[J-57-2024]
IN THE SUPREME COURT OF PENNSYLVANIA
MIDDLE DISTRICT

TODD, C.J., DONOHUE, DOUGHERTY, WECHT, MUNDY, BROBSON, McCAFFERY, JJ.

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,	:	No. 76 MAP 2023
	:	Appeal from the Order of the Commonwealth Court at No. 104 MD 2023 dated June 29, 2023
	:	ARGUED: September 10, 2024
Appellees	:	
v.	:	
PENNSYLVANIA DEPARTMENT OF HEALTH,	:	
Appellant	:	

OPINION

JUSTICE McCAFFERY **DECIDED: September 25, 2025**

With the enactment of Act 16 of 2016, known as the Medical Marijuana Act (the Act or the MMA), Pennsylvania became the 24th state to legalize medical marijuana. The Act created a medical marijuana program and tasked Appellant, the Pennsylvania Department of Health, with implementing and regulating the program. In turn, the Department required growers and processors (in the parlance of the Act, "growers/processors") of medical marijuana to employ one independent laboratory for testing harvest lots, and a second, distinct, independent laboratory for testing lots after processing. This is known as the "two-lab requirement."

Appellees, entities approved by the Department to engage in the business of medical marijuana,[1] contend the two-lab requirement exceeds the powers granted to the Department under the Act. Specifically, Appellees argue the two-lab requirement contradicts the Act's command that growers/processors use "one or more independent laboratories" to test lots at harvest and final processing. *See* 35 P.S. § 10231.704 (Section 704). The Commonwealth Court agreed with Appellees, concluding Section 704 granted growers/processors a right to decide how many independent laboratories to use.

We disagree. The primary goal of the Act is to alleviate the suffering of seriously ill patients. This goal necessarily relies upon a focus on patient safety – unsafe medical marijuana, by definition, will only increase the suffering of such patients. Since the Commonwealth Court engaged in an acontextual analysis of Section 704 of the Act with no consideration of patient safety, we reverse and remand to the Commonwealth Court for further consideration.

I. The Medical Marijuana Act

The Act legalized marijuana for medical purposes under Pennsylvania law, but marijuana otherwise remains illegal.[2] *See* 35 P.S. §§ 10231.303-10231.304. Through the MMA, the Legislature acknowledged that there is scientific evidence suggesting that medical marijuana "may mitigate suffering in some patients and also enhance quality of life." 35 P.S. § 10231.102(1).

The Legislature also indicated that it is "committed to patient safety." 35 P.S. § 10231.102(2). Indeed, the Act references patient safety three separate times in setting

[1] Green Analytics North, LLC (d/b/a Steep Hill Pa.) is an approved laboratory under the Act. Hanging Gardens, LLC, Pennsylvania Medical Solutions, LLC, Curaleaf, Pa, LLC, AES Compassionate Care, LLC, Standard Farms, LLC, and Parea BioSciences, LLC, are approved growers/processors under the Act.

[2] Marijuana is still classified as a schedule I narcotic under federal law. *See* 21 U.S.C. § 812.

forth its explicit policy goals. *See* 35 P.S. § 10231.102(2), (3)(i), (3)(ii). The Legislature also sought to incentivize research into the effectiveness and safety of medical marijuana. *See* 35 P.S. § 10231.102(2), (3)(iii).

Through the Act, the Legislature created a tightly regulated market with limited participants. Only growers/processors approved by the Department are permitted to grow or process medical marijuana. *See* 35 P.S. § 10231.601; 35 P.S. § 10231.101. Growers/processors may sell their product to dispensaries who have been approved by the Department. *See* 35 P.S. § 10231.616(7). Dispensaries act as retailers — selling medical marijuana to patients — and must obtain marijuana only from approved growers/processors. *See* 35 P.S. § 10231.101 (defining "Dispensary"); § 10231.616(6) (requiring dispensaries to only purchase medical marijuana from a grower/processor).

Dispensaries are subject to multiple statutory requirements, including packaging and labeling obligations. Package labels must include: (1) dispensing information; (2) the packaging date; (3) any applicable expiration date; (4) warnings about side effects; (5) the amount of doses, the species of marijuana, the percentage of tetrahydrocannabinol [THC]; and the percentage of cannabidiol [CBD];[3] (6) a warning that the medical marijuana must remain in the package as dispensed; (7) a warning that unauthorized use is subject to criminal penalties; and (8) "[a]ny other information required by the department." 35 P.S. § 10231.801(i).

The Department is tasked with creating and maintaining an electronic database capable of tracking virtually all activities in the medical marijuana program. *See* 35 P.S.

[3] "THC is delta-9-tetrahydrocannabinol, the main psychoactive ingredient in the cannabis plant. It's what makes you feel 'high' when you smoke marijuana or eat an edible. … CBD is short for cannabidiol. It's also made from the cannabis plant. CBD is related to THC, but it's not psychoactive, so it doesn't make you 'high' like THC does." *See* https://www.webmd.com/pain-management/cbd-thc-difference (last visited September 19, 2025).

§ 10231.301(a)(4). This database is to aid the Department in ensuring that "medical marijuana is not diverted or otherwise used for unlawful purposes[.]" 35 P.S. § 10231.301(a)(4)(i). Further, the Department's database must "[m]onitor[] all growth, transfer, possession, processing, testing and dispensing of medical marijuana" in Pennsylvania. 35 P.S. § 10231.301(a)(4)(iv). The database must be capable of providing this information in real time. *See* 35 P.S. § 10231.301(a)(4)(v).

II. The MMA's Independent Laboratory Requirement

As initially enacted, the Act required growers/processors to contract with an independent laboratory to test batches of product:

> 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.

35 P.S. § 10231.704 (Act 16 of 2016). However, the legislature subsequently amended Section 704:

> A grower/processor shall contract with ~~an independent laboratory~~ **one or more independent laboratories** to test the medical marijuana produced by the grower/processor. The department shall approve ~~the~~ **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 (Act 44 of 2021).[4]

[4] One consequence of marijuana remaining a prohibited narcotic under federal law is that any such "independent" laboratory is currently ineligible to contract with the federal government or receive a federal grant. *See* 41 U.S.C. § 701. These laboratories thus face a constricted market for their services.

III. The Department's "Two-Lab Requirement"

Several months after enactment, the Department published temporary regulations to implement, among other things, the testing referenced under Section 704. One temporary regulation identified the minimum sampling points for testing a lot of medical of marijuana: (1) after harvest but before any further processing ("harvest lot"); and (2) after processing but before marketing of the batch ("process lot"). *See* 46 Pa.B. 8036 (proposed 28 Pa.Code § 1171.29(c)). The Department simultaneously required that laboratories test samples for: "(1) Pesticides[;] (2) Solvents[;] (3) Water activity and moisture content; (4) THC and CBD concentration[; and] (5) Microbiological contaminants." *Id*. (proposed 28 Pa.Code § 1171.29(d)). Further, all testing was required to comply with scientific and Department standards. *Id*. (proposed Pa.Code § 1171.29(e), (f)).

In February 2021, the Department provided notice of its intent to update the testing regulations. The proposed update would still require, as a minimum, sampling of a harvest lot and a process lot. *See* 51 Pa.B. 1201 (proposed 28 Pa.Code § 1171a.29(c)). However, the updated regulation included the two-lab requirement:

> (c) At a minimum, testing, as prescribed by the Department, 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.

Id.[5] The two-lab requirement went into effect on March 4, 2023, when the Department published the regulation in its final form:

> (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.

53 Pa.B. 1275.

On that same day, Appellees filed a joint Petition for Review in the Commonwealth Court, contending the "two-lab requirement" contained in Section 1171a.29(c)(2) exceeded the Department's authority under the Act.[6] The Department subsequently agreed to suspend enforcement of the two-lab requirement pending litigation of Appellees' petition.

IV. The Commonwealth Court's Decision

On June 29, 2023, a divided *en banc* panel of the Commonwealth Court held that the regulation's two-lab requirement is inconsistent with Section 704 of the Act and declared the two-lab requirement unenforceable. *See Green Analytics North, LLC v. Pa. Dep't of Health*, 298 A.3d 181 (Pa. Cmwlth. 2023) (*en banc*). The Court applied what is often called the "*Tire Jockey* test." *See id*. at 186 (referencing *Tire Jockey Serv. Inc. v.*

[5] The proposed update of Section 1171a.29(c) was approved by the Independent Regulatory Review Commission on October 20, 2022. Notably, the legislature's amendment of Section 704 of the Act occurred in the interim — on June 30, 2021.

[6] The petition alleged Section 1171a.29(c) was invalid because: (1) it exceeds the Department's statutory authority; (2) it violates the non-delegation doctrine; and (3) it violates the Contracts Clauses of the Pennsylvania and U.S. Constitutions. The petition sought to temporarily and permanently enjoin the Department from enforcing Section 1171a.29(c).

Dep't of Env't Prot., 915 A.2d 1165, 1186 (Pa. 2007)). Under that test, a regulation is binding upon courts if (a) a statute empowers the agency to adopt it; (b) the agency followed proper procedure in issuing it; and (c) the regulation is reasonable. *See id*.

In granting summary relief, the Commonwealth Court majority reached only the first step — whether the two-lab requirement was adopted pursuant to a statutory grant of authority. *See Green Analytics North*, 298 A.3d at 187. The Commonwealth Court identified the issue before it as "whether [the two-lab requirement] is in conflict with the Act which mandates that growers/processors contract with one or more [labs] for testing." *Green Analytics North*, 298 A.3d at 187. The Court emphasized that the plain language of Section 704(a) of the Act utilized "or" in the phrase "one or more independent laboratories[.]" *See id*. "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." *Id.* (emphasis in original). As a consequence, the Court ruled that the two-lab requirement was invalid and unenforceable. *See id*. at 188. Once it concluded that the two-lab requirement conflicted with the explicit terms of the Act, the majority went no further.

President Judge Cohn Jubelirer dissented, joined by Judge McCullough. Judge Cohn Jubelirer focused on the breadth of regulatory power granted to the Department under Section 301 of the Act. *See Green Analytics North*, 298 A.3d at 189. She noted that Section 301(a)(1) established a medical marijuana program in Pennsylvania and requires the Department to implement and administer the program. *See id*. In her view, Section 301(a)(3) provides additional enlightenment, declaring that the Department "shall have regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana[.]" *Id*. (citation, emphasis, and brackets omitted). Judge Cohn Jubelirer also highlighted that Section 301(b) directed the Department to "promulgate all regulations necessary to carry out the provisions of the Act." *Id*. (citation, emphasis, and

brackets omitted). She also observes the Act repeatedly references a concern for patient safety. *See id*. at 190.

Judge Cohn Jubelirer thus concluded that "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." *Green Analytics North*, 298 A.3d at 190. Accordingly, the Act's 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 obligations and broad authority the Act grants the Department[.]" *Id*. at 190-191.

The Department appealed to this Court, challenging the Commonwealth Court Majority's conclusion that the Department lacks authority under the Act to impose the two-lab requirement.[7]

V. Standard of Review

The Commonwealth Court did not identify any dispute of material fact in granting summary relief. No party before this Court has done so either. Accordingly, in reviewing the Commonwealth Court's grant of summary relief, we simply determine whether the court committed an error of law. *See Pa. Med. Soc. v. Dep't of Pub. Welfare of Com.*, 39 A.3d 267, 277 (Pa. 2012). Here, the Commonwealth Court determined that the two-lab requirement imposed by the Department exceeded the Department's authority under the Act. We therefore begin by reviewing agency law principles.

VI. Agency Law

Commonwealth agencies have no power to impose regulations in the absence of authorization by the Legislature. *See Marcellus Shale Coalition v. Dep't of Evntl. Prot.*,

[7] As this matter was initiated in the Commonwealth Court's original jurisdiction, we have direct appellate jurisdiction. *See* 42 Pa.C.S. § 723(a).

292 A.3d 921, 927 (Pa. 2023) ("*MSC II*"). Agencies are authorized to impose regulations by complying with various statutes.[8] *See id*. Compliance with these statutes requires, pursuant to the *Tire Jockey* test, agencies to establish their regulations are: (a) adopted pursuant to a statutory grant of power; (b) issued using proper procedures; and (c) reasonable. *See id*. (*citing Tire Jockey*, 915 A.2d at 1186).

As the Department "is a creature of statute, it has only those powers which are expressly conferred upon it by the Legislature and those powers which arise by necessary implication." *Feingold v. Bell of Pa.*, 383 A.2d 791, 794 (Pa. 1977). Thus, our analysis begins with the Department's identification of an enabling statute. *See MSC II*, 292 A.3d at 938 (observing that a broad grant of power in an enabling statute lessens the need to scrutinize other sections of the statute that do not explicitly address regulatory authority). An enabling statute is a statute that "permits what was previously prohibited or that creates new powers; esp., a congressional statute conferring powers on an executive agency to carry out various delegated tasks." BLACK'S LAW DICTIONARY (12th ed. 2024).

As in all cases involving the interpretation of a statute, our foundational premise is to bring about the Legislature's intent in enacting the statute. *See Crown Castle NG East LLC v. Pa. Pub. Util. Comm'n*, 234 A.3d 665, 674 (Pa. 2020). While "the best indication of legislative intent is the plain language of the statute[,]" we identify the plain meaning by considering "the statutory language in context and give words and phrases their common and approved usage." *Id*. (citations and internal quotation marks omitted).

There is an often-unstated tension between the command to consider the statute in context and the command to give words their common meaning. Yet neither are elevated above our goal of accomplishing Legislative intent. Indeed, both commands are

[8] The Commonwealth Documents Law, 45 P.S. §§ 901 - 907; the Regulatory Review Act, 71 P.S. §§ 745.1 - 745.15; and the Commonwealth Attorneys Act, 71 P.S. §§ 732-101 – 732-506.

mere tools in service of identifying such intent. For example, when a different section of a statute provides an explicit definition for a word in a statute, we do not ignore the context in favor of giving the word its common meaning. *See* 1 Pa.C.S. § 1903(a). Nor do we give a word its common meaning when it is clear the word is used in a specialized, technical fashion. *See id*.

VII. Identifying the Parties' Duties and Rights Under the MMA

A. The Plain Language of the Act

As noted previously, the Commonwealth Court decided this case purely on the first step of the *Tire Jockey* test. It did not reach the issue of the procedures used by the Department in issuing the two-lab requirement, nor did it address whether the two-lab requirement is reasonable. Thus, the only issue before this Court at this time is whether the Commonwealth Court was correct in its conclusion that the Act prohibits the two-lab requirement.

Here, the Department points to several enabling statutes. First, it notes that Section 301(a) of the Act requires the Department to implement and enforce the medical marijuana program in Pennsylvania. *See* 35 P.S. § 10231.301(a). Section 301(a)(3) links that command to the Department having "regulatory and enforcement authority over the growing, processing, sale, and use of medical marijuana" in Pennsylvania. 35 P.S. § 10231.301(a)(3). According to the Department, this is a broad grant of regulatory discretion limited only by constitutional concerns and the reasonableness prong of the *Tire Jockey* test.

The Department also highlights that the Act requires the Department to issue regulations "necessary to carry out the provisions" of the Act. 35 P.S. § 10231.302. According to the Department, Section 302 imposes a duty upon the Department to issue regulations that accomplish the purposes of the Act.

In contrast, Appellees — and the Commonwealth Court below — focus entirely on Section 704 of the Act. They skip over the question of what the Legislature intended to accomplish with the enabling statutes, and instead read Section 704 as the only part of the Act that is relevant to the question before us.

We note that Appellees' position is immediately dubious. When interpreting a statute, we should not read the provisions in isolation, but instead understand each provision in the context of the statute as a whole. *See A.S. v. Pa. State Police*, 143 A.3d 896, 906 (Pa. 2016). Appellees' argument asks us to blind ourselves to the rest of the Act, including the provisions that **explicitly** address the question of the Department's power to regulate. We decline to accept that invitation.

While not completely equivalent, Appellee's argument is a variation on the concept of ignoring context through an obsessive focus on individual words. The question before us is **not** simply "what does Section 704 mean?" Rather, it is "who did the Legislature intend to empower to determine how many labs a grower/processor must use in testing its product?"

Through the first sentence of Section 704, the Legislature clearly imposes a duty upon growers/processors to use an **independent** laboratory to test harvest and process lots of medical marijuana: "A grower/processor shall contract with one or more independent laboratories to test the medical marijuana produced by the grower/processor." 35 P.S. § 10231.704(a). This sentence imposes a duty, not a right, on growers/processors using the word "shall." *See In re Canvass*, 241 A.3d 1058, 1087 (Pa. 2020) (Wecht, J., concurring) (declaring that "shall" can only be read as mandatory and stating "we must prefer the sometimes-unsatisfying clarity of interpreting mandatory language as such over the burden of seeking The Good in its subtext."); *see also* Antonin

Scalia and Brian A. Garner, *Reading Law: The Interpretation of Legal Texts*, (2012), at 112 ("Mandatory words impose a duty; permissive words grant discretion.").

Further, there are no permissive verbs in the first sentence. The Legislature clearly understood how to grant rights to growers/processors under the Act through the use of permissive language. For example, in another section the Legislature provided that growers/processors "**may** … [o]btain and transport seed and immature plant material from outside this Commonwealth during at least one 30-day period per year[.]" 35 P.S. § 10231.702(a)(1) (emphasis added). This a clear expression of a right granted to growers/processors. Section 702 thus clearly limits the Department's power to regulate. For example, the Department may not impose a regulation that completely prohibits growers/processors from obtaining marijuana seeds from outside the Commonwealth. Yet even the rights granted to growers/processors under Section 702(a) are explicitly conditioned on compliance with Department regulations. *See id*.

If the Legislature intended to grant growers/processors the right to choose the number of laboratories to employ in testing their product, the Legislature would have identified this right in Section 702(a). In the alternative, the Legislature could have granted this right to growers/processors in Section 704 through a clear expression of its intent to do so by using permissive language. The plain language of the Act includes neither of these options.

A similar analysis leads us to conclude that the plain language of Section 704 in isolation does not explicitly grant the Department the discretion to choose how many labs must be employed by growers/processors. The second sentence of Section 704 imposes duties upon the Department through use of the verb "shall." The plain language does not

grant the Department discretion.[9] We therefore cannot construe Section 704 as explicitly granting discretion to either growers/processors or the Department. Notably, the plain language of Section 704, viewed in isolation, does not answer the question of who is granted discretion in deciding the number of labs to use.

Appellees argue that the two-lab requirement "deletes" the word "one" from Section 704. This is simplistic sophistry. Section 704 clearly envisions a choice between "one" and "more than one." That someone gets to choose between those options does not "delete" the other option. Indeed, the very presence of the choice indicates that someone has the power to choose between the options; neither option is statutorily superior. As noted previously, our task is merely to determine to whom the Legislature intended to grant the discretion to decide between the options of "one" or "more."

In that vein, viewing Section 704 in context of the Act as a whole is necessary to answer the question of who gets to decide. The Act is not garden-variety legislation which seeks to regulate otherwise lawful behavior. *See*, *e.g.*, *MSC II*, 292 A.3d 921 (construing regulations governing gas wells); *Tire Jockey Serv. Inc., supra*. (construing regulations governing the disposal of discarded tires). Instead, the Legislature, through the Act, intended to repeal the wholesale prohibition of marijuana use under Pennsylvania law. *See* 35 P.S. § 10231.303(a) ("Notwithstanding any provision of the law to the contrary, use or possession of medical marijuana as set forth in this act is lawful within this Commonwealth."). Absent compliance with the Act, marijuana — medical or not —

[9] The second sentence of Section 704 highlights some of the difficulties created by an excessive focus on the common definitions of words used in a statute: "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." 35 P.S. § 10231.704(a). The sentence contains the word shall twice and clearly imposes duties upon the Department. The sentence does not contain the verb "may" or any other verb that indicates discretion. Nonetheless, there can be no doubt that, read in context of the whole Act, the Legislature intended to grant the Department discretion to determine the form and substance of testing reports.

remains illegal under Pennsylvania law. *See* 35 P.S. § 10231.304(a). Thus, the Act enables not only the Department to regulate, but also enables growers/processors to engage in, the business of medical marijuana.[10]

Under these circumstances, we must determine not only what rights, powers, and duties the Act grants or imposes on the Department, but also what rights, powers, and duties the Act grants or imposes on growers/processors.

B. Contextual Considerations

We have already demonstrated the plain language of Section 704(a) does not identify to whom the Legislature is granting discretion. We therefore must look to the rest of the Act, and especially (1) the explicit declaration of policies and (2) the explicit enabling statutes included in the Act.

Here, the Legislature provides an explicit list of its policies in Section 102 of the Act. As noted previously, the Legislature acknowledged that there is scientific evidence

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[10] This Court has historically recognized that under similar circumstances arising from the legalization of gambling on horse racing, the Legislature is likely to have intended a broader grant of regulatory power:

> While the authorizing statute removed the stigma of illegality from the operation, it did not remove all of the many perils, pitfalls, temptations and traps for the unwary, nor the occasions for corruption for the participants, all of which are inherent in any gambling operation of such proportions. The Legislature recognized the existence of these dangers unless the racing meetings were strictly governed and controlled by rules covering the many details which the statute did not cover. It is contemplated that the Commission would be best equipped to supervise the racing operations, and it gave the Commission the very broad powers necessary to accomplish the purpose.

Gilligan v. Pa. Horse Racing Comm'n, 422 A.2d 487, 490 (Pa. 1980) (internal parentheses omitted) (*quoting Colella v. State Racing Comm'n*, 274 N.E.2d 331, 334-336 (Mass. 1971)). While we believe this "thumb on the scale" approach is not consistent with our duty to effectuate the intent of the legislature, *Gilligan* demonstrates that there is a qualitative difference between the Act and a common regulatory scheme.

suggesting that medical marijuana "may mitigate suffering in some patients and also enhance quality of life." 35 P.S. § 10231.102(1). Thus, the Legislature explicitly sought to alleviate the suffering of seriously ill patients and improve their quality life.

Next, the Legislature stated that it is "committed to patient safety." 35 P.S. § 10231.102(2). As such, "[c]arefully regulating the program which allows access to medical marijuana will enhance patient safety while research into its effectiveness continues." *Id*. Through this provision, the Legislature identified "patient safety" as a concern, perhaps the primary concern, of the Act. Further, the Legislature recognized that "careful regulation" of the medical marijuana program serves the purpose of patient safety. When read in conjunction with subsection (1), it is clear the Legislature desired to provide the Department with sufficient regulatory power to avoid unsafe medical marijuana products that could increase the suffering of seriously ill patients. Thus, a focus on patient safety serves both of the first two policies explicitly identified by the Legislature.

Two of the remaining three policies identified by the Legislature in Section 102 also explicitly reference patient safety:

> (3) It is the intent of the General Assembly to:
>
> a. 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**.
> b. Provide **a safe** and effective method of delivery of medical marijuana to patients.
> c. Promote high quality research into the effectiveness and utility of medical marijuana.

35 P.S. § 10231.102(3) (emphasis added).

Accordingly, patient safety is explicitly mentioned in three of the five goals set forth in Section 102. Of the remaining two goals, patient safety is clearly related to the Legislature's desire to mitigate the suffering of seriously ill patients.

What other policies are set forth in Section 102? Three of the six subsections indicate that the Legislature desired to increase knowledge about the benefits of medical

marijuana. First, subsection (1) indicates that "scientific evidence **suggests**" that medical marijuana can be a useful treatment for some patients. 35 P.S. § 10231.102(1) (emphasis added). This implies the Legislature did not believe that such usefulness had already been scientifically established. Rather, the Legislature's statement opines that there is reason to believe marijuana has medical value, but that more research is necessary. Subsection (2) declares that regulation of the medical marijuana program "will enhance patient safety **while research into its [medical marijuana's] effectiveness continues**." 35 P.S. § 10231.102(2) (emphasis added). Again, this statement reveals a legislative preference for more scientific evidence regarding marijuana's effectiveness for treating ailments. Finally, Subsection (3)(iii) clearly sets forth a desire to "[p]romote high quality research into the effectiveness and utility of medical marijuana." 35 P.S. § 10231.102(3)(iii).[11]

Finally, we note that subsection (3)(i) provides a limiting principle for patient safety (and arguably research promotion): "It is the intent of the General Assembly to … [p]rovide 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." 35 P.S. § 10231.102(3)(i). Thus, the legislative intent is to prevent a situation where an excessive

[11] It is important to note that in pharmaceutical research, "effectiveness" can have a slightly specialized meaning. "Efficacy can be defined as the performance of an intervention [such as the administration of a pharmaceutical] under ideal and controlled circumstances, whereas effectiveness refers to its performance under 'real world' conditions." https://pmc.ncbi.nlm.nih.gov/articles/PMC3912314. (last visited September 19, 2025). Pharmaceutical effectiveness is directly correlated with dosage, while pharmaceutical safety is generally inversely correlated with dosage. *See*, *e.g.*, *Mayo Collaborative Svcs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 73 (2012) (noting that "[b]ecause the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently, and it has been difficult for doctors to determine whether for a particular patient a given dose is too high, risking harmful side effects, or too low, and so likely ineffective.")

focus on patient safety renders medical marijuana inaccessible to patients who might benefit from it.

With these goals in mind, we note the Legislature could have chosen to allow growers/processors to test their raw materials or product in-house, or through an otherwise dependent laboratory such as a wholly owned subsidiary. It clearly chose not to. The obvious purpose of requiring the use of an independent laboratory is to avoid conflicts of interest in generating accurate test results, since accurate and independent test results serve the clearly expressed statutory goals of patient safety.

Accurate test results serve another explicit statutory goal: the promotion of "high quality research into the effectiveness and utility of medical marijuana." *See* 35 P.S. § 10231.102(3)(iii). Needless to say, high quality research requires high quality, accurate testing. As but one example of many, consider whether clinical trials can support any meaningful scientific conclusions if clinicians cannot accurately determine how much THC they are administering to patients enrolled in the trial.

We cannot identify any rationale whereby granting growers/processors the discretion to choose the number of independent laboratories employed effectuates the Act's explicit goal of patient safety. Nor can we see how granting this power to growers/processors enhances the goal of high-quality research.

Arguably, the desire to maintain access to medical marijuana might support giving discretion to growers/processors as a method of cost containment. However, that policy is mentioned only as a factor to be balanced against patient safety; in other words, it imposes a reasonableness limit upon how much emphasis can be placed on patient safety. Since it is an explicit balancing test, it has less to do with the Department's or growers/processers' statutory authority to make a decision, and more to do with ensuring that decision is reasonable in light of the goals of the Act. As such, applying this policy to

the two-lab requirement is consigned to the third step of the *Tire Jockey* test – whether the regulation is reasonable.

With the goals of patient safety and high quality research in mind, we turn to the MMA's enabling statutes. Section 301 of the Act declares that the medical marijuana program "shall be implemented and administered by the [D]epartment." 35 P.S. § 10231.301(a). Further, the Department "shall promulgate all regulations necessary to carry out the provisions of" the Act. 35 P.S. § 10231.301(b). Section 1102 of the Act directs medical marijuana organizations to "periodically" file reports with the Department summarizing their "activities." 35 P.S. § 10231.1102. The Department "shall determine the information required in and the frequency of filing the reports." *Id*. Further, the second sentence of Section 704 contains enabling language, explicitly granting the Department discretion over the format and substance of laboratory testing reports. *See* 35 P.S. § 10231.704.

Taken as a whole, these provisions of the Act evince a comprehensive grant of regulatory power to the Department. While the Legislature set forth the broad outlines and goals of the medical marijuana program in the Commonwealth, it clearly intended to leave many of the details of accomplishing the goals of the program to the Department's discretion.

In turn, we must examine the duties imposed on the Department by the Act. Many, but not all, of these duties are located in Section 301. The first duty imposed is one to issue permits "to medical marijuana organizations … and ensure their compliance with this act." 35 P.S. § 10231.301(a)(1).[12] Further, the Department is tasked with "regulatory and enforcement authority over the growing, processing, sale and use of medical

[12] "Medical marijuana organization" is defined as "[a] dispensary or a grower/processor." 35 P.S. § 10231.103.

marijuana in this Commonwealth." 35 P.S. § 10231.301(a)(3). Elsewhere, the Act declares the lawful use of medical marijuana requires that "[p]roducts packaged by a grower/processor or sold by a dispensary shall only be identified by," among other requirements, "the percentage of [THC] and [CBD] contained in the product and any other labeling required by the [D]epartment." 35 P.S. § 10231.303(b)(8). Thus, the Department is explicitly charged with the duty of enforcing a requirement that medical marijuana products be labeled with the percentage of active ingredients contained in the products. While it is possible to imagine that the Legislature did not desire **accurate** percentages on the label, it strains credulity to call such an attribution reasonable. As noted above in fn. 11, dosage amounts are correlated not only with effectiveness of a drug, but also safety. Accurate results therefore contribute to two of the explicit goals for the Act as set forth by the Legislature in Section 102.

Similarly, the Act requires the Department to ensure that "medical marijuana is not diverted or otherwise used for unlawful purposes by a practitioner or medical marijuana organization." 35 P.S. § 10231.301(a)(4)(i). A medical marijuana organization commits a first degree misdemeanor if it intentionally distributes medical marijuana "to a person who is not lawfully permitted to receive medical marijuana[.]" 35 P.S. § 10231.1302(1). Accurate test results of harvest batches and final processing are reasonably necessary to ensure that a grower/processor is not diverting medical marijuana for unlawful purposes. Perhaps even more importantly, the Act similarly criminalizes the diversion of medical marijuana by a "laboratory utilized to test medical marijuana under section 704." 35 P.S. § 10231.1302(4). And it is inescapable that having a second independent laboratory involved in testing would help detect and deter such illegal diversions by laboratories. In fact, it may be the only way to do so.

The Department also is required to establish "the procedure to be used by a health care medical marijuana organization that grows and processes medical marijuana" when recalling "defective medical marijuana." 35 P.S. § 10231.907(4). This duty is reiterated under Section 1903(a)(3). *See* 35 P.S. § 10231.1903(a)(3). "Defective medical marijuana" is not defined in the Act. In the absence of an explicit definition, it is necessarily implied that the Legislature intended the Department to have a significant role in defining "defective" and how to determine whether a lot of medical marijuana (either pre- or post-processing) is "defective." By any reasonable construction, accurate test results are necessary to determine whether a lot of medical marijuana is "defective." The explicit language of Section 1903 demonstrates the Legislature intended to impose the duty of comprehensively regulating testing of medical marijuana on the Department. The two-lab requirement is one such regulation that serves multiple explicit purposes of the Act. Thus, the Department has the authority to enforce the two-lab requirement.

VIII. Conclusion

Under the Act, the Department has discretion in determining the number of laboratories necessary to achieve the explicit goals of the Act. Thus, contrary to the Commonwealth Court's analysis, the two-lab requirement does not exceed the regulatory authority granted to the Department by the Act. We therefore remand this matter to the Commonwealth Court to apply the remaining steps of the *Tire Jockey* test.[13]

[13] While our discussion touches on the reasonableness of the Department's **authority** to require multiple labs under the Act, we do not pass any judgment on whether the two-lab requirement itself is "reasonable" under the third step of the *Tire Jockey* test. In other words, the Department has the statutory authority to regulate testing, but its regulation must not be "made in bad faith, … arbitrarily executed, or constitute a manifest abuse of discretion." *Tire Jockey*, 915 A.2d at 1190. As but one example, the two-lab requirement could still be unreasonable if growers/processors establish that the costs of the two-lab requirement unreasonably exceeded the purported benefits such that the requirement constitutes a flagrant abuse of the Department's discretion. The third step of the *Tire Jockey* test allows for the balancing test envisioned in 35 P.S. § 10231.102(3)(i).

Chief Justice Todd and Justices Donohue, Dougherty and Mundy join the opinion.

Justice Wecht files a dissenting opinion in which Justice Brobson joins.