IN THE COMMONWEALTH COURT OF PENNSYLVANIA

No. ___ MD 2023

GREEN ANALYTICS NORTH, LLC D/B/A STEEP HILL PA, HANGING GARDENS, LLC, PENNSYLVANIA MEDICAL SOLUTIONS, LLC, CURALEAF PA, LLC, AES COMPASSIONATE CARE, LLC, STANDARD FARMS, LLC and PAREA BIOSCIENCES, LLC,

***Petitioners*,**

v.

PENNSYLVANIA DEPARTMENT OF HEALTH,

***Respondent*.**

BRIEF IN SUPPORT OF PETITIONERS' APPLICATION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Petitioners Green Analytics North, LLC d/b/a Steep Hill PA ("Green Analytics"), Hanging Gardens, LLC ("Hanging Gardens"), Pennsylvania Medical Solutions, LLC ("PAMS"), Curaleaf PA, LLC ("Curaleaf"), AES Compassionate Care, LLC ("AES"), Standard Farms, LLC ("Standard Farms") and Parea Bioscience, LLC ("Parea") seek a preliminary injunction against the Department of Health ("DOH") relating to its recently promulgated regulation at 28 Pa. Code § 1171a.29(c)(1)-(2) that requires medical marijuana grower/processors to use two different, independent approved testing laboratories to comply with their testing obligations under Section 704(a) of the Medical Marijuana Act, 35 P.S. § 10231.1101, *et seq.* (the "Act"), as amended by the Act of June 30, 2021, P.L. 210, No. 44 ("Act 44").

As explained *infra*, DOH's new requirement that medical marijuana grower/processors use at least two separate and independent testing labs ("Labs") to comply with the two-phase testing mandated by Section 704(a) of the Act (the "2-Lab Requirement") is unlawful for reasons that support Petitioners request to enjoin the 2-Lab Requirement during the pendency of this lawsuit. If the 2-Lab Requirement is permitted to go into effect, Petitioners and other stakeholders in the industry will immediately suffer millions of dollars in irreparable harm, which will

ultimately result in substantial harm to patients in Pennsylvania who rely on medical marijuana for treatment.

First, the 2-Lab Requirement violates the plain language of the Act, directly thwarts the General Assembly's intent, and will not achieve its intended purposes. By amending Section 704(a) through Act 44, the General Assembly declined to adopt DOH's proposed 2-Lab Requirement and, instead, codified statutory language enabling grower/processers to contract with "one ***or*** more independent laboratories" to comply with Section 704(a)'s testing requirements. Despite a swell of criticism, objections, and even concerns from the Commissioners themselves, the Independent Regulatory Review Commission ("IRRC") was forced to approve DOH's regulations with the 2-Law Requirement, because IRRC was not permitted to sever the improvident 2-Lab Requirement from the remainder of DOH's regulations.

Second, the 2-Lab Requirement violates Article 2, Section 1 of the Pennsylvania Constitution by attempting to establish a peer-to-peer regulatory scheme that unconstitutionally delegates DOH's responsibility and authority to regulate testing under the Act to private Labs in competition with each other under the guise of creating a system of "checks and balances." Rather than serve its intended purpose of establishing "checks and balances," the testing requirements imposed under Section 1171a.29(c) will cause loss of product inventory, delay in getting medical products to patients who rely on them, reduction of volume

discounts critical to keeping prices low for patients, and the potential loss of additional laboratory services that not only create operational efficiencies for growers and processors but also provide additional safeguards for patients that go well beyond DOH's minimum statutory requirements. The 2-Lab Requirement harms, not helps, all stakeholders including and most importantly, patients.

Third, the 2-Lab Requirement violates the right to contract under Article 1, Section 10 of the United States Constitution and Article 1, Section 17 of the Pennsylvania Constitution by interfering in Petitioners' existing business relationships without any significant or legitimate purpose for doing so. If permitted, the 2-Lab Requirement will result in the immediate loss of millions of dollars in revenue to Green Analytics and will substantially increase the operational costs to Hanging Gardens, PAMS, Curaleaf, AES, Standard Farms, and Parea, forcing them to use alternative and less experienced Labs.

DOH concedes there were no actual harms for which the 2-Lab Requirement is intended to address and, therefore, the issuance of the injunction will not cause any harm to DOH or the public interest because it is narrowly tailored to reinstate the testing requirements as they existed immediately prior to the promulgation of the 2-Lab Requirement. Accordingly, Petitioners respectfully request relief in the form of a preliminary injunction enjoining the enforcement of the 2-Lab Requirement during the pendency of this lawsuit

PRELIMINARY INJUNCTION STANDARD

The purpose of a preliminary injunction is to preserve the status quo and prevent imminent and irreparable harm that may occur before the merits of the case can be heard and resolved. *Nether Providence Twp. v. Coletta,* 133 A.3d 86, 91 (Pa. Cmwlth. 2016). Trial courts are afforded broad discretion in granting a preliminary injunction. *Commonwealth v. Schall*, 297 A.2d 190 (Pa. Cmwlth. 1972).

The party seeking a prohibitive preliminary injunction has the burden to establish irreparable harm and a clear right to relief, but because a preliminary injunction is, by its nature, temporary, "it is obvious that the 'clear right' requirement is not intended to mandate that one seeking a preliminary injunction establish his or her claim absolutely." *Fischer v. Dep't of Publ. Welfare*, 439 A.2d 1172, 1174 (Pa. 1982). Instead, "an injunction may properly be granted where substantial legal questions must be resolved to determine the rights of the respective parties." *Id*. In addition to showing it has a clear right to relief by demonstrating substantial legal questions, the party seeking a preliminary injunction must show the injunction is necessary to prevent immediate and irreparable harm that cannot be compensated adequately by damages; a greater injury resulting from refusing rather than granting the injunction, and, concomitantly, that issuance of an injunction will not substantially harm other interested parties; the injunction will properly restore parties to the status immediately prior to the alleged wrongful conduct; the injunction

is reasonably suited to abate the offending activity; and the injunction will not harm the public interest. *SEIU Healthcare Pa. v. Com*., 104 A.3d 495, 502 (Pa. 2014) (internal citations omitted).

STATEMENT OF THE QUESTIONS INVOLVED

1. Do Petitioners have a clear right to relief where DOH exceeded its statutory authority in promulgating its 2-Lab Requirement contravening the unambiguous express language of the Medical Marijuana Act, abdicating its regulatory oversight of testing laboratories to the private testing laboratories themselves, and substantially impairing Petitioners' existing and valid contracts and business relationships?

2. Will Petitioners suffer immediate and irreparable harm that cannot be adequately compensated by damages absent an injunction where Petitioners' business relationships and contracts will be immediately and negatively impacted resulting in millions of dollars in lost revenue, lost products, increased operational costs, diminished volume discounts and lost resources; where the 2-Lab Requirement contradicts the plain language of the Medical Marijuana Act; where products will be stuck in limbo pending disposition of the inevitable conflicts between laboratories; and where such violates both the United States and Pennsylvania Constitutions?

3. Will greater injury result from denying, rather than granting, the injunction where Petitioners will immediately and significantly lose millions of dollars of revenue, lose significant volume discounts, and experience an increase in the costs of producing medical marijuana, passed on to patients through higher prices, in order to comply with the 2-Lab Requirement?

4. Will an injunction properly restore parties to their status immediately prior to the promulgation of DOH's 2-Lab Requirement where Petitioners will continue to comply with the Medical Marijuana Act's mandatory testing requirements as they have, without any reported issues since the inception of the program, over five years ago?

5. Is Petitioners' requested relief reasonably suited to abate the offending activity which is the implementation and enforcement of the new 2-Lab Requirement that requires a grower/processor to use two different testing laboratories to complete the required testing at two completely different product production stages where no scientific, logistical, or health justifications exist for such an imposition?

6. Will delaying implementation of the 2-Lab Requirement and reverting back to the testing scheme that has been in place and been effective since the inception of the program while this court evaluates the legality of the 2-Lab Requirement harm the public interest?

STATEMENT OF THE CASE

Procedural History

Petitioners initiated this action on, March 4, 2023 by filing a Petition for Review seeking declaratory and injunctive (preliminary and permanent) relief against the implementation of DOH's newly promulgated regulation at 28 Pa. Code §1171a.29(c)(1)-(2) that requires medical marijuana grower/processors to use two completely different testing laboratories to comply with the Medical Marijuana Act's[1] (Act) mandated two lab testing requirements (2-Lab Requirement). Petitioners seek a permanent injunction preventing enforcement of the 2-Lab Requirement and concurrently seek a preliminary injunction pending resolution of the legality of the 2-Lab Requirement on the merits.

Contemporaneously with filing their Petition for Review, Petitioners filed an Application for Special Relief in the Nature of an *Ex Parte* Preliminary Injunction and an Application for Special Relief in the Nature of a Preliminary Injunction. This brief is filed in support of Petitioners' Applications.

The Medical Marijuana Act

In 2016, the Act was enacted and created a regulated industry to produce, sell, and consume medical marijuana treatments. The Act provides that DOH is the agency tasked with implementing, regulating, and enforcing the Commonwealth's

[1] Act of April 17, 2016, P.L. 84, No. 16, 35 P.S. §10231.101, *et seq*.

medical marijuana program as to grower/processors, dispensaries, practitioners, and laboratories. 35 P.S. §10231.301(a). Relevant portions of Section 301 of the Act specifically provide,

> (a) **Establishment.--**A medical marijuana program for patients suffering from serious medical conditions is established. The program shall be implemented and administered by the department. The department shall:
>
> …
>
> (3) Have regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana in this Commonwealth.
>
> (4) Establish and maintain an electronic database to include activities and information relating to medical marijuana organizations, certifications and identification cards issued, practitioner registration and electronic tracking of all medical marijuana as required under this act to include:
>
> …
>
> (iv) Monitoring all growth, transfer, possession, processing, testing and dispensing of medical marijuana in this Commonwealth.

35 P.S. §10231.301(a).

The General Assembly tasked DOH with creating the medical marijuana program and regulating the entities within it to ensure the medicines are safe for patients. 35 P.S. §10231.704. The Act requires that testing occur at two phases of the production process: at harvest and at final processing. *Id*. As enacted in 2016, Section 704 provided,

> A grower/processor shall contract with an independent laboratory to test the medical marijuana produced by the

> grower/processor. The department shall approve the laboratory and require that the laboratory report testing results in a manner as the department shall determine, including requiring a test at harvest and a test at final processing. The possession by a laboratory of medical marijuana shall be a lawful use.

Former 35 P.S. §10231.704.

As initially enacted, Section 704(a) required all grower/processors, including, but not limited to Hanging Gardens, PAMS, Curaleaf, AES, Standard Farms, and Parea (collectively the "Grower/Processor Petitioners") to contract with "an" independent Lab, such as Green Analytics, to conduct testing at both the harvest and final production testing stages. The Act requires that each testing relationship between a grower/processor and a Lab be memorialized in a written contract. 35 P.S. §10231.704.

DOH's Temporary Regulations

Pursuant to the Act, in June 2016, DOH promulgated temporary regulations at 28 Pa. Code §1131.1, *et seq*. (Temporary Regulations). DOH's Temporary Regulations followed the Act for Lab testing requirements. *Id*. In 2018, DOH created and provided to all approved laboratories, the "Office of Medical Marijuana Guidance for Quality Testing and Sampling by Approved Laboratories (Lab Guidance)."[2] Under the Temporary Regulations and the Lab Guidance, and since

[2] Available at https://www.health.pa.gov/topics/Documents/Programs/Medical%20Marijuana/20

the inception of the medical marijuana program more than six years ago, grower/processors entered into contracts with an approved Lab for the two testing stages.

DOH's Permanent Regulations and Act 44

On February 16, 2021, ahead of the expiration of its temporary regulations, DOH submitted to the Pennsylvania General Assembly and IRRC its Notice of Proposed Rulemaking – DOH's proposed permanent regulations. *See* PFR Exh. 2. On March 6, 2021, DOH published its proposed permanent regulations in the *Pennsylvania Bulletin*.

During the public comment period, DOH and IRRC received a plethora of comments highlighting problems with DOH's proposed 2-Lab Requirement, including from State Senator John DiSanto. *See*, PFR, ¶52; *see also* PFR Exh. 4. Among Senator DiSanto's many criticisms of the 2-Lab Requirement, he expressed concerns that having two different Labs perform tests on products at different phases of the manufacturing process (once as a flower and once as a finished product) would not ensure the consistency and accuracy that DOH seeks:

> 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.

18.8.10%20MM%20-%20Updated%20Guidance%20for%20Quality%20Testing%20and%20Sampling%20by%20Approved%20Laboratories.pdf (last accessed March 3, 2023).

> 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.

PFR Exh. 4 at 2.

In DOH's proposed 2-Lab Requirement, it proposed to *require* grower/processors to use two separate Labs: one to conduct testing at harvest and a different Lab to test final products. PFR Exh. 2 at 151 (§1171a.29(c)(1)-(2) Specifically, as initially proposed, DOH's 2-Lab Requirement provides,

> (c) Testing shall be performed as follows:
>
> (1) An approved laboratory shall test samples from a harvest batch or harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product.
>
> (2) An approved laboratory other than the one 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.

28 Pa. Code §1171a.29(c)(1)-(2).

Four months later, the General Assembly amended the Act resulting in the passage of the Act of June 30, 2021, P.L. 201, No. 44 (Act 44). Despite having full knowledge of DOH's desire to mandate that grower/processors use two separate Labs (one at each stage of production), the General Assembly amended the Act to

allow for a grower/processor to use "one or more" Labs to test the medical marijuana it produced – just as had been the case since the inception of the program. Specifically, Section 704 of the Act was amended as part of Act 44 to its current version which reads,

> (a) **General testing**.--A grower/processor shall contract with **one or more independent laboratories** to test the medical marijuana produced by the grower/processor. The department shall approve **a** laboratory **under this subsection** and require that the laboratory report testing results in a manner as the department shall determine, including requiring a test at harvest and a test at final processing. The possession by a laboratory of medical marijuana shall be a lawful use.

35 P.S. §10231.704(a) (emphasis added to indicate Act 44's amended text).

Importantly, absent from Act 44's amendment is the inclusion of DOH's proposed 2-Lab Requirement. The General Assembly was aware of DOH's proposed 2-Lab Requirement at the time of Act 44's amendment, yet specifically declined to codify it. Instead, Section 704 expressly codified grower/processors' right to use "*one* or more" Labs to complete testing at both harvest and final processing. 35 P.S. §10231.704(a) (emphasis added). The General Assembly gave grower/processors, not DOH, the flexibility to use one or more laboratories and reinforced the single Lab testing at both phases by adding that DOH shall approve "a" Lab for both testing phases.

DOH's Disregard of the General Assembly's Intent in Act 44

Despite the General Assembly's clear message that the Act would continue to provide grower/processors, not DOH, with the ability to contract "with one or more" Lab for their testing requirements, on September 19, 2022, DOH re-submitted to IRRC its Notice of Final Rulemaking which still proposed to implement the 2-Lab Requirement (Final Rulemaking). PFR Exh. 7.

In its Final Rulemaking, DOH continued to assert that the 2-Lab Requirement creates "checks and balances"[3] and protects against inflated THC results which have plagued other state's medical marijuana programs but which DOH acknowledged has not been a problem in the Commonwealth. PFR Exh. 7 at 65-66. DOH failed to answer any of IRRC's questions, including to: (1) explain why [DOH] believes the language of Section 704 of the Act 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. *Id.* In response to criticism that the 2-Lab Requirement would increase costs to grower/processors as well as

[3] *See* Declaration of Deborah Miran appended to Petitioners' App for PI as Appendix 1 wherein she states the 2-Lab Requirement will fail to provide "checks and balances" and will not protect against the imagined problem of collusion.

patients, DOH summarily, and without any support, concluded "[a]s such, there should be no increase in operating costs" and "[h]owever, since all permittees will have to comply with the new requirement to use different labs, it is expected that labs will adjust their pricing accordingly." *Id*. at 66.

Following DOH's re-submission of its Final Rulemaking, numerous public comments were again filed by both industry stakeholders and laboratory experts and elected officials objecting to DOH's continued push for the 2-Lab Requirement. In fact, eight members from the House Health Committee, that had just recently declined to codify the 2-Lab Requirement in Act 44's amendments submitted a letter to IRRC expressing their concerns with DOH's regulation. *See*, PFR, ¶70; *see also* PFR Exh. 8. Specifically, these elected officials stated that they were "concerned that this creates an undue burden on a nascent industry that goes against the plain language of the statute as enacted by the General Assembly" and that DOH "has not provided sufficient reasons why it has changed the testing requirements from the temporary regulations…". *Id*. at Exh. 8.

On October 20, 2022, despite extensive, persuasive, and compelling on-the-record criticisms and reservations concerning the 2-Lab Requirement, IRRC—which was bound under the enabling statute to either approve or reject DOH's proposed regulations in their entirety and could not have carved the 2-Lab Requirement out from the remainder of the regulations—approved DOH's Final

Rulemaking because, as Chairman Bedwick stated, "[o]verall, I just feel it's in the public interest that some permanent regulation get into place rather than continuing along with temporary regulations."[4] PFR Exh. 9 at 90:2-4. However, Commissioner Soroko expressed his concerns on the 2-Lab Requirement stating:

> I'm a little concerned that you're out somewhere in thin air with that two separate testing lab requirement and the justification for it speaks to language that I'm not sure is best interpreted the way you [DOH] would need to interpret it to find the Act 44 basis for regulation with respect to two testing labs."

PFR Exh. 9 at 24:12-16.

Commissioner Soroko also inquired of DOH "where do I look to find the authority [in the Act] that requires a different lab to be used at each [testing stage]." *Id.* at 83:10-11. DOH did not and could not respond to that question. During the vote, Commissioner Soroko expressed his concerns and reservations about the 2-Lab Requirement and Chairman Bedwick spoke directly to DOH that he "would just emphasize on what Commissioner Soroko has said, and on [the 2-Lab Requirement] issue, I would urge you to please work with the regulated community to try and arrive at something that everyone believes [in]." *Id.* at 94:1-4. DOH, however, has declined to follow this recommendation.

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[4] IRRC's meeting was recorded and can be found on IRRC's public website at http://www.irrc.state.pa.us/meetings/ (last accessed March 3, 2023).

DOH's newly promulgated regulations do not include how the 2-Lab Requirement will be implemented or how to reconcile the inevitable discrepancies that will occur when 2 different labs with different processes, using different equipment, and different personnel obtain two different results for products at two very different phases of the manufacturing process: harvest and final products. *See*, 28 Pa. Code §1171a.29(c)(1)-(2).

No other state in the country has adopted a two-lab system. Miran Declaration, §11.

SUMMARY OF THE ARGUMENT

Petitioners meet the requirements for a preliminary injunction. Petitioners have a clear right to relief because DOH, in promulgating a regulation that conflicts with its enabling statute, abdicates its regulatory role, unjustifiably interferes with contracts and ongoing business relationships, and causes negative impacts on patients, erred as a matter of law in several ways. DOH's 2-Lab Requirement would have exceeded its statutory authority even before the Act was amended by Act 44. However, the General Assembly, while fully aware of DOH's desire to implement the 2-Lab Requirement, nonetheless amended the Act to further provide the authority for grower/processors to select "one or more Labs" to perform both phases of the testing requirements. The General Assembly's language choice and DOH's decision to ignore it only serves to brighten the line that DOH has crossed in violating the instructions given to it by the General Assembly. Furthermore, by justifying its 2-Lab Requirement as a "check and balance on Labs", DOH is abdicating its regulatory role. It is not for competitors to place a check and balance on one another, but rather, it is the mandate of the Act that DOH regulate the Labs.

The General Assembly purposefully amended the Act to add that grower/processors "shall contract with one or more independent laboratories" to test the medical marijuana produced.[5] In its promulgation of its unlawful regulation,

[5] Act of June 30, 2021, P.L. 210, No. 44, 35 P.S. § 10231.704, *as amended*.

DOH has mandated the loss of a substantial portion of Petitioner Green Analytics' contract revenue and erased Grower-Processor Petitioners' ability to select with whom they want to engage in business to achieve critical cost savings, accurate testing results, and volume discounts. This curtailment violates both the United States and Pennsylvania Constitutions' Contract Clauses. This is especially egregious given DOH's admission that there is no problem in Pennsylvania for which this 2-Lab Requirement is necessary and that no cost impact study was performed to determine the effect of the 2-Lab Requirement on grower/processors. In the truest American spirit, for the past six-plus years grower/processor were permitted to select the Lab that had the highest accuracy, fastest services, and best prices during which time there have been no documented problems with the testing process. As Senator DiSanto stated in his letter to IRRC, the temporary regulations "have resulted in extremely low rates of unacceptable medicine" and that DOH's stated justification for promulgating the 2-Lab Requirement "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." PFR Exh. 4. With the implementation of the 2-Lab Requirement and with no justification, Grower-Processor Petitioners will be forced to use Labs not of their choosing, and high-quality Labs, like Petitioner Green Analytics, will be mandated to lose a substantial part of their business.

First, absent a preliminary injunction Petitioners will suffer immediate and irreparable harm that cannot be adequately compensated by damages. High caliber Labs who have garnered market share by providing quality services to grower/processors for both phases of testing (harvest and final product) will lose significant revenue as their grower/processor customers are forced to use other Labs for a portion of their testing needs. Grower/processors who take advantage of economic efficiencies in using the same Lab for both stages of testing will lose this cost-savings advantage. Grower/processors who have carefully vetted and relied on specific Labs who perform at the highest technical levels will be forced to use unvetted Labs that may not even have the requisite personnel, equipment, or expertise to test a specific product. Grower/processors who have painstakingly vetted all the Labs to determine which Lab is appropriate for their products will be forced to immediately use another unvetted-Lab. In such a competitive state as Pennsylvania, grower/processors are rightfully concerned that a single misstep by an unvetted Lab could force grower/processors to: (1) destroy products that actually meet or exceed regulatory standards; (2) redirect material to the wrong medical marijuana products based on inaccurate THC levels due to human error or equipment calibration issues at harvest; or (3) reformulate processed products or retest them (a third time); all of which would cost millions of dollars in damages to the product or grower/processor's brand identity. Additionally, patients will experience higher

prices as volume discounts are erased and products are caught in the inevitable discrepancies between two different Lab results (rotting or going stale) as the 2-Lab Requirement provides no means of reconciliation.

Petitioners will suffer significant immediate and ongoing financial losses in the amount of millions of dollars that cannot be recouped due to sovereign immunity limitations. Petitioners will also suffer *per se* harm as DOH's 2-Lab Requirement exceeds DOH's authority under the Act and constitutes violations under both the United States and Pennsylvania Constitutions.

Second, greater injury will result from refusing, rather than granting, a preliminary injunction. Denying a preliminary injunction will result in Petitioners immediately sustaining a substantial amount of lost business, millions of dollars in lost revenue, increased costs and loss of volume discounts while granting a preliminary injunction will still allow the testing mandated by the Act to be implemented as it has been successfully performed for the last six years.

Third, a preliminary injunction will properly restore the parties to their status immediately prior to the promulgation of DOH's 2-Lab Requirement by enabling Grower-Processor Petitioners to continue to use a single Lab to comply with the Act's testing mandate, which is in the best interests of Pennsylvania medical marijuana patients.

Fourth, the requested relief – to enjoin Section 1171a.29(c)(1)-(2) only – is reasonably suited and narrowly tailored to abate the offending activity, the enforcement of the unlawful 2-Lab Requirement.

Finally, the public interest will not be harmed by halting the implementation of the 2-Lab Requirement and proceeding under the required testing practices, established more than six years ago, while the Court evaluates the legality of DOH's 2-Lab Requirement.

ARGUMENT

I. Petitioners Have A Clear Right To Relief Because DOH's 2-Lab Requirement Is Unlawful And Unconstitutional

a. DOH exceeded its statutory authority in promulgating the 2-Lab Requirement

As the IRRC Commissioners pointed out at the October 20, 2022 public hearing, if the legislature wanted to allow for the 2-Lab Requirement, the legislature could have amended the Act to just say "two" instead, as Commissioner Soroko succinctly pointed out, "looking at the language, you need to base your regulations on, 'one or more' is hard to equate that with two because better language would have said 'two or more' or 'more than one'". PFR. Exh 9 at 23:23-24—24:1-2.

Petitioners respectfully ask the Court to do what the IRRC Commissioners felt they could not, sever the offending 2-Lab Requirement from the other DOH regulations and disapprove the 2-Lab Requirement because it goes beyond the authority expressly granted in the Act.

Section 704(a) expressly prohibits the 2-Lab Requirement and no other sections of the Act confer such authority upon DOH to impose its 2-Lab Requirement. 35 P.S. §§10231.101—2110. Legislative intent is best expressed through the plain language of the statute; the inquiry of whether DOH exceeded its statutory powers begins with the Act's plain text. *See*, 1 Pa. C.S. § 1921(a); *Commonwealth. v. Brown*, 981 A.2d 893, 897 (Pa. 2009) ("The General Assembly's

intent is best expressed through the plain language of the statute."). On its face, the first sentence of Section 704(a) makes clear that, to comply with the Act's testing mandates at both the harvest and final processing, grower/processors "shall contract with *one* or more" Labs. 35 P.S. §10231.704(a) (emphasis added). The first sentence literally protects the ability of "grower/processors" to use "one" Lab to comply with the Act's testing requirements. *Id*. The text of the second sentence in Section 704(a) further reinforces the General Assembly's intent in allowing grower/processors to use a single lab to complete testing at both stages, which provides "[t]he department shall approve *a laboratory* under this subsection and require that *the laboratory* …" *Id*. (emphasis added).

Inherent in these first two sentences of Section 704(a) is the General Assembly's contemplation that a grower/processor could fulfill its testing obligations with a single Lab. In the first instance, the Act provides that grower/processors may contract with a single Lab; in the second instance, the General Assembly describes the mandatory testing in the singular "a laboratory" and "the laboratory". The only coherent reading of Section 704(a) is that grower/processors are *required* to contract with one Lab, as has always been the case, but that at the grower/processor's option, under Act 44's amendments, it may now contract with additional Labs. Act 44 simply enshrines the ability of a grower/processor to use one or more than one Lab as has been customary through

the first six-plus years of the medical marijuana program but does not require grower/processors to use two. To interpret this section as requiring grower/processors to use two Labs renders the legislature's deployment of the word "one" superfluous and consequently yields a non-sensical result.

The plain text of Section 704(a) makes clear that DOH's new regulation has no footing in the Act and therefore is unlawful. *Aetna Cas. & Sur. Co. v. Com., Ins. Dep't.*, 638 A.2d 194, 200 (Pa. 1994) ("An administrative agency can only exercise those powers which have been conferred upon it by the Legislature in clear and unmistakable language.") (internal quotations and citation omitted).

Although Section 704(a) is unambiguous in authorizing grower/processors to use a single Lab to satisfy the Act's testing requirements and therefore no statutory analysis is needed to ascertain the intent of the legislature, a statutory analysis confirms that the 2-Lab Requirement is unlawful. *See*, 1 Pa. C.S. §1921; *see also*, *A.S. v. Pa. State Police*, 143 A.3d 896, 903 (Pa. 2016) ("It is only when statutory text is determined to be ambiguous that we may go beyond the text and look to other considerations to discern legislative intent.").

DOH first publicly proposed its 2-Lab Requirement in February 2021; the General Assembly amended the Act four months later in June 2021. The General Assembly had full knowledge of DOH's desire for the 2-Lab Requirement yet, far from codifying DOH's proposed scheme, the General Assembly chose to amend the

Act to make clear that one laboratory would suffice for both testing phases. *See*, PFR Exh. 2. The significance of this is that the General Assembly was aware of DOH's desire to implement its new 2-Lab Requirement prior to amending Section 704. PFR, ¶¶50—52. In fact, on June 9, 2021, twenty-one days prior to enactment of Act 44, Senator DiSanto submitted a public comment to IRRC questioning the validity and rational for DOH's 2-Lab Requirement. *Id*. at ¶52. Senator DiSanto stated that the temporary regulations "have resulted in extremely low rates of unacceptable medicine" and that DOH's stated justification for promulgating the 2-Lab Requirement "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." PFR Exh. 4. Senator DiSanto further explained that the 2-Lab Requirement would provide contrary results than what DOH wanted, which is causing more problems than solving them by way of Labs yielding two different results because of utilizing different testing methods. *Id.* Having full knowledge of DOH's desire to implement its 2-Lab Requirement, the General Assembly, instead of codifying it, amended Section 704(a) in a way that specifically precludes the implementation of the mandatory 2-Lab Requirement. *See*, 1 Pa. C.S. §1921(c)(2) (considering "[t]he circumstances under which [the statute] was enacted"). The General Assembly was aware of DOH's 2-Lab Requirement and rejected it, instead opting for language that preserves a grower/processors' right to

use a single Lab and simultaneously prohibits a requirement that it use two Labs to complete the mandatory testing requirements. Accordingly, Petitioners have raised a substantial legal question with respect to Count I of its Petition for Review.

b. DOH's 2-Lab Requirement abdicates regulatory oversight of the Labs to private entities in violation of the Act and the Pennsylvania Constitution

Under the 2-Lab Requirement, DOH effectively abdicates its regulatory responsibility over the Labs and, instead, asks competing Labs to regulate themselves in contravention of the Act and in violation of Article II, Section 1 of the Pennsylvania Constitution. The legislature created the medical marijuana program and deemed that the "program shall be implemented and administered by the department" and defined the "department" as the "Department of Health of the Commonwealth". 35 P.S. § 10231.103. Specifically, DOH is entrusted to "[h]ave regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana in this Commonwealth." *Id*. at §10231.301(a)(3). Because DOH is the agency charged with implementing and administering the medical marijuana program which includes the "regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana in this Commonwealth", 35 P.S. § 10231.301(a)(3), it is necessarily charged with regulating the Labs. *See MERSCORP, Inc. v. Delaware Cnty.,* 207 A.3d 855, 884 (Pa. 2019) ("an agency of the government is invested with the implied authority necessary to the effectuation

of its express mandates.") (internal citations omitted). *See also, Pa. Dep't of Envt'l. Res. v. Butler Cnty. Mushroom Farm*, 454 A.2d 1, 4 (Pa. 1982) ("We begin with the well settled principle that the power and authority to be exercised by administrative agencies must be conferred by the legislature. The powers and authority must be either expressly conferred or given by necessary implication.") (internal citations omitted). Indeed, the Act makes this clear by requiring DOH to "approve a laboratory … *and require that the laboratory report testing results in a manner as the [DOH] shall determine, including requiring a test at harvest and a test at final processing*." 35 P.S. §10231.704(a) (emphasis added). Moreover, Section 301 of the Act expressly requires DOH to "monitor[ ] all growth, transfer, possession, processing, *testing* and dispensing of medical marijuana in this Commonwealth." 35 P.S. §10231.301(a)(4)(iv) (emphasis added). The Act establishes the medical marijuana program and requires DOH to administer it giving DOH very specific guidelines which includes the regulatory authority to effectuate these responsibilities. For the Act to confer exclusive jurisdiction to DOH but limit DOH's ability to regulate the Labs such that delegation of Lab oversight would be necessary or permissible would yield an absurd result. 1 Pa. C.S. §1922(1); *see also*, *Koken v. Reliance Ins. Co*., 893 A.2d 70, 81 (Pa. 2006) (explaining that when ascertaining the intent of the General Assembly, courts are to presume that the General Assembly did not intend for an absurd result).

Pursuant to the Act, DOH is responsible for regulating the Labs. But, in its promulgation of its 2-Lab Requirement, DOH cedes this responsibility to the Labs themselves—this delegation of responsibility is not consistent with the Act and is in violation of the Pennsylvania Constitution. Pa. CONST. Art. II, §1 (Non-Delegation Clause); *Hetherington v. McHale*, 329 A.2d 250, 253 (Pa. 1974) ("governmental powers cannot be delegated to private individuals or organizations."). With the 2-Lab Requirement, DOH abdicates its regulatory responsibility over the Labs and instead places that responsibility in the hands of private competing entities – something no other state does.

Any agency tasked with regulating medical marijuana should know and expect that testing results at harvest (a plant) will be decidedly different from test results at final product processing (e.g. pills, tinctures, vape oil, creams, and suppositories) because of the highly refined manufacturing processes harvested marijuana is subjected to during the manufacturing process. PFR, ¶87. DOH's regulation at § 1171a.29(c)(1)-(2) fails to account for this expected discrepancy and as a result, DOH, whether intentionally or not, delegates to the Labs the responsibility of determining the consequences of the vastly different test results that will be produced between the harvest testing and final process testing. DOH has provided no guidance on what should occur when THC, cannabidiol (CBD), terpene, heavy metals, microbial levels, or hundreds of other elements tested are different at

the two different testing stages nor could it since there is no relevant regulatory or scientific process through which this reconciliation can occur.

The purported impetus for its 2-Lab Requirement is to create "checks and balances" in the testing process and to prevent against the non-existent problem of Labs inflating THC results. PFR Exh. 7 at 65, 66. But the reality is that §1171a.29(c)(1)-(2) accomplishes neither and is, instead, a solution in search of a problem. DOH admitted this in its response to IRRC's substantial inquiries, stating that "Pennsylvania's medical marijuana program has not seen wide-spread corruption in the testing of medical marijuana" but the "Department is proactively insulating the program from such issues." *Id.* at 66. The 2-Lab Requirement creates a testing scheme that compares apples to oranges and leaves the establishment of the standards, reconciliation of disparate results, as well as the mechanics, interpretation, and enforcement of those results to private entities in violation of the Non-Delegation Clause of the Pennsylvania Constitution. Accordingly, Petitioners have raised a substantial legal question with respect to Count II of its Petition for Review.

c. DOH's 2-Lab Requirement violates the contract clause of both the United States and Pennsylvania Constitutions

The 2-Lab Requirement substantially impairs Petitioners' existing contracts and business relationships in violation of both the United States and Pennsylvania Constitutions. *South Union Twp. v. Commonwealth*, 839 A.2d 1179, 1188 (Pa.

Cmwlth. 2003), *affirmed*, 854 A.2d 476 (Pa. 2004) (holding that the test for an unconstitutional impairment of a contract is the same under both the United States and Pennsylvania Constitutions). Petitioners have existing contracts and long-standing business relationships whereby Grower-Processor Petitioners use a single Lab to conduct both harvest and final product testing on some or most of their products and the 2-Lab Requirement artificially curtails those existing relationships by half as well as the contractual relationships Petitioner Green Analytics has with other grower/processors.

"The severity of an impairment of contractual obligations can be measured by the factors that reflect the high value the Framers placed on the protection of private contracts … [and so] once arranged, those rights and obligations are binding under the law and the parties are entitled to rely on them." *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 245 (1978). Thus, "[a]ny law which enlarges, abridges, or in any manner changes the intention of the parties as evidenced by their contract … impairs its obligation. *Beaver Cnty. Bldg. & Loan Ass'n v. Winowich*, 187 A. 481, 492 (Pa. 1936). Here, Petitioners entered into their testing services contracts and cultivated long-standing business relationships with the intention of Petitioner Green Analytics conducting all of the harvest and final product testing for some of the Grower-Processor Petitioners. DOH's 2-Lab Requirement now prohibits the Petitioners from carrying out this intention and from entering into similar

agreements in the future. The impairment is substantial in that it will immediately cut the volume of testing in half for Green Analytics and will cost Grower-Processor Petitioners millions of dollars in increased costs, lost revenues, lost products, lost volume discounts, increased shipping costs, and lost resources. Perhaps more importantly, the harm from these operational inefficiencies, though substantially detrimental to Petitioners, will also be borne by patients who rely on affordable medical marijuana to treat their serious health conditions. One such patient has expressed his concerns that the 2-Lab Requirement will have a negative impact on several factors, including product supply, consistency, safety, and pricing. *See*, PFR, Exh. 15.

The impairment on Petitioners' existing contractual relationships is not justified because it does not remedy "a broad and general social or economic problem." *Energy Reserves Group, Inc. v. Kansas Power & Light Co*., 459 U.S. 400, 411—412 (1983); *South Union Twp*., 839 A.2d 1179, 1188 (Pa. Cmwlth. 2003) (same). DOH itself concedes that there are no current problems that the 2-Lab Requirement has been enacted to remedy. In fact, the 2-Lab Requirement is more likely to cause substantial problems than to solve them. The impairment imposed by the 2-Lab Requirement is not based upon reasonable conditions nor does it serve any public purpose. *South Union Twp*., 839 A.2d at 1188. Accordingly, Petitioners have raised a substantial legal question with respect to Count III of its Petition for Review.

II. DOH's 2-Lab Requirement Is Causing Petitioners Immediate And Irreparable Harm

Petitioners are being immediately and irreparably harmed and, unless the 2-Lab Requirement is enjoined, that harm will continue pending resolution of Petitioners' underlying petition for review. Over the last six-plus years of the Pennsylvania medical marijuana program Petitioner Green Analytics has invested millions of dollars in state-of-the-art equipment, cutting-edge technology, employing highly educated Ph.D. scientists, and other infrastructure in order to garner the business from the majority of grower/processors in Pennsylvania. For years, Petitioner Green Analytics has exclusively conducted mandatory testing, at both required testing phases, for certain types of medicine produced by Petitioners PAMS, Curaleaf and AES, but under the 2-Lab Requirement Petitioners PAMS, Curaleaf and AES will be required to source fifty percent (50%) of its mandatory testing to a different Lab; for Petitioner Green Analytics, which has exclusive testing relationships with over 20 different grower/processors, this same scenario will play out for each of the contracts and business relationships. Petitioner Green Analytics calculates that its immediate damages total approximately $8,000,000 in net losses in the first year.[6] However, once the 2-Lab Requirement is implemented and

[6] *See* Declaration of Joseph Estabrook appended to Petitioners' App. for PI as Appendix 2.

Petitioner Green Analytics' services for any one grower/processor are capped at one mandatory test, it will never be able to regain its revenue numbers that existed prior to the 2-Lab Requirement and, in that sense, the harm is not only immediate and irreparable but also on-going. Additionally, Petitioners will suffer irreparable harm as a result of a lack of any recourse against DOH because state agencies are immune from suit under sovereign immunity. *See Stackhouse v. Pa. State Police*, 892 A.2d 54, 58 (Pa. Cmwlth. 2006) (explaining that the "Commonwealth and its agencies, officials and employees acting within the scope of their duties are immune from suits for damages"); *Marcellus Shale Coalition v. Dep't of Envt'l. Prot.,* 185 A.3d 985 (Pa. 2018) (affirming that the immediate and irreparable harm requirement had been met when petitioners suffered damages but would be unable to seek said damages due to the state agency enjoying sovereign immunity).

Grower-Processor Petitioners also suffer immediate and irreparable harm as a result of the 2-Lab Requirement because their freedom to contract with their desired Lab is severely impaired. For example, Petitioners, PAMS, Curaleaf and AES selected Petitioner Green Analytics as their exclusive Lab for certain products because of its experience, quality, consistency, speed, and reliability. Now the 2-Lab Requirement compels Grower-Processor Petitioners to utilize another Lab which may be qualitatively inferior or logistically more expensive. As the testimony will show, this causes quantifiable harm in at least two distinct ways. First, as a result of

Grower-Processor Petitioners exclusively using Green Analytics for its mandatory testing, Grower-Processor Petitioners were provided with volume discount pricing. If Grower-Processor Petitioners are no longer able to use Green Analytics for all the testing it currently performs, the discount in pricing will either be rescinded or decreased commensurate with the volume of testing. Second, the 2-Lab Requirement will require Grower-Processor Petitioners to expend time and resources in vetting, selecting, and contracting with another Lab to complete the half of the mandatory testing that may no longer be completed by Green Analytics.[7] Because each non-employee entering a grower/processor facility must be chaperoned by an employee of grower/processor, the 2-Lab Requirement will double the labor expense associated with this activity. In addition to these certain monetary harms, Grower-Processor Petitioners face additional harm in that the immediate effectiveness of the 2-Lab Requirement with absolutely no guidance as to how it will be implemented, how to comply with inventory requirements while also coming into compliance with this new regulation, and what the consequences are for differing test results between the two testing phases threatens to leave a significant quantity of medical marijuana

[7] In addition to any safety concerns among patients that may arise due to separate Labs conducting half of the state's product testing, any increase in costs to grower/processors, which will occur as a result of the 2-Lab Requirement due to vanishing or reduced testing volume discounts and costs associated with the use of a second Lab, will ultimately be borne by the patients. *See*, PFR ¶¶101, 109; PFR Exh. 15.

in limbo deteriorating and rotting until DOH addresses these flaws in its new regulation.

Petitioners also suffer *per se* harm because DOH's 2-Lab Requirement violates the Act and is unconstitutional. *SEIU Healthcare Pa. v. Com*., 104 A.3d at 508 (irreparable harm occurs "where the offending conduct sought to be restrained through a preliminary injunction violates a statutory mandate"); *Unified Sportsmen of Pa. v. Pa. Game Comm'n.*, 950 A.2d 1120 (Pa. Cmwlth. 2008) (finding the Game Commission's failure to fulfill its statutory obligations constitutes *per se* irreparable harm); *Com. ex rel. Corbett v. Snyder*, 977 A.2d 28 (Pa.Cmwlth. 2009) (concluding irreparable harm had occurred and that preliminary injunction was justified when there was a violation of the Consumer Protection Law); *Fischer v. Dep't of Publ. Welfare*, 439 A.2d 1172 (Pa. 1982) (finding irreparable harm and affirming the issuance of a preliminary injunction where constitutional violations are alleged). Here, the 2-Lab Requirement violates the Act and both Art. I, §17 and Art. II, §1 of the Pennsylvania Constitution as well as Art. I, §10 of the United States Constitution by substantially impairing Petitioners' existing contracts and violating the Non-Delegation clause of the Pennsylvania Constitution. Because these harms are immediate, irreparable, and cannot be compensated adequately at law, Petitioners are entitled to a preliminary injunction. *Fischer v. Dep't of Publ. Welfare*, 439 A.2d 1172, 1174 (Pa. 1982).

III. Not Issuing Petitioners An Injunction Will Cause More Harm Than If One Is Issued

Greater harm will befall Petitioners and the patients in the medical marijuana program if DOH's 2-Lab Requirement is permitted to be enforced than if an injunction is granted. DOH's stated reason for the 2-Lab Requirement is to protect against Labs inflating THC levels, an issue DOH concedes has not been an issue in Pennsylvania since the program's inception. PFR, ¶69. It is a solution in search of a problem. But, for the reasons explained *supra* and as will be detailed at the hearing, the 2-Lab Requirement offers no protection against this phantom problem but instead will create issues that have the potential to undermine the integrity of the medical marijuana program.

If the 2-Lab Requirement is not preliminarily enjoined, then Petitioners and patients will be immediately and severely harmed. The industry will be dramatically and possibly irrevocably changed if the Grower-Processor Petitioners that utilize and have relied on Green Analytics for their testing needs at both the harvest and final product phases are required to enter into a binding contract and utilize a second-choice and possibly an inferior Lab to complete half of its testing. Petitioners will also lose a significant amount of revenue. Grower-Processor Petitioners may lose significant amounts of medical marijuana to deterioration while DOH attempts to reconcile the irreconcilable differences between the two different Labs. Patients too

will be harmed. Increased costs in testing associated with using two different Labs and on the loss of volume discount pricing will assuredly be passed through to patients; patients may also see increased costs if a bottleneck in production occurs because DOH has not provided details on how the 2-Lab Requirement is to be implemented or differences reconciled. But even more fundamentally, Petitioner Green Analytics is preferred by many grower/processors for good reasons: because of its experience, R&D services, enhanced safety protocols, state-of-the-art equipment, advanced scientific methods, and experienced Ph.D personnel that yield consistent, accurate, fast, and reliable results. If grower/processors are forced to use Labs with less experience, inferior equipment, and less stringent protocols, questions of testing reliability and product safety emerge with medically vulnerable patients at risk.

IV. Issuing An Injunction Will Restore The Status Quo

Granting an injunction to suspend the application and enforcement of the 2-Lab Requirement pending a final resolution on its legality will restore the status quo that existed prior to DOH's regulation having taken effect. *Ambrogi v. Reber*, 932 A.2d 969, 979 (Pa. Super. 2007) ("the relevant standard requires that an injunction must address the status quo as it existed between the parties before the event that gave rise to the lawsuit, not to the situation as it existed after the alleged conduct but before entry of the injunction") (internal citation omitted). The status quo –

permitting grower/processors to use one or more Labs to comply with the Act's mandatory testing regimen – is lawful, desirable, and has been used for over six years without issue. DOH has acknowledged the impetus of its new regulation is to protect against a non-existent problem. *See*, PFR Exh. 7 at 66. Enjoining the 2-Lab Requirement will simply return Pennsylvania's medical marijuana testing protocols to the status quo of the past six-plus years. Granting Petitioners' injunction restores medical marijuana testing to its last lawful status prior to the 2-Lab Requirement taking effect while the legality of the 2-Lab Requirement is determined.

V. The Injunction Is Narrowly Tailored To Abate Petitioners' Harms

Granting Petitioners' application for a preliminary injunction is narrowly tailored to abate the harm pending final adjudication of Petitioners' complaint. *SEIU*, 104 A.3d at 509. Petitioners are seeking only to enjoin DOH from enforcing its 2-Lab Requirement pending resolution of Petitioners' claims. Petitioners are not challenging the entirety of DOH's regulations, but rather they are challenging only Section 1171a.29(c)(1)-(2) insofar as it requires that grower/processors use two or more Labs to comply with the Act's testing requirements. To further clarify, Petitioners are not challenging the Act's requirement to conduct testing at both the harvest and final product phases, only the Department's implementation of that statutory requirement, which overturns the testing procedures that have been in place

for the last six-plus years and thus it is narrowly tailored to abate DOH's unlawful testing requirements.

VI. Issuing An Injunction Is In The Public Interest

A preliminary injunction is in the public interest. Petitioners raise substantial legal challenges to DOH's 2-Lab Requirement and are likely to succeed on those claims. DOH's imposition of its new and unlawful regulation that significantly alters the testing mandates that have been in place, without incident, since the program's inception to combat a phantom problem is not in the public interest. *See*, *SEIU supra* (affirming the issuance of a preliminary injunction because maintaining the status quo protects the public pending the court's final decision on whether the Commonwealth's actions were unlawful). Imposing a preliminary injunction will enable Petitioners and similarly situated industry stakeholders to continue operating in accordance with existing medical marijuana testing contracts to best serve Pennsylvania patients while a determination as to the legality of the 2-Lab Requirement is considered by this Court and whether its imposition is in the public interest. And given that DOH admits that there is no current problem with medical marijuana testing, it is in the public interest to carry on the testing scheme which has kept the medical marijuana program free from problems for the last six-plus years while this Court determines whether the 2-Lab Requirement is beyond the DOH's

statutory authority, is an abdication of its regulatory responsibility, and violates both the U.S. and Pennsylvania Constitutions.

CONCLUSION

WHEREFORE, for the reasons stated above, Petitioners respectfully request that this Court grant their application for a preliminary injunction and enjoin DOH from applying and enforcing its 2-Lab Requirement at 28 Pa. Code §1171a.29(c)(1)-(2) pending a final decision on the merits of Petitioners' lawsuit.

Respectfully submitted,

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