

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

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,	:	No. 104 M.D. 2023
Respondent	:	Argued: May 10, 2023

BEFORE: HONORABLE RENÉE COHN JUBELIRER, President Judge  
HONORABLE PATRICIA A. McCULLOUGH, Judge  
HONORABLE ANNE E. COVEY, Judge  
HONORABLE MICHAEL H. WOJCIK, Judge  
HONORABLE CHRISTINE FIZZANO CANNON, Judge  
HONORABLE ELLEN CEISLER, Judge  
HONORABLE STACY WALLACE, Judge

OPINION BY  
JUDGE COVEY

FILED: June 29, 2023

Before this Court are the Pennsylvania Department of Health's (Department) Application for Summary Relief, and Green Analytics North, LLC d/b/a Steep Hill PA's (Green Analytics), Hanging Gardens, LLC's, Pennsylvania Medical Solutions, LLC's, Curaleaf PA, LLC's, AES Compassionate Care, LLC's, Standard Farms, LLC's, and Parea BioSciences, LLC's (collectively, Petitioners) Application for Partial Summary Relief (Cross-Applications). There are four issues before this Court: (1) whether Petitioners' right to relief as to Count I of their Petition for Review (Declaratory Judgment - Lack of Statutory Authority) (Count I) is clear because the Department lacked the statutory authority to enact Section 1171a.29(c)(1)-(2) of the Department's Regulations, 28 Pa. Code § 1171a.29(c)(1)-

(2) (Regulation), which mandates that growers/processors use a different medical marijuana laboratory (Lab) for the harvest stage and production stage of growing and processing medical marijuana (2-Lab Requirement); (2) whether Petitioners' right to relief as to Count II of their Petition for Review (Declaratory Judgment - Improper Delegation of Authority) (Count II) is clear because the 2-Lab Requirement unconstitutionally delegates to private Labs the regulatory oversight of medical marijuana testing without any standards or protections; (3) whether Petitioners are entitled to a permanent injunction against the 2-Lab Requirement (Count V); and (4) whether Petitioners have shown that the 2-Lab Requirement amounts to a violation of the Contracts Clauses of the United States and Pennsylvania Constitutions<sup>1</sup> (Count III).<sup>2</sup>

### **Background**

Pennsylvania's medical marijuana program began in 2016 pursuant to the Medical Marijuana Act (Act).<sup>3</sup> Section 301(a)(3) of the Act states that the Department shall "[h]ave regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana in this Commonwealth." 35 P.S. § 10231.301(a)(3). Section 103 of the Act defines a "[g]rower/processor" as "[a] person, including a natural person, corporation, partnership, association, trust or other entity, or any combination thereof, which holds a permit from the Department under this [A]ct to grow and process medical marijuana." 35 P.S. § 10231.103. The

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<sup>1</sup> The Contract Clause of the United States Constitution provides, in relevant part, that "[n]o state shall enter into any . . . [l]aw impairing the [o]bligation of [c]ontracts." U.S. CONST. art. I, § 10. The Contract Clause of the Pennsylvania Constitution similarly provides that "[n]o . . . law impairing the obligation of contracts . . . shall be passed." PA. CONST. art. I, § 17.

<sup>2</sup> The parties' first two issues are the same in the Cross-Applications. Issue three herein is Petitioners' third issue, and issue four herein is the Department's third issue.

<sup>3</sup> Act of April 17, 2016, P.L. 84, *as amended*, 35 P.S. §§ 10231.101-10231.2110.

Department has issued permits to growers/processors. Petitioners Hanging Gardens, LLC, Pennsylvania Medical Solutions, LLC, Curaleaf PA, LLC, AES Compassionate Care, LLC, Standard Farms, LLC, and Parea BioSciences, LLC (collectively, Growers/Processors), have received such permits.

Former Section 704(a) of the Act required a grower/processor to contract with “**an independent laboratory** to test the medical marijuana produced by the grower/processor.” *Former* 35 P.S. §10231.704(a) (emphasis added). Green Analytics is a Department-approved Lab for medical marijuana testing and has been providing testing for both stages of growing and processing medical marijuana (harvest and processing) for several growers/processors, including some of the Growers/Processors. On June 30, 2021, the Act was amended by the Act of June 30, 2021, P.L. 210, No. 44 (Act 44). Act 44 revised Section 704(a) of the Act to mandate:

A grower/processor shall contract with **one or more independent laboratories** to test the medical marijuana produced by the grower/processor. The [D]epartment shall approve a laboratory under this subsection and require that the laboratory report testing results in a manner as the [D]epartment shall determine, including requiring a test at harvest and a test at final processing. . . .

35 P.S. § 10231.704(a) (emphasis added).

Prior to Act 44’s passage, in February 2021, the Department submitted Proposed Regulations to the Independent Regulatory Review Commission (IRRC), which included the 2-Lab Requirement, in order to create checks and balances in the testing process. The 2-Lab Requirement was located at Section 1171a.29(c)(1)-(2) of the Proposed Regulations.<sup>4</sup>

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<sup>4</sup> See [http://www.irc.state.pa.us/docs/3290/COMMENTS\\_FINAL/329007-13-22CannabisLawPA.pdf](http://www.irc.state.pa.us/docs/3290/COMMENTS_FINAL/329007-13-22CannabisLawPA.pdf) (state.pa.us) (last visited June 28, 2023).

On June 9, 2021, Pennsylvania State Senator John M. DiSanto (Senator DiSanto), by way of a formal letter to the IRRC, expressed his opposition to the proposed 2-Lab Requirement. On or about September 19, 2022, *after* the new Section 704(a) of the Act had been enacted, the Department submitted to the IRRC its proposed Final Regulations. The IRRC discussed and approved the Department's Final Regulations, including the 2-Lab Requirement, at its October 20, 2022 public meeting. The Regulations had an effective date of Saturday, March 4, 2023.

### **Facts**

On March 4, 2023, the Department's Regulations were published in the Pennsylvania Bulletin at 53 Pa. B. 1275 (March 4, 2023), including Section 1171a.29(c)(1)-(2) of the Department's Regulations, which imposes the 2-Lab Requirement, and stating therein that the new Regulations were effective immediately. On the morning of March 4, 2023, Petitioners filed a Petition for Review (Petition), an Application for Special Relief in the Nature of a Preliminary Injunction (Application for Special Relief), an Application for Special Relief in the Nature of an Ex Parte Preliminary Injunction, and a Brief in Support of Petitioners' Application for Preliminary Injunction. Later that same day, this Court granted Petitioners' Application for Special Relief in the Nature of an Ex Parte Preliminary Injunction and temporarily enjoined the Department from enforcing the 2-Lab Requirement.

On March 6, 2023, this Court held a telephone conference with the parties, during which the parties agreed that the Petitioners would withdraw their Application for Special Relief and the Department would not enforce the 2-Lab Requirement pending this Court's final order on Petitioners' Petition. On March 7, 2023, the parties filed a stipulation in this Court memorializing their agreement that

Petitioners would withdraw their Application for Special Relief, without prejudice, in consideration for the Department's agreement not to enforce the 2-Lab Requirement pending final order of this Court on all counts and that Petitioners and the Department would file cross-applications for summary relief in accordance with this Court's forthcoming scheduling order.

On March 20, 2023, the Department filed its Application for Summary Relief seeking judgment in its favor and against Petitioners, with prejudice. Also on March 20, 2023, Petitioners filed their Application for Partial Summary Relief seeking judgment for Petitioners as to Counts I, II, and V of their Petition and for this Court to order that: the Department's 2-Lab Requirement is unlawful because it exceeds the Department's authority under the Act and does not track the meaning of the statute; the Department's 2-Lab Requirement is unlawful because it violates the Act and article II, section 1 of the Pennsylvania Constitution insofar as it delegates the regulatory oversight of the Labs to private and competing third-party Labs; and the Department is permanently enjoined from applying or enforcing any aspect of the Department's 2-Lab Requirement.

### **Discussion**

Initially,

[t]his Court may grant an application for summary relief if the moving party's right to judgment is clear and no material issues of fact are in dispute. *See* Pa.R.A.P. 1532(b); *Eleven Eleven Pa., LLC v. State Bd. of Cosmetology*, 169 A.3d 141, 145 (Pa. Cmwlth. 2017). In ruling on an application for summary relief, this Court must “view the evidence of record in the light most favorable to the non-moving party and enter judgment only if there is no genuine issue as to any material facts and the right to judgment is clear as a matter of law.” *Eleven Eleven*, 169 A.3d at 145 (citation omitted).

*Cao v. Pa. State Police*, 280 A.3d 1107, 1109 (Pa. Cmwlth. 2022).

Petitioners first argue that they have a clear right to relief on Count I because the Department's 2-Lab Requirement exceeds the scope of the Department's statutory authority since neither Section 704 of the Act, nor any other Act provision authorizes the Department to mandate its 2-Lab Requirement. Petitioners contend that the Act unambiguously provides growers/processors the right to contract with **one or more Labs** for the two stages of required testing - at harvest and at final processing. Petitioners further assert that, even if Section 704(a) of the Act is found to be ambiguous (which Petitioners declare it is not), and a statutory construction analysis is required to ascertain the General Assembly's intent, the result remains the same: the Department's 2-Lab Requirement exceeds the scope of the Department's authority under the Act and does not track the language of Section 704 of the Act. In addition, Petitioners claim that the Department's interpretation of the Act yields an absurd result because the Act expressly states that growers/processors shall contract with *one or more* Labs, and the insistence of *two* Labs makes the *one* language superfluous.

The Department rejoins that Petitioners improperly focus on the first sentence of Section 704(a) of the Act, which requires growers/processors to contract with "one or more independent laboratories." 35 P.S. §10231.704(a). The Department retorts that Petitioners put great emphasis on the fact that *independent laboratory* was singular in the previous version of Section 704 of the Act and it is plural in the current version when in fact the Pennsylvania rules governing statutory construction specifically state that "[t]he singular shall include the plural, and the plural, the singular." 1 Pa.C.S. § 1902. The Department further asserts that, to the extent the change from singular to plural is considered, it actually undercuts Petitioners' position as it would indicate an intention to permit the 2-Lab

Requirement. The Department also emphasizes that Senator DiSanto had argued shortly before the statutory language change that the prior version precluded the 2-Lab Requirement because *independent laboratory* was in the singular. The Department submits that a reasonable interpretation is that the reason, or at least one of the reasons, the word was then pluralized was to allow for the 2-Lab Requirement.

The Department further proclaims that the current Act language gives it the flexibility to implement testing requirements it deems appropriate in furtherance of its obligation to regulate and enforce the growing and processing of medical marijuana. The Department insists that the fact that the Act gives it this discretion is the basis for its authority to act herein. The Department declares that, if the General Assembly wanted to limit the Department's options, the General Assembly could have chosen to so state in the Act, yet it did not, despite being aware that the Department had begun efforts to implement the 2-Lab Requirement when the General Assembly passed Act 44.

This Court has explained:

It is axiomatic that all regulations “must be consistent with the statute under which they were promulgated.” *Slippery Rock Area Sch[.] Dist[.] v. Unemployment Comp[.] [Bd.] of Rev[.]*, . . . 983 A.2d 1231, 1241 ([Pa.] 2009). “A statute is the law and trumps an administrative agency’s regulations.” [*Commonwealth v. Kerstetter*, 62 A.3d [1065,] 1069 [(Pa. Cmwlth. 2013), *aff’d*, 94 A.3d 991 (Pa. 2014)]]. Similarly, “[w]here there is a conflict between the statute and a regulation purporting to implement the provisions of that statute, the regulation must give way.” *Commonwealth v. Colonial Nissan, Inc.*, 691 A.2d 1005, 1009 (Pa. Cmwlth. 1997).

“[W]hen an agency adopts a regulation pursuant to its legislative rule-making power, as opposed to its interpretive rule-making power, it is valid and binding upon courts as a statute so long as it is (a) adopted within the agency’s granted power, (b) issued pursuant to proper procedure, and (c) reasonable.” *Tire Jockey Serv[.], Inc.*

*v. Dep[ 't] of Env[ 't] Prot[.]*, . . . 915 A.2d 1165, 1186 ([Pa.] 2007). When analyzing whether a regulation is adopted within an agency's granted power, a court should consider, *inter alia*, whether the regulation is "consistent with the enabling statute" because "clearly, **the [General Assembly] would not authorize agencies to adopt regulations inconsistent with the enabling statutes.**" *Marcellus Shale Coal[.] v. Dep[ 't] of Env[ 't] Prot[.]*, 216 A.3d 448, 459 . . . (Pa. Cmwlth. 2019) (internal quotation marks omitted). Thus, **when "a regulation presents 'an actual conflict with the statute,' we cannot reasonably understand the regulation to be within the agency's ambit of authority, and the statute must prevail."** *Id.* (quoting *AMP Inc. v. Commonwealth*, 814 A.2d 782, 786 (Pa. Cmwlth. 2002), *aff'd*, . . . 852 A.2d 1161 (Pa. 2004)).

*Victory Bank v. Commonwealth*, 219 A.3d 1236, 1242 (Pa. Cmwlth. 2019), *aff'd*, 240 A.3d 95 (Pa. 2020) (emphasis added; footnote omitted).

Section 301(a) of the Act provides, in relevant part:

**(a) Establishment.--**A medical marijuana program for patients suffering from serious medical conditions is established. **The program shall be implemented and administered by the [D]epartment. The [D]epartment shall:**

(1) Issue permits to medical marijuana organizations to authorize them to grow, process or dispense medical marijuana and ensure their compliance with this [A]ct.

(2) Register practitioners and ensure their compliance with this [A]ct.

**(3) Have regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana** in this Commonwealth.

35 P.S. § 10231.301(a) (text emphasis added).

Section 704(a) of the Act mandates:

**General testing.--**A grower/processor shall contract with **one or more independent laboratories** to test the medical marijuana produced by the grower/processor.



**The [D]epartment shall approve a laboratory under this subsection and require that the laboratory report testing results in a manner as the [D]epartment 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) (text emphasis added).

Section 1171a.29(c) of the Department's Regulations requires:

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.

(3) An approved laboratory may test other samples and test samples at the request of a grower/processor or the Department.

28 Pa. Code § 1171a.29(c) (emphasis added).

The issue before this Court is whether the Department's Regulation that mandates growers/processors to contract with one Lab for testing the harvest batch or harvest lot, and another Lab to test the medical marijuana before sale is in conflict with the Act which mandates that growers/processors contract with one or more Labs for testing.

The Pennsylvania Supreme Court has explained:

In construing a statute, a court's duty is to give effect to the legislature's intent and to give effect to all of the statute's provisions. 1 Pa.C.S. § 1921(a). The plain language of the statute is the best indicator of the legislature's intent. *Crown Castle NG E. LLC v. Pa. Pub. Util. Comm'n*, . . . 234 A.3d 665, 673-74 ([Pa.] 2020). To ascertain the plain meaning, **we consider the operative**

**statutory language in context and give words and phrases their common and approved usage.** *Id.* Courts must give effect to a clear and unambiguous statute and cannot disregard the statute’s plain meaning to implement its objectives. *Id.* “Only if the statute is ambiguous, and not explicit, do we resort to other means of discerning legislative intent.” *Matter of Priv[.] Sale of Prop. by Millcreek Twp. Sch. Dist.*, . . . 185 A.3d 282, 291 ([Pa.] 2018).

*Commonwealth v. Chesapeake Energy Corp.*, 247 A.3d 934, 942 (Pa. 2021) (emphasis added).

It is well settled that “[o]ne way to ascertain the plain meaning and ordinary usage of terms is by reference to a dictionary definition.” *In re Beyer*, . . . 115 A.3d 835, 839 ([Pa.] 2015) (citing *Commonwealth v. Hart*, . . . 28 A.3d 898, 909 ([Pa.] 2011) (explaining that “common and approved usage [of term undefined by legislature] may be ascertained by examining its dictionary definition”)).

*Commonwealth v. Coleman*, 285 A.3d 599, 608 n.4 (Pa. 2022). The word “**or**” is “**used** as a function word **to indicate an alternative[.]**”<sup>5</sup> Merriam-Webster.com. (emphasis added). Further, “**alternative**” is defined as “offering or expressing **a choice[.]**”<sup>6</sup> *Id.* (emphasis added). Thus, the plain meaning of Section 704(a) of the Act is that growers/processors may contract with *only one* Lab if they so choose. Notwithstanding, Section 1171a.29(c)(1)-(2) of the Department’s Regulations mandates growers/processors to contract with *at least two* separate Labs. Consequently, there is a conflict between the Act and the Regulation. Accordingly, because “when ‘a regulation presents ‘an actual conflict with the statute,’ . . . [] the statute must prevail[.]” this Court must conclude that the Department lacked the authority under the Act to enact Section 1171a.29(c)(1)-(2) of the Department’s

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<sup>5</sup> See <https://www.merriam-webster.com/dictionary/or> (last visited June 28, 2023).

<sup>6</sup> See <https://www.merriam-webster.com/dictionary/alternative> (last visited June 28, 2023).

Regulations. *Victory Bank*, 219 A.3d at 1242 (quoting *Marcellus Shale*, 216 A.3d at 459).

Moreover,

[a]lthough the [Department] argues that its [R]egulations reflect a reasonable interpretation of the [] Act . . . , the [Department] cannot alter the [] Act. By . . . adding requirements that the legislature did not see fit to include, the [Department] has stepped beyond its appropriate legislative mandate and into the realm of making law. Such changes amount to policy decisions that require legislative review. For these reasons, [this Court] conclude[s] that the [Department’s] [2-Lab Requirement] is unenforceable because [it] . . . conflict[s] with the [] Act.<sup>7]</sup>

*Hommrich v. Pa. Pub. Utils. Comm’n*, 231 A.3d 1027, 1040 (Pa. Cmwlth. 2020).

### Conclusion

“[V]iew[ing] the evidence of record in the light most favorable to the [Department],” as we must, *Cao*, 280 A.3d at 1109 (quoting *Eleven Eleven*, 169 A.3d at 145), this Court holds that “[Petitioners’] right to judgment is clear and no material issues of fact are in dispute.” *Id.* Accordingly, Petitioners’ Cross-Application is granted as to Count I, and this Court declares that Section 1171a.29(c)(1)-(2) of the

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<sup>7</sup> The Dissent similarly maintains that because the Act grants the Department authority to promulgate regulations with respect to growing and processing medical marijuana, and the Act repeatedly refers to patient safety, the Department has the authority to enact the 2-Lab Requirement. However, said authority cannot authorize the Department to enact regulations inconsistent with its enabling statute. See *Victory Bank*, 219 A.3d at 1242; *Marcellus Shale Coal.*, 216 A.3d at 459. Here, because Section 1171a.29(c)(1)-(2) of the Department’s Regulations clearly conflicts with the plain language of Section 704(a) of the Act, the Act “must prevail.” *Victory Bank*, 219 A.3d at 1242 (quoting *Marcellus Shale Coal.*, 216 A.3d at 459).

Department's Regulations is invalid and unenforceable.<sup>8</sup> The Department's Cross-Application is denied.

For the foregoing reasons, Judgment is entered in Petitioners' favor.

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ANNE E. COVEY, Judge

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<sup>8</sup> Given this Court's disposition of Count I of Petitioners' Petition, it need not reach the additional claims in either Cross-Application.

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

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,	:	No. 104 M.D. 2023
Respondent	:	

O R D E R

AND NOW, this 29<sup>th</sup> day of June, 2023, Green Analytics North, LLC d/b/a Steep Hill PA's, Hanging Gardens, LLC's, Pennsylvania Medical Solutions, LLC's, Curaleaf PA, LLC's, AES Compassionate Care, LLC's, Standard Farms, LLC's, and Parea BioSciences, LLC's (collectively, Petitioners) Application for Partial Summary Relief is GRANTED as to Count I, and Section 1171a.29(c)(1)-(2) of the Pennsylvania Department of Health's (Department) Regulations, 28 Pa. Code § 1171a.29(c)(1)-(2), is declared invalid and unenforceable. The Department's Application for Summary Relief is DENIED.

Judgment is entered in Petitioners' favor.

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ANNE E. COVEY, Judge

**IN THE COMMONWEALTH COURT OF PENNSYLVANIA**

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.	:	No. 104 M.D. 2023
	:	Argued: May 10, 2023
Pennsylvania Department of Health,	:	
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**BEFORE:**    **HONORABLE RENÉE COHN JUBELIRER**, President Judge  
                  **HONORABLE PATRICIA A. McCULLOUGH**, Judge  
                  **HONORABLE ANNE E. COVEY**, Judge  
                  **HONORABLE MICHAEL H. WOJCIK**, Judge  
                  **HONORABLE CHRISTINE FIZZANO CANNON**, Judge  
                  **HONORABLE ELLEN CEISLER**, Judge  
                  **HONORABLE STACY WALLACE**, Judge

**DISSENTING OPINION BY**  
**PRESIDENT JUDGE COHN JUBELIRER**

**FILED: June 29, 2023**

Respectfully, because I would find the Pennsylvania Department of Health (the Department) has the statutory authority pursuant to the Medical Marijuana Act (the Act)<sup>1</sup> to enact Section 1171a.29(c) of the Department’s Regulations, 28 Pa. Code § 1171a.29(c) (Regulation), and, specifically, the provision found in Subsection (2) thereof (“2-Lab Requirement”), mandating that each process lot sample must be tested by a different laboratory (Lab) than that which tested the

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<sup>1</sup> Act of April 17, 2016, P.L. 84, *as amended*, 35 P.S. §§ 10231.101-10231.2110.

samples from the harvest batch or harvest lot before medical marijuana may be sold or offered for sale, I must dissent from the thoughtful Majority opinion.

The salient question before us is whether the Department acted within its grant of statutory authority under the Act when it included the 2-Lab Requirement within its Regulation. To answer this question, we must begin with an analysis of the Act, mindful that “[w]hen the words of a statute are clear and free from all ambiguity, the letter of it is not to be disregarded under the pretext of pursuing its spirit.” Section 1921(b) of the Statutory Construction Act of 1972, 1 Pa.C.S. § 1921(b).

“To determine whether a regulation is adopted within an agency’s granted power, we look for statutory language authorizing the agency to promulgate the legislative rule and examine that language to determine whether the rule falls within the grant of authority.” *Hommrich v. Pa. Pub. Utils. Comm’n*, 231 A.3d 1027, 1034 (Pa. Cmwlth. 2020) (citation omitted). As part of our analysis, we consider a statute’s purpose, “its reasonable effect[,] and whether the regulation is consistent” therewith. *Id.* (internal quotation marks and citation omitted). The General Assembly would not authorize an agency to adopt a binding regulation that is “inconsistent with the applicable enabling statute.” *Id.* (internal quotation marks and citation omitted).

In some instances, the General Assembly confers broad regulatory power upon an agency. *Id.* at 1035. “If the statute makes a clear grant of authority, then neither a court nor the agency can disregard the clearly expressed intent of the General Assembly.” *Marcellus Shale Coal. v. Dep’t of Env’t Prot.*, 292 A.3d 921, 936 (Pa. 2023). Notably, legislative rules that are properly enacted are presumed to be reasonable, and reviewing courts will accord them a “particularly high measure of deference.” *Id.* at 927 (citation omitted). While this Court cannot substitute its

own judgment for that of an agency, we will defer to a regulation an agency has promulgated pursuant to its interpretative powers where the regulation is reasonable and “genuinely tracks the meaning of the underlying statute.” *Id.* at 929 (citation omitted). “[N]o deference is due where an agency exceeds its legal authority or its interpretation is clearly erroneous.” *Id.* (citations omitted).

Section 301(a)(1) of the Act establishes a medical marijuana program in the Commonwealth and requires the Department to implement and administer the program. 35 P.S. § 10231.301(a)(1). Section 301(a)(3) of the Act states, in pertinent part, that “[t]he program **shall be implemented and administered** by the [D]epartment,” which “**shall [h]ave regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana** in this Commonwealth.” 35 P.S. § 10231.301(a)(3) (emphasis added). Section 301(b) states “**Regulations.--**The [D]epartment **shall promulgate all regulations** necessary to carry out the provisions of th[e] [A]ct.” 35 P.S. § 10231.301(b) (emphasis added).

In discerning the legislative intent behind the Act, it is significant that when conferring legislative power upon the Department, the General Assembly broadly charged the Department with regulating and enforcing the Act’s provisions and required the Department to adopt “all regulations necessary to carry out” its responsibility. *Id.* Had the General Assembly wished to limit the terms by which the Department was to regulate and enforce the provisions of the Act, it could have done so. “The Legislature knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion. . . . Here, the General Assembly spoke capaciously.” *Marcellus Shale*, 292 A.3d at 944 (internal quotation marks and citation omitted).



Moreover, in Section 102(2) and (3), the “Declaration of Policy” of the Act, the General Assembly repeatedly references its concern for patient safety:

(2) **The Commonwealth is committed to patient safety. Carefully regulating the program which allows access to medical marijuana will enhance patient safety** while research into its effectiveness continues.

(3) It is the intent of the General Assembly to:

(i) Provide a program of access to medical marijuana which **balances the need of patients to have access to the latest treatments with the need to promote patient safety.**

(ii) Provide a **safe and effective method of delivery** of medical marijuana to patients.

. . . .

35 P.S. § 10231.102(2), (3) (emphasis added). Of particular import herein, Section 704(a) of the Act provides:

A grower/processor **shall** contract with **one or more independent laboratories** to test the medical marijuana produced by the grower/processor. The [D]epartment shall approve a laboratory under this subsection and require that the laboratory report testing results in a manner as the [D]epartment shall determine, including requiring a test at harvest **and** a test at final processing. . . .

35 P.S. § 10231.704(a) (emphasis added). Significantly, the prior version of the first sentence of this provision required only that a grower/processor “contract with **an independent laboratory** to test the medical marijuana produced by the grower/processor.” *Former* 35 P.S. § 10231.704(a) (effective May 17, 2016, to June 29, 2021) (emphasis added).

The Majority narrowly focuses on the term “one” in the “one or more independent laboratories” language in Section 704(a) in determining that its plain meaning permits growers/processors to contract with only one Lab if **they choose** to do so. *Green Analytics N., LLC v. Pa. Dep’t of Health*, \_\_ A.3d \_\_, \_\_ (Pa. Cmwlth., No. 104 M.D. 2023, filed June 29, 2023), slip op. at 10. However, the plain text thereof requires growers/processors to “contract with one **or more independent laboratories**” and dictates that **the Department** shall approve of the Lab as well as determine the procedure for reporting testing results “**including requiring a test at harvest and a test at final processing.**” 35 P.S. § 10231.704(a) (emphasis added). The plain language of Section 704(a) allows for both a singular laboratory and, in the alternative, multiple laboratories to be utilized in the testing process. The plain language also gives the Department the authority to approve a Lab, determine the reporting procedure, and require a test at both harvest and final processing of the medical marijuana. This language evinces that the General Assembly authorized the Department to implement testing requirements through more than one Lab as the Department may deem appropriate in furtherance of the stated obligation and broad authority the Act grants to the Department to regulate and enforce the cultivating and processing of marijuana in the Commonwealth. *See* 35 P.S. § 10231.301(a). As the Department points out, the General Assembly was aware that the Department intended to promulgate regulations requiring testing through multiple laboratories, as the Department had taken steps to implement the 2-Lab Requirement when the Act was passed. (Department’s Memorandum of Law in Support of [its] Application for Summary Relief (Department’s Br.) at 16-17.) Indeed, the record reflects a public meeting was held on the final regulation before the Independent Regulatory Review Commission (IRRC) on October 20, 2022, at which time the IRRC

Commissioners discussed the 2-Lab Requirement and the impetus behind it. (Meeting Minutes at 3-8, Department's Br. at Exhibit R-1.)

It is well established that “when an agency adopts a regulation pursuant to its legislative rule-making power . . . it is valid and binding upon courts as a statute so long as it is (a) adopted within the agency’s granted power, (b) issued pursuant to proper procedure, and (c) reasonable.” *Tire Jockey Serv., Inc. v. Dep’t of Env’t Prot.*, 915 A.2d 1165, 1186 (Pa. 2007) (*Tire Jockey* test). At the public meeting, in its appellate brief, and at oral argument, the Department explained that in implementing the 2-Lab Requirement, it sought to be proactive and, in accordance with the General Assembly’s interest in protecting patients, provide for a system of checks and balances in the testing process to ensure the safety of the medical marijuana that is distributed to the public.<sup>2</sup> The plain language of the Act granted the Department the authority to do so. Thus, in light of the plain language of the Act, the Department was authorized to promulgate the 2-Lab Requirement, for the current version clearly allows the Department to enable the implementation of contracts between growers/processors and more than one independent Lab.

As there is no dispute herein that the Department promulgated the challenged Regulation pursuant to the proper procedure, it is only necessary to next consider the third prong of the applicable *Tire Jockey* test regarding whether the 2-Lab Requirement is reasonable, for where an agency is authorized to promulgate a regulation and issues the same according to proper procedure, that regulation is valid

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<sup>2</sup> For instance, Denise Johnson, M.D., Acting Secretary of Health and Physician General, spoke of the “[D]epartment’s commitment to effectively treat patients while ensuring they are not exposed to harmful contaminants” and “reaffirmed [that] the Department’s focus is on keeping patients safe and ensuring contaminated products are not sold.” (Meeting Minutes at 4, 7, the Department’s Br. at Exhibit R-1.)

if it is deemed to be reasonable. *Marcellus Shale*, 292 A.3d at 937; *Tire Jockey*, 915 A.2d at 1186.

In deciding whether an agency action, such as promulgation of a legislative regulation, is reasonable, we are not at liberty to substitute [our] own discretion for that of administrative officers who have kept within the bounds of their administrative powers. To show that these have been exceeded in the field of action involved, it is not enough that [the agency's regulation] shall appear to be unwise or burdensome or inferior to another. Error or unwisdom is not equivalent to abuse. What has been ordered must appear to be so entirely at odds with fundamental principles as to be the expression of a whim rather than an exercise of judgment.

*Slippery Rock Area Sch. Dist. v. Unemployment Comp. Bd. of Rev.*, 983 A.2d 1231, 1242 (Pa. 2009) (citation omitted) (bracketed text in original). In *Tire Jockey*, the Pennsylvania Supreme Court explained that “[r]egarding the reasonableness prong, appellate courts accord deference to agencies and reverse agency determinations only if they were made in bad faith or if they constituted a manifest or flagrant abuse of discretion or a purely arbitrary execution of the agency’s duties or functions.” 915 A.2d at 1186 (internal quotation marks and citation omitted).

The Regulation reads in its entirety:

(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.**

- (3) An approved laboratory may test other samples and test samples at the request of a grower/processor or the Department.

28 Pa. Code § 1171a.29(c) (emphasis added).

In light of the broad conferment of authority granted to the Department under Section 301(a)(3) of the Act to implement and administer the medical marijuana program, the 2-Lab Requirement is reasonable. The plain terms of the Act set forth the General Assembly’s concern for patients’ safety and, as Petitioners admit, “[t]he General Assembly tasked [the Department] with implementing the medical marijuana program and regulating the entities within it to ensure the medicines are safe for patients.” (Petitioners’ Br. at 8-9.) The Department posited the 2-Lab Requirement will achieve this goal by allowing it to “flag and investigate potential issues with a particular Lab or grower/processor, such as trends in discrepancies between the two states of testing” and will “decrease the ability for a Lab to enter false data without detection.” (Department’s Br. at 18.) It will also eliminate the Department’s current concern regarding “having one Lab control almost all testing in the Commonwealth.” (*Id.* at 23.) This checks-and-balances approach is in line with the Department’s commitment to carefully regulate the medical marijuana program to enhance patient safety expressed in Section 102(2) of the Act. As Justice Wecht has eloquently observed:

A balance must be struck. A court reviewing the validity of regulations necessarily must engage in its own statutory interpretation analysis in order to determine whether the regulations are “consistent with the statute under which they were promulgated.”<sup>¶</sup> Yet, an agency empowered to implement a statute through its legislative rulemaking prerogative must be allowed the flexibility to do so without fear that a court may strike down its properly promulgated regulations merely because the court differs with the agency on some minor point of statutory interpretation.<sup>¶</sup> As we previously have explained, “substantive rulemaking is a widely used administrative practice, and

its use should be upheld whenever the statutory delegation can reasonably be construed to authorize it.”<sup>□</sup> This does not mean that we must afford unqualified “deference” to an agency’s statutory interpretation—a jurisprudential shortcut of which I continue to disapprove.<sup>□</sup> But it does mean that, in conducting our own statutory construction, we must maintain a “healthy judicial respect” for the intent of the General Assembly to imbue the agency with rulemaking authority, as expressed in the enabling statute.<sup>□</sup> In practice, when a statute is equally amenable to two constructions—one that would permit the agency’s regulation and one that would not—any “deference” to the agency effectively should take the form of a “tiebreaker,” rather than any substantive limitation upon the court’s duty and prerogative to independently interpret the statute.<sup>□</sup>

*Marcellus Shale*, 292 A.3d at 960 (Wecht, J., concurring and dissenting) (footnotes omitted).

In light of the foregoing, I believe the 2-Lab Requirement is a proper exercise of the Department’s authority under the Act, which gives the Department the authority to closely regulate the testing process in furtherance of the General Assembly’s concern for the safety of consumers of medical marijuana. As I would hold the Department had the authority to adopt the 2-Lab Requirement as a binding legislative regulation, I would grant the Department’s Cross-Application for Summary Relief seeking judgment in its favor and against Petitioners with prejudice. Consequently, I would deny Petitioners’ Cross-Application for Partial Summary Relief as to Count I, and I would proceed to a consideration of the merits of the additional claims presented in the Cross-Applications, namely, whether the 2-Lab Requirement constitutes an improper delegation of the Department’s authority under the Act to private entities and whether it violates the Contract Clause of the Pennsylvania Constitution.<sup>3</sup>

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<sup>3</sup> Providing “[n]o . . . law impairing the obligation of contracts . . . shall be passed.” Pa. Const. art. I, § 17.

For these reasons, I respectfully dissent.

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**RENÉE COHN JUBELIRER**, President Judge

Judge McCullough joins in this dissent.