and quality products – with the possibility of making them available over-the-counter.

4. Evaluative criteria

4.1. Impact and political feasibility

In the USA, the use and possession of marijuana or any of its product is still a criminal offense by law [13]. However, some states, leveraging the headings of separation of powers, are now beginning to 'soften' their stance on the use of medicinal marijuana [14]. Mostly, these states have gone the legislative route, which may be an 'easier' route compared to the previously mentioned alternatives. Making it a ballot issue, political candidates or incumbents may be compelled to pass a bill that supports the use of medicinal marijuana to get elected. The outcome of this not only addresses the medical needs of patients who have been certified to require these therapies, but also a potentially positive impact on the state's economy. This is why the alternative approaches are paths less traveled. There are no political or economic incentives, which provides for a more objective platform. However, the state's medical board and the FDA must consider the political feasibility and evaluate the impact of approval decisions.

From the perspective of stipulations embedded in the Hippocratic Oath, medical boards have the flexibility, after careful considerations of scientific evidence, to grant a prescribing physician the liberty, based on his/her clinical judgement, to recommend the use medical marijuana for health issues outside the scope of the state's legislation. It is important to note that the state's medical board, albeit self-regulated, may still be subject to political pressures from legislators. If legislators determine that medical practice guidelines or law could jeopardize the health and safety of voters, they can unify across the aisle to address this issue. Therefore, it is advisable for medical boards exploring these options to do so in states that have legalized the use of medical marijuana.

As earlier stated, the impact of the FDA approval and over-the-counter availability offers important protections for patient populations suffering from debilitating medical conditions resistant to traditional therapies. Because the FDA is bound by federal laws, which prohibits the use and possession of marijuana, making medicinal marijuana or its components available must be done only when they: (1) are standardized by identity, quality, potency, and purity (2) are accompanied by adequate directions for use as medically approved and indicated (3) have risk and benefit profiles that have been defined in well-controlled clinical trials. Furthermore, the approval rate of these drugs could be determined by political pressures and incentives facing regulators from lobbyists [15,16].

4.2. Cost and access

The alternative approach can also be evaluated using the cost and access criteria. The medical boards and FDA's decisions to respectively lower restrictions and fast-track approval must be representative of efforts to improve care such as improving access and reducing the cost of healthcare. One way to determine cost-effectiveness and improved access is to compare each alternative approach to the legislative approach. Under both the legislative and medical board approaches, physicians who prescribe medical marijuana may be prone to tort laws. This means they can be sued by a third party who experiences pain, suffering, or loss in the hands of a patient who was under the influence of medical marijuana. This could result in high malpractice insurance premiums and ultimately, increased cost of care [17,18]. As mentioned previously, the medical boards can circumvent these potential liabilities by including the clause 'recommend' or 'certify' as opposed to 'prescribe' when physicians encounter patients who may require the use of these drugs. When it comes to access, both the legislative and medical board approaches may yield similar outcomes. Unless there is a legislation that mandates insurers to pay for services and consults related to medical marijuana use, providers are not guaranteed reimbursement from insurers. As a result, providers may tend to avoid these services, thus limiting access to patients who may need these treatments/services.

The FDA and over-the-counter approval approach could force a competitive market, thus leading to reduced cost of medical marijuana. Similarly, the cost can be reduced for patients, especially those with medical insurance, with legislation that confers prescribing freedom to physicians. On the other

hand, slight differences exist between the legislative and FDA approval approaches with regards to access. For many, reduced cost equates access. In the USA, the insurance system often plays a major role in whether or not a patient gets access [19,20]. Unlike the over-the-counter alternative, the legislative approach may limit access, particularly to those patients without medical insurance. The reverse would be the case if the legislative law mandating the prescription and dispensation of medical marijuana is also accompanied by a law mandating insurers to provide coverage for these services.

4.3. Repercussions of patient impairment

Could a patient be criminally prosecuted for possessing or cultivating marijuana for medicinal purposes when approved by a physician? Should drivers who are suspected of being intoxicated with medical marijuana be prosecuted? Is it reasonable for employers to ban the use of marijuana at any time by employees? [21] At present, 14 La. Rev. Stat. § 98 Louisiana law states 'The crime of operating a vehicle while intoxicated is the operating of any motor vehicle, aircraft, watercraft, vessel, or other means of conveyance when the operator is under the influence of any dangerous controlled substance or not controlled dangerous substances and which are legally obtainable with or without a prescription'. Authors believe that patients should follow the state law, that assume a specific threshold above which a person is considered to be 'under the influence' and workers who are suspected of being intoxicated with medical marijuana should be removed from the workplace immediately [21].

5. Stakeholder analysis

5.1. Industry – health care providers

Health care providers are likely to support the Louisiana legislation due to the expansion potential for treatment plans and the ability to use their judgment when making recommendations. This legislation expands the autonomy of decisions for how to treat a larger patient pool (now to include conditions listed previously) with another approach. No patient journey or treatment plan is identical to another. Adding another avenue for the healthcare provider to attempt for a larger group of patients would cause one to think the health care providers would support the more expansive legislation in this sense and the FDA/over-the-counter alternative.

Besides, this piece of legislation gives the physician the ability to recommend medical marijuana even for instances that may not be listed, therefore increasing the autonomy of developing treatment plans. This raises a connection to malpractice as the legislation allows doctors to prescribe using their best judgment. The legislation will impact the interpretation of a 'reasonable physician,' given that courts will typically hold that the liability of a physician depends on whether the chosen treatment plan would have been accepted by other physicians [22]. professional standard of care is the comparison point for a medical malpractice [17]. The legislation inherently expands on what a reasonable physician is permitted to do and what the standard of care is. These added components of the legislation could limit the possibilities malpractice suits, further demonstrating that healthcare providers would embrace this legislation.

As mentioned previously, this legislation removes an additional regulatory level between the doctor-patient relationship. The legislation amendment will now only require that a physician is licensed by and in good standing with the Louisiana State Board of Medical Examiners to recommend medical marijuana to a patient. This makes the doctor-patient relationship that much easier to establish.

Healthcare providers would be impacted immensely by both alternative approaches, mentioned in the previous section, but would likely be in support of the second alternative (FDA approval & over-the-counter access) as opposed to the first (partnering with state medical boards). As stated, physicians would be given more liberty to prescribe medical marijuana based on their clinical judgment for conditions outside the scope of the state legislature in both of the alternatives. This would mean increased access for all of the doctor's applicable patients and would support the development of proper treatment plans for a patient requiring medical marijuana.

The first alternative approach would allow for more collaboration between the state government and the medical community but would yield an increase in the doctor's susceptibility to tort laws when they prescribe medical marijuana. In regards to the second approach, making medical marijuana available over-the-counter may remove the need for patient care from a physician. Doctors may be able to focus on patient care for the population requiring more comprehensive treatment plans should medical marijuana be approved for use over-the-counter. This alternative would provide the ability for patients to seek out their treatment plan with more accessible resources without frequently having to go through a doctor. The cost of care may be lower with this alternative and health care providers would not be as concerned with reimbursement or payment options.

5.2. State government

The state government plays a key role in the expansion of marijuana use in the USA – marijuana laws currently vary by state [23]. Each state controls

multiple aspects of marijuana consumption such as, but not limited to: permitted levels of tetrahydrocannabinol (THC), how it can be ingested, amounts that can be purchased and grown, caregiver restrictions, and methods for dispensing [23]. The state government of Louisiana was in favor of this legislation enough to pass it; however, the government may be susceptible to more updates to applicable areas of law in the coming times to keep up with the growing industry.

Louisiana specifically regulates the list of qualifying conditions, possession limits, cultivation and production and dispensaries [4]. While this legislation will expand the 'prescribing freedom', other aspects of medical marijuana remain stringently regulated. As there is more demand with this legislation to produce marijuana, the need to allocate more resources, such as land, increases. The Louisiana state government maintains control of land and zoning laws that inherently affect the medical marijuana industry [23]. The Louisiana Department of Agriculture and Forestry is to oversee the production of medical marijuana [24]. Given the potential for more patients to be treated, the state government will need to continue to regulate the industry to accommodate more patients requiring access to medical marijuana.

The state government would likely not be in strong, immediate support of the first alternative approach of collaborating with the state's medical board to reduce regulatory restrictions on the prescription of medical marijuana. The Louisiana state government would need to grant full liberty to the physicians to prescribe medical marijuana to patients. The state would likely oppose this alternative only until the proper resources and additional legislation has been considered. This would require extensive collaboration with the state's medical board taking money, time and resources from the state government. Nevertheless, the state ultimately has power over the medical board. If the medical board is expanding the availability of medical marijuana to 'too many patients', it becomes a difficult legal question of revoking access to medical marijuana from pre-existing patients with the 'newly approved' conditions.

One of the main reasons the Louisiana state government would be in support of this alternative approach would be the expected increase in revenue from taxation and application/licensing fees from dispensaries [25]. Each state has legislative power over the taxation rates and administrative fees of medical marijuana. An expected 5% sales tax on medical marijuana as well as current application and or registration fees from dispensaries could increase income to the state [25].

It is plausible the Louisiana state government would be supportive of the second alternative approach – pushing for FDA approval of medical marijuana and allowing for over-the-counter availability. As in the case above, political pressures to increase access and lower costs would be a large incentive of FDA approval, but most importantly, the state government would be less susceptible to legislative specifics of the medical marijuana industry. FDA approval and access is likely to increase access more efficiently from the state's eyes as well as offer greater political feasibility by relying on a federal agency rather than partnering with the state medical board.

An inhibiting factor of this alternative approach that could sacrifice the state of Louisiana's support, would be the risk of losing the state-regulated medical marijuana taxation. The FDA's approval and over-the-counter access may put a nation-wide tax mandate and/or restriction in place that could be lower than the current revenue stream for Louisiana. The state government may ultimately prefer to keep the autonomy of taxation decisions and legislation out of federal jurisdiction.

5.3. Comparison

The most compelling stakeholder's perspective in the case of medical marijuana legislation expansion in the state of Louisiana is the health care provider. Both the health care providers and the state government would likely prefer the second alternative – the FDA approval and over-the-counter availability. There are many aspects the health care provider can relate to when analyzing the medical marijuana legislation for the state of Louisiana and as stakeholders, they are perhaps impacted the most.

The impact of the legislation on the providers is immense. The physicians are being granted more freedom to prescribe medical marijuana for conditions outside the original scope of the legislation. The state government could have control over what conditions can be treated; however, the physician is ultimately liable despite the government's rulings (whether that is through the newest legislation expansion or via alternative one). Given this 'freedom', the physician could be impacted by tort laws, as previously discussed. Authors see in the second alternative that physicians could have more structure from the FDA regarding prescribing medical marijuana, but cost risks still come into play. While the state government is at risk for regulating specific parts of the industry or allocating resources, their decisions will always ultimately impact the physician (or the patient) in the end.

Creating medical marijuana legislation requires the perspective of many parties when considering the cost. The state government's ability to tax combined with the lack of required reimbursement from insurance

providers leaves health care providers to charge a higher rate to the patient (those either with and without medical insurance). Additionally, due to the nature of prescribing medical marijuana and the lack of FDA approval, the cost to the provider is more than just what they are charging the patient for their relationship. The state government capitalizes through taxes and administrative fees as long as state jurisdiction controls the medical marijuana industry. Finally, physicians ultimately provide the care to patients given that the state governments have a large control over how patients access their care.

6. Conclusions

Any properly trained healthcare provider should have the ability to develop a treatment plan which, in their clinical judgement, they feel is in the best interest of their patient. HB819 legislation accomplishes this objective for the residents of Louisiana by providing ‘medical marijuana’ as another therapy to be used in various medical disorders. Most of the stakeholders involved may benefit from this legislation. Manufacturers of this product may experience increased profit from the increased access and availability. The government may enjoy increased tax revenue since the overall availability has increased. Healthcare providers and patients may notice an overall decreased cost and increased access to care. As a whole, this law also benefits society since it also decreases the overall demand for marijuana from those who profit from its sale through illegal means. As a result, this law may be in the best interest of most stakeholders.

Highlights

- Medical Marijuana HB819 bill in the state of Louisiana authorizes the recommendation of medical marijuana for a number of medical conditions and allows any state-licensed physician to recommend medical marijuana.
- Alternative options to this policy would include state medical board to lessen its medical marijuana regulation.
- The new legislation may allow providers to have more ‘freedom in medical marijuana treatment plans’.

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