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Senate of Pennsylvania

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June 9, 2021

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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
Proposed Permanent Regulation 28 Pa. Code § 1171a.29(c)

Dear sirs:

In my capacity as a member of the Senate of Pennsylvania, I have reviewed this section of the proposed regulations and I respectfully submit these comments to the Pennsylvania Independent Regulatory Review Commission regarding proposed permanent regulation 28 Pa. Code § 1171a.29(c).

Under the current temporary regulation, growers are free to contract with laboratories which they find to be the most accurate, efficient, cost-beneficial, and geographically convenient for the purpose of testing both their harvest samples as well as their finished product samples (the two phases for which testing is required). Under the proposed permanent regulation, medical marijuana grower/processors will be required to test their harvest lots using one permitted laboratory and a different laboratory to test the finished products. This new regulation constitutes a significant change to our medical marijuana testing protocol, which historically has allowed grower/processors to select testing labs based on merit and value.

The current temporary regulations have resulted in extremely low rates of unacceptable medicine, which is presumably why the Department of Health has offered no evidence that the current testing protocol is insufficient. The Department's stated justification for the change—"checks and balances in the testing process"— is vague, unrelated to the process of

manufacturing safe medical marijuana, and, moreover, undermines the very criteria used by growers to select the most appropriate labs to test their products. The Department's reliance on two separate labs to test two completely different products at two different phases of the process provides no such claimed check or balance. In fact, this new rule is likely to create many more problems. ISO17025, the standard that the Department requires laboratories to meet under 28 Pa. Code 1171, ensures only that laboratories use certain quality management systems, not that laboratories use the same methods or that these different methods produce consistent results. Two laboratories holding ISO17025 accreditation could test the same process lot but produce drastically different results because they may use different methods to conduct their tests. Such discrepancy in testing fails to provide the consistent feedback growers need in order to adjust growing practices to produce the safest medicine.

Given the proposed regulation's lack of any clear benefit to the safety of patients, I have four specific concerns: it violates the enabling act; it was not intended by the legislature when Act 16 was enacted; it is unreasonable, given its drastic negative impact on patients and business with no discernable benefit; and it will directly harm small businesses and their employees.

The Regulation Violates Act 16

Act 16 requires grower/processors to "contract with *an* independent laboratory to test the medical marijuana produced by the grower/processor." By requiring that grower/processors contract with at least two labs, the Department's new regulation would go beyond the Act.

The Regulation Violates Legislative Intent

The General Assembly properly delegated policymaking authority over medical marijuana testing labs to the Department. Rather than regulating labs to ensure the accuracy of their results as the General Assembly intended, the Department's new regulation abdicates its authority to regulate labs to *other labs* by requiring growers to ship processed product to a different lab than the plant material. Testing two different products at two very different stages does not create checks and balances; it creates inconsistent and unreliable results.

This is particularly troubling because the Department already has the power under Act 16 and the Department's own temporary regulations to conduct proficiency testing on labs to determine whether they accurately conduct tests. Despite the General Assembly granting this authority to the Department, the Department has failed to test its labs for proficiency and accuracy.

The Regulation is Unreasonable

The new regulation is unreasonable because it offers no discernable benefit to patients but will increase the price that patients must pay for medical marijuana for three reasons: 1) by eliminating volume discounts for testing, 2) by creating a wave of expensive litigation over existing contracts, and 3) by forcing destruction of medical marijuana products due to faulty results.

Grower/processors enjoy low testing costs because they have contracts with labs based on the volume of testing. The Department's new regulation will prohibit grower/processors from doing their testing at a single lab, which eliminates grower/processors' ability to commit to volume

testing at a single, preferred lab. This will force grower/processors to pay more for the same testing volume, a cost increase that will trickle down to patients.

Further, grower/processors negotiate those contracts for a pre-determined number of tests and select a lab based on quality, accuracy, efficiency and discounts. Those existing contracts will be substantially impaired by the new regulation, leading to expensive litigation and, again, increased costs.

Finally, under the current regulation, grower/processors can select a lab based on merit, which is important because the quality of PA's seven approved labs varies, especially when it comes to the testing of specific products. The new regulation may force grower/processors to use labs that have less familiarity with a specific product. DOH will require destruction of failed process lots regardless of the accuracy of the labs results for harvest lots, which will decrease supply in an already tight retail market.

The Regulation Will Harm Small Businesses and Their Employees

PA's seven approved marijuana testing labs are all small businesses. They are an integral part of the medical marijuana program in that they are the key to providing patients with safe medicine. Pennsylvania labs are also stable employers that offer hourly wages in excess of $14/hour, plus health benefits. Two of these facilities are located within my district. The proposed regulation will unnecessarily deprive some labs of current, ongoing business while giving that same business to other labs. Further, the regulation interferes with grower/processors' freedom to choose and contract with the best labs for them. This will penalize the small businesses that have innovated the most and worked the hardest to provide the best value to industry stakeholders.

The current testing regulations are intended to ensure that patients receive safe and effective medicine at the lowest possible price. That is why, as Acting Secretary of Health Allison Beam recently said, our Commonwealth's medical marijuana program is among the most successful in the United States. The proposed regulation would undermine all of that success for no discernable benefit.

Thank you for taking the time to consider my comments. Please do not hesitate to reach out if you have any questions.

Sincerely,

John DiSanto
District 15
Senate of Pennsylvania

cc: Honorable Michele Brooks, Majority Chair, Senate Health & Human Services Committee
Honorable Art Haywood, Minority Chair, Senate Health & Human Services Committee