Testimony of Deborah Miran
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Good afternoon Chairman Regan, Minority Chairman Brewster, and members of the Senate Law and Justice Committee. My name is Debby Miran and I was on the first Maryland Medical Cannabis Commission serving a 3 year term from 2013-2016. As a chemist and a 30 year regulatory affairs professional in the traditional pharmaceutical industry, I focused on building rules to establish product quality in the Maryland program not unlike what the FDA would expect. I am also a leukemia patient who benefitted from cannabis use after I experienced wasting syndrome as a result of a bone marrow transplant.

Today, I would like to highlight six key issues in my written testimony which I consider to be the most important issues facing the Office of Medical Marijuana in PA and other state regulatory bodies for that matter. In my work as a consultant post Commission, I have had the opportunity to work with regulators in 10 states and D.C. to create new programs, fix problem programs, and support the continuation of good programs. It is with this background and experience, that I offer my remarks today.

Six Key Issues

Issue 1. Access to Office and Staff

Access to the Office Director, Deputy Director, CR Director, and other key staff when the industry has issues or questions is the single biggest issue that Pennsylvania or any other state for that matter must manage. In my career, I have been on both sides meaning the regulator (MMCC commissioner) and the regulated industry (30+ years interacting with the FDA). As the regulator, especially in a new industry like medical cannabis, interaction with industry in the form of open public meetings, Q&A sessions, speaking at industry sponsored events, etc. was a learning experience that was invaluable. Often, the industry knows more than the regulators in highly technical matters of best practices in cultivation, processing, and retailing. Regulators, rather than fearing interaction with industry, should welcome open and appropriate interaction with the goal of creating the best rules for this highly regulated industry.

Issue 2. Role, Responsibility, and Makeup of Medical Advisory Board

Pennsylvania is fortunate to be a state with an advisory board to aid in the decision making process on key issues for the Office. Many states, like Maryland, don't have a board of advisors to conduct reviews and make recommendations to the Office. While the current PA advisory board largely exists to review petitions for new medical conditions, its scope could be so much broader. An ideal board would be comprised of subject matter experts, not political appointees, with a wide range of disciplines from

PhD scientists, pharmaceutical experts, medical professionals (especially trained and knowledgeable in cannabis science and therapeutics), economists, and public health policy people. As an example, the recent, massive product recall that was ordered by the Office for certain products for inhalation, could likely have been averted if the Office had access to subject matter experts to guide their decision making process.

Issue 3. Training, Experience, and Knowledge of Office Staff

Many state laws and rules require some minimum amount of training for medical providers, dispensary agents, clinical directors at dispensaries, and internal training programs at cultivation and processing facilities. Very few states, if any, require training or experience and knowledge of any aspect of medical cannabis for their staff members. Pennsylvania, like some other states require review and approval of any new products introduced in the dispensaries. I support this approach as it attempts to mimic the FDA drug approval process to assure that patients receive pure and potent medical marijuana products. In order to conduct a meaningful review of these new product applications, staff reviewers need a background in a scientific field. Additionally, the Office needs to include staff that are knowledgeable and experienced to monitor the published material and websites of permit holders regarding matters related to medical claims (eg. the recent Spotlight PA investigation regarding treatment for opiate use disorder). With the increasing availability of access to higher education in cannabis science, the Office could lead the way in hiring these recently educated graduates who are interested in public service.

Issue 4. Use of Guidance Documents to Supplement Law and Regulation

State cannabis regulators rely on a variety of ways to disseminate information to regulated industry. Obviously, there are laws and regulations that establish the framework. Beyond this, states like Maryland and Pennsylvania rely on guidance documents to add a level of detail for the industry that would be inappropriate for laws and rules. A good example, is the Maryland Technical Authority for sampling and testing cannabis flower and processed products. These guidance documents do not have the force of rule or law, but are generally accepted as the current scientific standard and accepted by industry. Review and revision of guidance documents are performed on an as needed basis with industry input in order to keep the science and technology current.

The use of Bulletins or Directives should be reserved only for emergencies or imminent human health risks when a change must be effected immediately. A good example was the 2019 EVALI crisis when the CDC determined that a carrier oil in certain vaporized products, Vitamin E Acetate, was causing serious pulmonary illnesses, including death, in some patients. A Bulletin or Directive was issued in many states requiring the removal of products containing this diluent.

Issue 5. Industry/ Office Work Groups for Information Exchange

Another very useful communication tool are ad hoc industry/ Marijuana Office work groups. This approach is sometimes used to address a specific issue that could have a

major impact on the industry. For example, in Maryland, the Commission was asked to review their position on advertising. The Executive Director at the time reached out to the trade association and asked for some industry representatives to join staff members to address this issue. After a few meetings, a mutually agreeable outcome was reached, and the ad hoc committee was disbanded. Then, when the time comes to formalize these changes in revised regulations, the industry is already on board and the public comment process proceeds much more expeditiously.

Issue 6. Eliminate List of Approved Medical Conditions

Recently, we have seen a trend in some states to eliminate the list of approved diseases and conditions. Instead, states like Maryland, New York, and Virginia have removed the lists in statue and rules and opted for physicians and other medical providers to make the decision about the appropriate medical use. In the early years of medical cannabis use, lists of approved conditions were based on some published studies, lots of anecdotes and case studies, and tradition. In the intervening decades, the rate of research and published studies has increased dramatically. A review in PubMed using the terms “cannabis” and “cannabinoids” resulted in 27,800 and 31,000 citations respectively. Universities and colleges are now offering courses and full undergraduate and masters programs in the science and therapeutics of medical cannabis. Additionally, physicians and other medical providers now have more years of experience with treating patients with a wide range of diseases and conditions. Accordingly, it makes good medical sense for the medical professionals rather than politicians to make medical decisions for our patients.

As Pennsylvania moves forward with an adult use program, the state will need a medical program that is stronger than ever. Patients, and people suffering from serious and chronic physical illnesses, as well as mental health issues, cannot be forgotten when adult use comes into force. Once when I testified in New Jersey at an adult use hearing, I raised the issue of their very anemic and underserved medical program, and someone responded, “ oh, don’t worry about the medical program, it will fix itself”. Well, we all know that nothing fixes itself. The PA medical program has a chance for a fresh start, beginning with the appointment of a new Director.

I look forward to helping this state in any way that I can, and welcome your questions.
Thank you for the time and attention.

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