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Independent Regulatory
Review Commission

Steep Hill Pennsylvania

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
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The Honorable Dan Frankel
332 Main Capitol Bldg.
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Executive Director:
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Dear Representatives:

Senate Health and Human Services:

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

Executive Director
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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.

With over five years of accredited testing experience in Pennsylvania and other states, we have developed a comprehensive understanding into successful laboratory testing practices and regulation in the cannabis industry. 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,

Dr. Daniel Niesen
Laboratory Director
Steep Hill Pennsylvania

We have **many concerns** regarding the proposed final laboratory regulations and their intended implementation. Several pieces of critical testing information have been omitted or inconsistently applied which could threaten patient safety and render the proposed regulations ineffective. In addition to what is otherwise absent or incomplete, the proposed regulations as written are not reflective of, nor supported by, the operation of the current system. Given the uncertainty attached in reviewing an incomplete regulatory submission with a direct impact on patient safety we respectfully request that IRRC disapprove the final form regulations, or in the alternative, return them to the DOH for reconsideration and resubmission.

1. *Guidance* Clarifications:

We ask that DOH provide clarification on how the *"Guidance for Quality Testing and Sampling for Approved Laboratories"* (Issued: Jan 2018, Updated: August 2018) ("*Guidance*"), will continue to fit within the program. The *Guidance* was issued as an updated response to the original 2016 §1171 Temporary Regulations, making key clarifications to the testing program. The *Guidance* provided information on definitions, batch sizes, testing analyte requirements, safety acceptance limits for contaminants, and stability testing requirements. The 2018 *Guidance* has led the state's approved laboratories and DOH over the last 4 years but is unclear what DOH's intentions are for this keystone piece of regulatory documentation. In pertinent part, the Department stated:

> "*Per concern from IRRC regarding the incorporation of the laboratory guidance into the regulations as an Appendix to be updated by publication of periodic notices in the Pennsylvania Bulletin,* ***the Department on final-form incorporated testing methods and standards into this rulemaking.***" (§1171a.27 comments, page 64)

> "*One commentator requested clarification to multiple sections found within tables of the previously proposed laboratory guidance attached in the appendix of the originally submitted final-form rulemaking. The Department takes no action in response to these comments as the tables are no longer included as part of the annex and* ***the standards to be followed are incorporated into this chapter.***" (§1171a.28 comments, page 65)

2. Omissions:

While some information from the *Guidance* was adopted by DOH for the final regulations, several pieces of critical information has been omitted. DOH's unclear and incomplete adoption of the *Guidance* leaves a large gap in the laboratory regulations. DOH failed to include batch sizes, testing analyte requirements, safety acceptance limits for contaminants, and stability testing requirements in its final regulations submitted to IRRC. As proposed, DOH's regulations are incomplete:

- Without clear batch weights, the Department allows for increased risk to patient safety;
- There are no listed analytes for solvent, pesticide, or terpene testing. Without a standard, the state-approved laboratories will be left to choose their own patient safety standards; and
- There are no listed acceptance maximums for the listed contaminants, leaving state-approved laboratories to choose their own patient safety standards.

3. Inconsistencies:

In addition to what is absent in the final regulations from the *Guidance*, what DOH has provided in chapter §1171 is inconsistent and unsupported by the current system:

- §1171a.29(c)(3) describes the minimum testing on **any test sample**. As written all test samples, even a "Research and Development" (RnD) sample, would require a large testing package.

- In §1171a.31(e)(1), The Department specifically requires conformity testing with the use of "*conforms to the approved chemical profile of the strain for the following compounds: (i) THC. (ii) THCA. (iii) CBD. (iv) CBDA. (v) CBC. (vi) CBN (vii) THCV. (viii) CBDV. (ix) CBG. (x) D8.*". Conformance testing is testing to see if a product meets the requirements of a standard or specification. The requirements or criteria for conformance must be specified in the standard or specification. There are no 'approved chemical profiles' for strains.
- §1171a.31(e)(2) testing requirements are inconsistent with the *Guidance. P. aeruginosa, Aspergillus spp.*, and *S. aureus* are new and would be unsupported by the current seed-to-sale system (ie. MJ Freeway).
- §1171a.31(e)(2) also asks for a foreign material (hair, insects) inspection. This evaluation is not within the current *Guidance* and is currently not supported by MJFreeway.
- Current *Guidance* supported testing involves "Bile Tolerant Gram-Negative Bacteria" on all harvest batches or lots, and process lots. This test has not been included in the final regulations.
- §1171a.31(e)(2)(iv) describes testing products to see if they are "*within the specification for the strain for the characteristics of: (A) Odor, (B) Appearance, (C) Fineness...*" Much like the chemical profiles mentioned previously, there are no specifications or any applicable acceptability parameters for these characteristics. Additionally, these are not required testing under the current *Guidance.*
- §1171a.35 lists the information required for a compliant test result upload to MJFreeway, however the system is not currently designed to accept many of these new information fields. Examples of this are:

  "(1) The unique sample identification number the approved laboratory assigns to the sample...

  (3) The employee identification number of the employee of the approved laboratory who identified and collected the sample at the request of the grower/processor.

  (4) The date and time the sample was collected from the grower/processor.

  (5) The date and time the sample was received by the approved laboratory...

  (7) The condition of the sample when it was received by the approved laboratory.

  (8) A description of each test performed,

  (9) The results from the certificate of analysis under §1171a.31 (relating to test results and reporting)...

  (10) The date the testing results were provided to the grower/processor..."

In addition to the reporting requirements in §1171a.35, MJFreeway currently does not support critical commentary from the Department. DOH makes several statements that daily users of the system know to be untrue. We believe these statements to be unsupported:

> "*One commentator asserted that the system does not provide a way or section to insert the information in (3), (4), and (5).* ***The Department verified with MJ Freeway that the system does allow for entry of this information.***" (§1171a.35 comments, page 72)

> *"The commentators' concerns cannot occur as a* ***grower/processor must designate the nature of the sample—research and development or harvest/process—prior to receiving the results from the approved laboratory****. As this prevents grower/processors from adjusting the purpose of the test after receiving results, the Department takes no action in response to this comment."* (§1171a.31 comments, page 68)

> *"§1171a.29 Testing Requirements (c)(2): An approved laboratory other than the that tested the harvest batch or harvest lot* ***shall test samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.***"

The confusion continues regarding new legislation which requires that stability sample eligibility be "*determined by the seed-to-sale system.*" **MJFreeway remains unable to provide this capability.**

Additionally, MJFreeway is unable to support stability sample and RnD test reporting. DOH has quietly acknowledged this in §1171a.35 (b)(1) by having these test results reported via email. The system is not designed to make selections for testing destination (RnD vs Compliance) or even what tests are being ordered.

Finally, it should be noted that the 2018 *Guidance* claims applicability to §1171.27, §1171.29, and §1171.30. It is critically not for §1171.31 "*Test Results and Reporting*", where DOH lists the required testing. Since the beginning of the program there has been a direct conflict between the two lists of required testing: The 2018 *Guidance* and §1171.31. MJFreeway has always been built to support the 2018 *Guidance* listed testing requirements and contamination limits. During the promulgation of these regulations DOH had an opportunity to correct the inconsistencies but has failed to do so.

The testing performed by state-approved laboratories is meant to support a high quality, efficient and compliant medical marijuana program for commonwealth residents with serious medical conditions. As currently proposed, ***the final regulations are incomplete and inconsistent.*** The absence of critical components of the *Guidance* in the final regulations remove the necessary safeguards for the Pennsylvania patients. On this basis, we urge IRRC to dismiss the final form regulations and return them to the DOH for resubmission at a later date.