NORML®
Working to Reform Marijuana Laws

TO: **Pennsylvania Law & Justice Committee**
FROM: **JM Pedini**
SUBJECT: **March 14, 2022 Hearing Testimony**

Good morning, Mr. Chair and members of the Committee. I am JM Pedini, the Development Director of the National Organization for the Reform of Marijuana Laws (NORML). I also serve as the Executive Director for the state affiliate chapter, Virginia NORML. In Virginia, I serve as a cannabis and cannabis policy subject matter expert to the legislature and state agencies. My work in Virginia has directly resulted in the legalization of cannabis for both medical and adult-use, the establishment of the Virginia Legislative Cannabis Caucus, and a new state agency, the Virginia Cannabis Control Authority. In 2020, I was appointed to Governor Ralph Northam's Marijuana Legalization Work Group and as Co-Chair of the Legal and Regulatory Subcommittee. Additionally, I have served on multiple medical cannabis workgroups convened by legislative authority and have contributed to multiple legislative studies on cannabis policy enactment in Virginia. It's a pleasure to be here today and I hope my experience and expertise will be valuable to the Committee as you and the General Assembly assess the Commonwealth's Medical Marijuana Program and consider the future of evidence-based cannabis policy in Pennsylvania.

Based on my experience, there are a number of common issues that impact the success of a state's medical cannabis program, particularly how effectively the program meets the needs of patients and how regulatory structure and regulator engagement can be the difference between an exceptionally successful program and a program that fails to meet consumer needs or the government's objectives.

Importance of Effective Communication Between Regulator and the Regulated Community

Perhaps one of the most critical elements of a successful legal cannabis program is how that program is regulated. In this respect, the primary considerations are (i) which governmental bodies and/or agencies are responsible for regulation; and (ii) how those entities exercise their regulatory authority.

With respect to regulating bodies, many states house their medical cannabis programs in the state department of health or similar public health agency. Often, medical cannabis is 'tacked on' to these agencies' existing responsibilities with the assumption that medical cannabis is analogous – or at least similar to – the substantive areas in which the agency involved has expertise. In most instances though, we're seeing that the public health regulator is grossly underprepared to regulate cannabis – lacking in expertise, staff, funding, and desire to regulate.

As a result, it is entirely common for this type of regulator to become frustrated in performing its regulatory functions, which can take the form of ineffective regulations, misapplication of regulations, administrative inefficiency, and the breakdown of ordinary and customary procedures. Common manifestations of the foregoing issues include adoption of regulations that are either impossible to effectuate or that fail to provide necessary points of regulation. Further, it is common for the regulator and the regulated community to ultimately become frustrated with one another, and for the regulator to eventually take an adversarial posture toward the regulated community. A review of Pennsylvania's Medical Marijuana Program suggests that the above-described situation has occurred in the Commonwealth.

Unfortunately, the stakeholder group with the most at risk – and that is harmed to the greatest extent – is patients. For example, when a regulator does not maintain a working relationship with the regulated community and its leadership does not include cannabis-specific experts on staff, as is the case in Pennsylvania, there is a heightened risk that the regulator will act (or fail to act) to control the market in some manner based on a misunderstanding of information, flawed information, or information poorly tailored to the cannabis industry. A review of Pennsylvania's Medical Marijuana Program suggests that this situation has occurred and may currently be playing out with respect to a broadly issued recall of certain inhalation products.

These types of issues can have a tremendously negative impact on patients. One of the principal problems patients face under these conditions is supply disruption. It can take several months for patient to find the right formulation and administration form to treat their condition.[1] When patients do not have access to a stable supply of the products they come to depend on, it is not uncommon for them to seek alternatives outside of the regulated market.

To this end, the Department's recent decision to recall certain products on the grounds that the terpenes in these products are not approved by the FDA for ***inhalation*** was made absent any adverse event or newly identified public health or safety hazard. Actions like this can have the effect of confusing and scaring patients, particularly when there is little or no information provided about the reason for the recall, potential health risks upon which the recall was based, or how patients should move forward.

What is of greater concern is the Department's position that the form and formulation of a cannabis medication is irrelevant to patient outcomes. As the Executive Director of Virginia NORML, the organization that represents patients in legislative and regulatory debates, I am acutely aware that formulation and administration form are absolutely important, and neither are irrelevant to a patient's treatment plan. In short, the formulation and administration form of medical cannabis are critical to positive health outcomes for patients.

Interrupting that continuity of care can have several negative consequences. For patients dealing with the seizure disorders for example, certain inhalable preparations are especially effective and are often relied upon by patients to prevent seizures. And, there is no shortage of similar examples in the context of other medical conditions.

Another notable concern with interruption to continuity of care is the added anxiety that patient experience with not having access to one's medication. Patients *rely* on these medications to help relieve their symptoms and treat their serious medical conditions. When there is a supply disruption and patients can no longer access their medication, unfortunately, some of these patients will turn to opioids, resort to illicit market cannabis, or purchase unregulated and untested synthetic marijuana products like delta-8. Each of these choices pose substantial risk to the patient's health.

These problems illustrate some of the practical issues associated with DOH's regulation of the Pennsylvania Medical Marijuana Program and the necessity of having a regulator that effectively, consistently communicates with stakeholders – especially patients – to ensure the program is in practice what the Legislature intended it to be.

I want to thank you for the opportunity to testify today. Again, I hope my perspective and expertise is valuable to the Committee, and I am happy to answer any of your questions.

---

[1] With respect to patients finding the proper formulation and administration form of medical cannabis, it is noteworthy that Pennsylvania's Program under the Department of Health has yet to approve standard dosage forms available to any other medication, in particular "chewable" products and lozenges. Resistance to approving these types of products purportedly stems from the misconception they are used only recreationally. This is simply not the case. Chewable and lozenge preparations are dispensed daily for non-cannabis medications, and for some patients, these formulations are most therapeutically appropriate.