#3290

Steep Hill Pennsylvania

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Independent Regulatory
Review Commission

October 17, 2022

Pennsylvania Independent Regulatory Review Commission
333 Market St, 14th Floor
Harrisburg, PA 17101
Via Electronic Mail to irrc@irrc.state.pa.us
RE: Rulemaking #10-219: Medical Marijuana IRRC #3290

Chairperson George D. Bedwick
Vice Chairperson John F. Mizner, Esq.
Commissioner John J. Soroko, Esq.
Commissioner Murray Ufberg, Esq.
Commissioner Dennis A. Watson, Esq.

Dear Commission Members:

House Health Committee:

The Honorable Kathy Rapp
150 Main Capitol
PO Box 202065
Harrisburg, PA 17120-2065

Executive Director:
Michael Siget
msiget@pahousegop.com
717260-6494

The Honorable Dan Frankel
332 Main Capitol Bldg.
PO Box 202023
Harrisburg, PA 17120-2023

Executive Director:
Erika Fricke
efricke@pahouse.net

Dear Representatives:

Senate Health and Human Services:

The Honorable Michele Brooks
Senate Box 203050
168 Main Capitol Bldg.
Harrisburg, PA 17120-3050

Executive Director
jbradbury@pasen.gov (Joan)
717-787-1322

The Honorable Arthur Haywood
Senate Box 203004
10 East Wing
Harrisburg, PA 17120-3004

Executive Director
clarissa.freeman@pasenate.com
717-787-1427

To the Commission Members of the Independent Regulatory Review Commission (IRRC),

Thank you for the opportunity to submit our Public Comments in response to the Final Form Regulations for #10-219: Medical Marijuana. Steep Hill Pennsylvania is an ISO 17025:2017 accredited laboratory conducting analytical testing as part of the Green Analytics LLC network of laboratories operating in six highly regulated cannabis markets.

Our experience in a variety of regulatory structures, in six different states, has given us insight into successful regulation in laboratory testing programs. We look forward to working with IRRC and the Department of Health to continue our mission to provide quality testing services on behalf of the patients of Pennsylvania.

Best Regards,

Andrew Rosenstein, MD
Chief Executive Officer
Steep Hill Pennsylvania

In the Final Form Regulations, the Department of Health ("DOH") has failed to respond to IRRC and commentors regarding the proposed changes to *§1171a.29 Testing requirements Subsection (c)(2).* IRRC reasonably expected DOH to provide adequate responses to their direct questions:

> **(1):** explain why it believes the language allows for testing of harvest batches and final product by two different approved laboratories;
>
> **(2):** provide a more detailed explanation of the specific problems it has encountered with the existing testing protocols and how testing by two different approved laboratories solves those problems; and
>
> **(3):** quantify the costs for growers/processors associated with entering into a contract with a second approved laboratory.

The DOH's response to **(1)**, "why it believes the language allows for testing by multiple laboratories," states that Act 44 of 2021 specifically revised section 704 from "A grower/processor may contract with *an* independent laboratory" to "*one or more* independent laboratories." DOH's response only underscores its misinterpretation of the Act. Act 44 provides a clear legislative intent to offer a "one laboratory system". Any deviation toward a compulsory "two laboratory system" violates Section 704 of the Act in an unjustified overreach of regulatory influence and power.

In their response to **(2)**, DOH has failed to respond at all to IRRC and commentors. DOH was asked directly to "provide any specific problems that it has encountered with the existing testing protocols" yet was unable to comply. They comment on vague patient "allegations" but do not cite to any specific examples or how they have investigated these alleged allegations. The bottom-line is that DOH provides **no direct evidence** from investigation and **no due diligence** to support the allegations. The DOH even admits in its response to IRRC and commentors that the Pennsylvania Medical Program has not experienced widespread corruption,

> *"...the commentators correctly point out that Pennsylvania's medical marijuana program has not seen widespread corruption in the testing of medical marijuana." – Pennsylvania Department of Health Final Regulations, June 2022.*

Several months ago, our team presented DOH with a Freedom Of Information Act (FOIA) request for any information surrounding Pennsylvania medical marijuana laboratory generated data. DOH provided no documentation, or correspondence, about the above request.

DOH has **the burden of proof** to show that the change in regulation improves protection of the public health safety and welfare. **DOH has unequivocally failed to prove there is a need** to change the regulation in the interest of public safety. We request that IRRC strongly consider what is truly behind this regulatory change when clearly it is not patient safety or the protection of public welfare.

The proposed "two lab system" as a Regulatory vehicle is unclear, ill-conceived, and presents an unreasonable marketplace disruption. There is **no mechanism described** for how a "two lab system" would protect the patients and regulate the testing industry. **There are no consequences or processes**, stated or otherwise, **that will ensure that this system will have any regulatory effect**. There is no evidence that a required addition of a second approved laboratory will improve the existing testing

process. The existing testing structure has been effective and DOH has been unable to provide any evidence to the contrary.

The two lab proposal is without justification, experience, research, or data support. One "piece of data" the DOH does provide is an opinion-based non-peer reviewed article that does not draw any connections to Pennsylvania's program. Countering DOH's intentions, when read thoroughly the article contradicts DOH's position. The article expressively encourages **regulators to be in constant review of the laboratory data** and **provide regular proficiency tests**, ideas that were previously provided to the Department by several commentors,

> *"There's a simple way to keep Pot labs honest, just look at their data. McRae said state regulators should pour over lab data to spot fraudsters" – fivethirtyeights.com*
>
> *"[In] The strictest lab regulations in the country... Pot labs face regular proficiency tests and the state requires labs to collect two samples for every test and then hold a reserve sample, which is used to investigate complaints." – fivethirtyeight.com*

Nowhere does the article support a "two lab system". What is clear from the article is that DOH needs to take an active role in laboratory regulation and oversight. Inexplicably, DOH has knowingly given up its legislatively conveyed responsibility to the labs permitting them to essentially "regulate themselves". DOH needs to regulate and not abdicate its responsibility to safeguard patients in Pennsylvania. DOH **must not** be allowed to pass on their regulatory responsibility to the very labs that they are responsible for regulating.

Even with the additional time taken to resubmit these regulations, the DOH's only additional support for this feckless regulation was to use a frivolous lawsuit filed in Arkansas. That suit had not been adjudicated and has since been withdrawn by the very plaintiffs that filed. The lawsuit was dismissed on October 13th, 2022. This inexplicable lack of proper due diligence should make the patients and stake holders of Pennsylvania concerned and demand the DOH rescind the "two lab" system.

Finally, **of critical importance**, the harvest lots and process lots represent different stages of production. One is an in-process good, while the other is a finished good ready for dispensary sale and the patients of Pennsylvania. The comparison of test results representing different stages of production as a regulatory measure is unthinkable. These results cannot be used as a "check and balances" and suggesting that they should only highlights ignorance of how Pennsylvania's medical marijuana system functionally operates.

In the Department of Health's response to **(3)**, they cavalierly dismiss the economic effects of this proposed change by stating that the labs can adjust their prices. Even though asked, **DOH provides no evidence** that it has done financial audits for small businesses, any understanding of the financial impact on the laboratories, or determined the full scope of the impact of the growers and processors having to change internal processes, re-contract, and to reconcile contradictory results. DOH has not studied or produced any analysis on how these costs to growers/processors might be passed onto patients. The cumulative impact of these multiple issues financially far outweighs the minimal cost of the DOH actively regulating the laboratories within the current rules. The IRRC must recognize the DOH proposed regulation disadvantages **small businesses and patients** in Pennsylvania by adding to their regulatory cost burden without any corresponding articulated benefit.

There is a much less costly and intrusive method of achieving the goals of protecting patient safety. DOH should accept its responsibility to the patients of Pennsylvania and regulate the laboratories themselves. This could be done inexpensively by hiring several staff members with expertise, or through training existing staff members. In other active medical marijuana programs the state makes the laboratories pay for third-party audits that the state witnesses which removes much of the cost to the state. There is no regulatory need for a "two lab" system considering the **many low-cost alternatives** which involves basic regulatory attention by DOH.

Given that the source of the proposed regulation did not come from scientific evidence, reported patient adverse events, actual examples of laboratory failures, or any economic justifications, it begs the question, where did the Department come up with this regulation that only serves to benefit a handful of unsuccessful laboratories. How is it that DOH asserts a regulation that strips the business away from successful state-of-the-art scientifically based laboratories and hands that business to laboratories who are not successful because they lack the attributes to achieve success.

In summary, DOH has unequivocally failed to respond to the IRRC request and commentators to justify this regulatory change. DOH was unable to provide evidence of how this change benefits public safety health and welfare. The proposed "two lab system" is unclear, unreasonable, and disruptive. The proposal will financially strain the small businesses of Pennsylvania. We insist IRRC reject this proposed regulation and urge DOH to adopt their responsibility to regulate the laboratories participating in the Pennsylvania Medical Marijuana program. The ensuing chaos resulting from this ill-conceived change will have profound consequences, many unintended ramifications, and disruptions. The severity of this decision will send shockwaves through the performance of the program. The state has the responsibility to reject this proposal. DOH must start over in their attempt to update the Pennsylvania Medical Marijuana regulations. Moving forward with these regulations, including this profound misstep by the DOH, is not an acceptable pathway.