IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Medical Marijuana Access & Patient Safety, Inc., Petitioner	:	
v.	:	No. 58 M.D. 2022
	:	Heard: February 24 and 28, 2022
Keara Klinepeter, Acting Secretary, Pennsylvania Department of Health, John J. Collins, Director of the Pennsylvania Department of Health, Office of Medical Marijuana, and Sunny D. Podolak, Assistant Director and Chief Compliance Officer of the Pennsylvania Department of Health, Office of Medical Marijuana, Respondents	:	

BEFORE: HONORABLE MICHAEL H. WOJCIK, Judge

OPINION NOT REPORTED

MEMORANDUM OPINION
BY JUDGE WOJCIK FILED: June 2, 2022

Before the Court is Medical Marijuana Access & Patient Safety, Inc.'s (Petitioner) application for special relief in the nature of a preliminary injunction (Application), and the answer in opposition thereto of Respondents Keara Klinepeter, Acting Secretary, Pennsylvania Department of Health (DOH), John J. Collins, Director of DOH's Office of Medical Marijuana (OMM), and Sunny D. Podolak, Assistant Director and Chief Compliance Officer of OMM (collectively, Respondents). After a hearing, argument, and written submissions, the Application is ripe for disposition.

I. Background

The pertinent facts are as follows. The Medical Marijuana Act (Act),[1] which took effect on May 17, 2016, establishes a framework for the legalization of medical marijuana in the Commonwealth for certain medical conditions. DOH, and in particular OMM, is the Commonwealth agency responsible for administering and enforcing the Act, including regulating the medical marijuana program in a way "which balances the need of patients to have access to the latest treatments with the need to promote patient safety." Section 102 of the Act, 35 P.S. § 10231.102. The Act also outlines the application process through which medical marijuana grower/processors and dispensaries,[2] also known as medical marijuana organizations (MMOs), can obtain a permit from DOH to grow, process, or dispense medical marijuana. *See* Sections 601-616 of the Act, 35 P.S. §§ 10231.601-10231.616. Of note here, Petitioner is an association consisting of various stakeholders in the medical marijuana industry, including DOH-permitted grower/processors and dispensaries, as well as medical marijuana patients.

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[1] Act of April 17, 2016, P.L. 84, *as amended*, 35 P.S. §§ 10231.101 – 10231.2110.

[2] Section 103 of the Act provides the following definitions:

> "Dispensary." A person, including a natural person, corporation, partnership, association, trust or other entity, or any combination thereof, which holds a permit issued by [DOH] to dispense medical marijuana. . . .
> . . . .
> "Grower/processor." A person, including a natural person, corporation, partnership, association, trust or other entity, or any combination thereof, which holds a permit from [DOH] under this [A]ct to grow and process medical marijuana. . . .

35 P.S. § 10231.103.

Section 303 of the Act specifically authorizes the dispensing and patient use of certain forms of medical marijuana, including "a form medically appropriate for administration by vaporization . . . ." 35 P.S. § 10231.303(b)(2)(iv). The cannabis in vaporization products contains substances known as terpenes, which are naturally occurring chemical compounds found in cannabis and other plants that give the plant its flavor, aroma, and color. Petition for Review (Petition) ¶ 28. Medical marijuana producers add terpenes extracted from either cannabis itself or other, external sources—such as lemons, hemp, or botanicals—to add flavor to the vapor and to improve the aromatic component of the medicine.[3] Petition ¶ 29. Petitioner asserts that its grower/processor members have added terpenes to their medical marijuana vaporization products since 2018, when medical marijuana first became legally available in Pennsylvania, and that DOH has reviewed and approved each such product before it became available for use by medical marijuana patients. Petition ¶¶ 27, 30, 38-39.

Of particular note to this action, Act 44 of 2021 (Act 44)[4] made numerous changes to the Act, including amending Section 702 (relating to grower/processors) so that it now provides, in pertinent part:

> (a) Authorization.--Subject to subsection (b), a grower/processor may do all of the following in accordance with [DOH] regulations:
> . . . .

[3] When added to medical marijuana, terpenes qualify as a type of "excipient," a term which the Act defines as: "Solvents, chemicals or materials reported by a medical marijuana organization and approved by [DOH] for use in the processing of medical marijuana." Section 103 of the Act, 35 P.S. § 10231.103.

[4] Act of June 30, 2021, P.L. 210, No. 44. Act 44 went into effect immediately.

> (5) Add excipients or hemp or hemp-derived additives obtained or cultivated in accordance with paragraph (4). Excipients must be pharmaceutical grade, unless otherwise approved by [DOH]. **In determining whether to approve an added substance, the department shall consider the following:**
>
> > (i) **Whether the added substance is permitted by the United States Food and Drug Administration [(FDA)] for use in food or is Generally Recognized as Safe (GRAS) under Federal guidelines.**
> >
> > (ii) Whether the added substance constitutes a known hazard such as diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.

35 P.S. § 10231.702(a)(5) (emphasis added).

On November 16, 2021, after Act 44 went into effect, Respondent Podolak sent an email to a group of MMOs advising them that DOH was "conducting a review of all vaporized medical marijuana products containing additional ingredients (anything that alters the dosage level, color, appearance, smell, taste, effect[,] or weight of the medical marijuana)" and that DOH was "requiring every grower/processor to submit for approval each vaporized product that contains additional ingredients, even if the product had previously been approved." Petition Exhibit 2; *see also* Petition ¶ 41. The November 16, 2021 email included a form for MMOs to use when submitting their products for approval and indicated that the deadline for product submissions was November 30, 2021. Petition Exhibit 2. The email concluded by indicating that failure to comply may result in DOH suspending the sale of an MMO's entire line of vaporized products. *Id.* Petitioner avers that its grower/processor members timely provided all information requested in the November 16, 2021 email. Petition ¶ 43.

On December 2, 2021, OMM emailed all patients in the medical marijuana program advising them that DOH had

> instituted a state-wide review of vaporized products containing added ingredients such as externally sourced flavorings or terpenes. Grower/processors have submitted information regarding these products to [DOH] for review, to include whether these added ingredients are safe for inhalation. [DOH] will review this information as expeditiously as possible. Should [DOH]'s review reveal products containing added ingredients that are not safe for inhalation, those products will be removed from the market. In the interim, you should be aware that products with added ingredients may not be safe for inhalation and you should make your own decision about whether to use these products. If you have any questions or concerns about products, you should consult with your medical professional.

Petition Exhibit 3. Petitioner avers that Luke Schultz, the Medical Marijuana Advisory Board Patient Advocate, emailed Respondent Collins asking whether any adverse events had provoked the December 2, 2021 email. Petition Exhibit 3; *see also* Petition ¶ 45. Schultz's email explained that because DOH did not state a reason for the warning over additives in vaporized products or specify which products were of concern, patients did not feel as though they had enough information to properly make their own decisions about whether to use the products. *Id.* Petitioner avers that DOH never responded to Schultz's email. Petition ¶ 46.

On December 13, 2021, Respondent Podolak sent another email to MMOs requesting further information, as follows:

> In addition to what you may have already provided, and in order to continue our review, please provide any information you have regarding the determined safety of the externally sourced additives for inhalation, including

> artificial terpenes or flavorings, used in your vaporized products.
>
> If you are using additives, including artificial terpenes or flavorings, in other states, please provide the product name and the state in which it is approved.
>
> Please provide this information no later than close of business on Wednesday, December 15, 2021.

Petition Exhibit 5; *see also* Petition ¶¶ 47-48. In response to the December 13, 2021 email, Petitioner's members provided DOH with hundreds of pages of submissions, "including declarations from medical doctors and scientists that affirmed that there are no known safety concerns associated with fruit or botanically-derived terpenes while also confirming that there are benefits to adding these terpenes in medical marijuana vaporized products." Petition ¶ 49; *see also* Petition Exhibit 6 (providing a sample of such member submissions).

The crux of this litigation is a February 4, 2022 email from OMM to grower/processors instituting a mandatory recall of at least 670 individual vaporization products (the Terpene Recall Mandate or Recall). Stipulation ¶¶ 4-5 and Exhibits 1 & 2. That email provides, in pertinent part, as follows:

> [DOH] has reviewed your submission, and your product approval request is **DENIED**.[]
>
> Prior approval for the product(s), if issued, is hereby **RESCINDED**.
>
> [DOH] has reviewed every additive contained in the attached list of products and has determined that additive(s) contained in your product(s) have not been approved for inhalation by the [FDA]. Accordingly, you may no longer produce the product(s). By this notice, [DOH] advises that products on the attached list meet the

conditions for recall under 28 Pa. Code § 1151.42(c)(1).[5] **Accordingly, you MUST follow the mandatory recall procedures outlined in 28 Pa. Code § 1151.42(c)**. Failure to comply will result in [DOH] acting to impose sanctions against you under 28 Pa. Code § 1141.47.

[DOH] provides the following rationale for this determination:

In passing the [Act], the General Assembly specifically declared:

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[5] This section of the regulations (regarding complaints about or recall of medical marijuana products) provides as follows:

> (c) The following requirements apply to mandatory recalls:
>
> (1) If a grower/processor discovers that a condition relating to the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products grown or processed at its facility poses a risk to public health and safety, the grower/processor shall:
>
> (i) Immediately notify [DOH] by phone.
>
> (ii) Secure, isolate and prevent the distribution of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products that may have been affected by the condition and remains in its possession. The grower/processor may not dispose of affected seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products prior to notifying [DOH] and coordinating the disposal with [DOH].
>
> (2) If a grower/processor fails to cooperate with [DOH] in a recall, or fails to immediately notify [DOH] of a need for a recall under paragraph (1), [DOH] may seek a cease and desist order under § 1141.47 (relating to general penalties and sanctions) and the grower/processor may be subject to any other penalties or sanctions provided for in the [A]ct or this part.

28 Pa. Code § 1151.42(c).

> (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.*
>
> [Section 102 of the Act,]35 P.S. § 10231.102 [].
>
> Further, the [Act], when recently amended under Act 44 [], explicitly states:
>
> Excipients must be pharmaceutical grade, unless otherwise approved by [DOH]. In determining whether to approve an added substance, [DOH] shall consider the following:
>
> > (i) Whether the added substance is permitted by the [FDA] for use in food or is [GRAS] under Federal guidelines.
> > (ii) Whether the added substance constitutes a known hazard such as diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.
>
> [Section 702(a)(5) of the Act,]35 P.S. § 10231.702(a)(5).
>
> You may appeal this action to the Secretary of Health in writing **within 30 days of the date of emailing** of this Notice in accordance with 28 Pa. Code Chapter 1230 (relating to practice and procedure – temporary regulations).

Stipulation Exhibit 1 (emphasis in original). That same day, February 4, 2022, DOH sent a separate email to all patients in the medical marijuana program advising them that "DOH was instructing grower/processors to initiate a mandatory recall of

medical marijuana products that contain additives that 'have not been approved for inhalation by the [FDA].'" Stipulation ¶ 19 (quoting Stipulation Exhibit 7).

II. The Petition and Application

On February 10, 2022, Petitioner filed in this Court's original jurisdiction its Petition seeking declaratory and injunctive relief from DOH's Terpene Recall Mandate, on behalf of itself and its members. Petitioner avers that to comply with the Terpene Recall Mandate, its grower/processor and dispensary members immediately halted production and sales of the affected products, and dispensaries started shipping the products subject to the recall back to the originating grower/processors. Petitioner's Brief at 9. The recalled products received by grower/processors were initially being quarantined until DOH could coordinate their disposal pursuant to 28 Pa. Code § 1151.42(c)(1)(ii). Petition ¶ 58; Petitioner's Brief at 9-10. However, Respondents subsequently agreed that the destruction of the recalled products would be suspended pending the outcome of this litigation and the Court issued a consent order to this effect on March 1, 2022.[6]

As for the specific counts asserted in the Petition, Count one requests declaratory judgment for lack of statutory authority. Petitioner claims that Act 44 does not authorize DOH to base approval or disapproval of the addition of an excipient upon whether the FDA has approved it "for inhalation." Petition ¶ 91. Rather, Act 44 authorizes DOH to disapprove a proposed excipient only if the FDA has not approved it "for use in food" or as GRAS. *See* section 702(a)(5) of the Act, 35 P.S. § 10231.702(a)(5).

[6] That Order states: "All recalled products resulting from the Department of Health, Office of Medical Marijuana's February 2022 notice to grower/processors may be held in quarantine and destruction will not occur until the conclusion of this matter." (Pa. Cmwlth., No. 48 M.D. 2022, Order filed Mar. 1, 2022).

Count two seeks declaratory relief on the basis that the Terpene Recall Mandate is an unlawful *de facto* regulation. Petitioner argues that the Recall announces an immediately effective industry-wide rule that purportedly has the force and effect of law. As such, it creates a binding norm which may only be imposed through a properly promulgated regulation.

Count three avers that DOH's regulation set forth in 28 Pa. Code § 1151.42(c) does not grant authority to DOH to initiate a mandatory recall because that section applies when grower/processors discover a condition that poses a risk to public health and safety, which did not occur here.

Count four sounds in declaratory judgment based on vested rights, detrimental reliance, and promissory estoppel. Essentially, Petitioner asserts that its grower/processor and dispensary members have a vested right in producing and dispensing the vaporized medical marijuana products that are subject to the Recall, and which have been approved by DOH since 2018.

Count five asserts that the Terpene Recall Mandate violates the Fifth Amendment of the United State Constitution[7] and article I, section 10 of the Pennsylvania Constitution,[8] in that it effects an unconstitutional taking of private property without compensation. *See Pennsylvania Coal Company v. Mahon*, 260 U.S. 393, 415 (1922) ("while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking"). Petitioner asserts that its members will lose tens of millions of dollars due to the Recall, given that the recalled

[7] U.S. Const. amend. V. The Fifth Amendment provides, in pertinent part: "No person shall be . . . deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."

[8] Pa. Const. art. I, § 10. This provision of the Pennsylvania Constitution provides, in pertinent part: "[N]or shall private property be taken or applied to public use, without authority of law and without just compensation being first made or secured."

products will be destroyed or may expire in quarantine, and that the Recall interferes with members' distinct investment-backed expectations. *See Penn Central Transportation Company v. City of New York*, 438 U.S. 104 (1978).

Count six claims that the Terpene Recall Mandate violates the due process rights of Petitioner's members under both the United States and Pennsylvania Constitutions. Pursuant to the Recall, MMOs must immediately cease distributing products containing certain added terpenes and return the products to the grower/processor without a meaningful pre-deprivation hearing. Petitioner maintains that the products will expire if quarantined and, therefore, an administrative appeal absent a supersedeas provision does not provide adequate due process.

Count seven requests declaratory judgment for damage to reputation under article I, section 11 of the Pennsylvania Constitution.[9] Petitioner asserts that by publishing on its website a list of over 670 vaporization products subject to the Terpene Recall Mandate and identifying the grower/processor of each product by name, DOH has communicated to medical marijuana patients that the grower/processor's product is unsafe. Petitioner maintains that its members are not aware of any complaint being made by a caregiver or practitioner concerning an adverse event from using vaporized medical marijuana products, and that DOH has failed to provide any evidence that the identified products are unsafe. Petitioner reiterates that DOH previously approved for production and distribution all of the recalled products containing terpenes. DOH's conflicting messages have caused

[9] Pa. Const. art. I, § 11. This section guarantees "[a]ll courts shall be open; and every man for an injury done him in his lands, goods, person or reputation shall have remedy by due course of law[.]"

mass confusion with medical marijuana patients and impugned the reputation of Petitioner's members.

Finally, counts eight and nine aver that Petitioner is entitled to a preliminary and permanent injunction, respectively. Petitioner filed the instant Application contemporaneously with its Petition, seeking an order from this Court preliminarily enjoining Respondents' enforcement of the Terpene Recall Mandate.

As directed by the Court, Respondents filed an Answer to the Application on February 17, 2022. Among other things, Respondents deny that DOH initiated a recall in this matter, instead noting that the February 4, 2022 email instructed grower/processors that *they* must follow the mandatory recall procedures outlined in 28 Pa. Code § 1151.42(c). Respondents further deny that Section 702(a)(5) of the Act expressly limits DOH's authority, arguing instead that it gives DOH the authority to revoke or deny approval of medical marijuana products containing additives (here, terpenes) which Petitioner admits alter the smell and taste of the medicine.

With respect to the preliminary injunction standard, Respondents argue that Petitioner cannot demonstrate that releasing products for sale that include additives which have not been deemed safe for inhalation by the FDA will not adversely affect the public interest. Further, Respondents assert that any claim that medical marijuana patients will be inconvenienced and might turn to the "black market" because they no longer have access to their preferred medicine is speculative. Respondents maintain that patients still have access to a substantial number of products even after the purported Recall.

The Court held a hearing on the Application on February 24 and 28, 2022, at which Petitioner presented the testimony of the following witnesses: Trent

Woloveck, Chief Commercial Director, Jushi Holdings, Inc. (Jushi); Shawna Vreeke, PhD (Dr. Vreeke), Head of Research, True Terpenes;[10] Suzanne Sisley, MD (Dr. Sisley), practicing internist, President and Chief Medical Officer, Scottsdale Research Institute and Field to Healed Foundation;[11] and Jon Ahern, CPA, CGMA, Senior Director, Alvarez & Marsal Disputes and Investigations, LLC.[12] The Court finds all four of these witnesses credible.

Of particular importance to the Application, Mr. Woloveck testified[13] that Jushi is the parent company of multiple MMOs, including both grower/processors and dispensaries that are licensed by DOH. (Notes of Testimony, 2/24/22 (N.T.) at 33-36.) He explained that Petitioner "is a group of grower/processors, retailers, patients, a doctor, cannabis operators, as well as experts around terpenes and other practices within the space." (*Id.* at 37.) Mr. Woloveck stated that Jushi is one of the operators within Petitioner and that he himself is specifically authorized to speak on behalf of Petitioner. (*Id.*)

Mr. Woloveck testified that Jushi's subsidiaries have been affected by the Recall in several ways. First, Jushi's dispensaries had to return recalled products to the appropriate grower/processors, and Jushi's grower/processors had to place the

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[10] Dr. Vreeke was offered as an expert in the field of vaporization chemistry and terpene toxicology. The Court admits her as such, over the objection of Respondents.

[11] Dr. Sisley was offered as an expert in the areas of state and federal medical marijuana research, FDA approval processes, and patient impacts. The Court admits her as such, over the objection of Respondents.

[12] Mr. Ahern was offered, and so admitted, as an expert in the areas of analyzing accounting financial and economic issues, including business valuation and calculating damages, with an emphasis on damages to cannabis-related entities and markets.

[13] Respondents objected to the rebuttal testimony of Mr. Woloveck, presented on February 28, 2022, as the substance of his testimony was known to him at the time he was called on direct. The Court sustains the objection. Mr. Woloveck's rebuttal testimony is stricken and was not considered by the Court in its resolution of the Application. As such, the entirety of Mr. Woloveck's testimony can be found at pages 33-117 of the transcript.

recalled products in quarantine. (*Id.* at 43-44, 75-76.) Mr. Woloveck stated that the 670 recalled products, including roughly 330,000 individual units, accounted for several million dollars of inventory. (*Id.* at 41, 76.) In addition, Jushi was no longer able to provide certain medical marijuana patients with their preferred medicine. (*Id.* at 41, 77-78.) He further testified that medical marijuana vaporization products all have an expiration date which is 12 months from when final testing and labeling is done; however, he was unable to give specific expiration dates for any of Jushi's recalled products. (*Id.* at 44, 98-102.)

Mr. Ahern stated[14] that he was retained by Petitioner to evaluate the economic and financial impact and other harms to Petitioner's members due to the Terpene Recall Mandate. (N.T. at 280-81.) In conducting his evaluation, Mr. Ahern relied upon the legal filings in this case as well as financial information provided by five of Petitioner's member MMOs[15] which included sales data, recall data (including the volume of recalled products), product data, margin data, historical advertising spending, and third-party sales. (*Id.* at 283-85, 288-90.) He also had discussions with individuals from the providing MMOs to ensure that he understood the data, and conducted his own independent research. (*Id.* at 285.)

Mr. Ahern testified as to his findings and his expert report was admitted into evidence. His primary conclusion was that Petitioner's members for which he specifically reviewed data have suffered tens of millions of dollars in damages due to the Recall. (N.T. at 281-82.) More pointedly, for the five members of Petitioner he reviewed, he stated: "I've quantified damages between $17 and $18 million. And then if you extrapolate that based on estimates of market share, the number quickly

[14] Mr. Ahern's testimony can be found at pages 261-349 of the transcript.

[15] Mr. Ahern testified that "all five of the entities for which I reviewed data are both operators of dispensaries and grower/process[o]rs." (N.T. at 288.)

gets up to $30-ish million estimated for all dispensaries and grower/processors in the market." (*Id.* at 292.) Mr. Ahern also testified to reputational harm to Petitioner's MMO members given DOH's direct communication to medical marijuana patients that the recalled products are potentially unsafe and no longer approved. (*Id.* at 298-99.)

Respondents did not call any witnesses at the hearing. Instead, Respondents raised arguments that Petitioner lacks standing to bring this action and, in the alternative, that Petitioner failed to establish the requirements necessary for a preliminary injunction.

At the Court's request, the parties also submitted post-hearing memoranda of law addressing, in particular, the issue of standing. Because "[s]tanding is a justiciability concern, implicating a court's ability to adjudicate a matter[,]" it is a threshold issue that must be resolved before addressing the merits of the case. *Firearm Owners Against Crime v. Papenfuse*, 261 A.3d 467, 481 (Pa. 2021) (citations omitted) (*FOAC*); *also Pennsylvania Social Services Union, Local 668 v. Department of Public Welfare*, 699 A.2d 807, 810 (Pa. Cmwlth. 1997) (*PSSU*).

IV. Analysis

A. Standing

As our Supreme Court has explained:

> The doctrine of standing "stems from the principle that judicial intervention is appropriate only where the underlying controversy is real and concrete, rather than abstract." *City of Phila*[*delphia v. Commonwealth*], 838 A.2d [566,] 577 [(Pa. 2003)]. The touchstone of standing is "protect[ing] against improper p[etitioner]s." *In re Application of Biester*, . . . 409 A.2d 848, 851 ([Pa.]1979). To do so, courts require a p[etitioner] to demonstrate [it]

> has been "aggrieved" by the conduct [it] challenges. *In re Hickson*, . . . 821 A.2d 1238, 1243 ([Pa.]2003). To determine whether the p[etitioner] has been aggrieved, Pennsylvania courts traditionally examine whether the p[etitioner]'s interest in the outcome of the lawsuit is substantial, direct, and immediate. *Robinson T*[*ownship v. Commonwealth*], 83 A.3d [901,] 917 [(Pa. 2013)]. "A party's interest is substantial when it surpasses the interest of all citizens in procuring obedience to the law; it is direct when the asserted violation shares a causal connection with the alleged harm; finally, a party's interest is immediate when the causal connection with the alleged harm is neither remote nor speculative." *Commonwealth, Office of Governor v. Donahue*, . . . 98 A.3d 1223, 1229 ([Pa.]2014).

FOAC, 261 A.3d at 481.

Here, because Petitioner is an association and it is the only named petitioner in this matter, asserting claims on behalf of its members, the Court must examine the concept of associational standing. "It is well settled that an association, as a representative of its members, may have standing to bring a cause of action even in the absence of injury to itself." *PSSU*, 699 A.2d at 810. As this Court has explained,

> [a]n association has standing to bring an action on behalf of its members where at least one of its members is suffering an immediate or threatened injury as a result of the challenged action. . . . To have standing on this basis, the . . . organization must allege sufficient facts to show that at least one of its members has a substantial, direct[,] and immediate interest. General descriptions of an organization's members cannot establish standing if they do not show that a member or members are sufficiently adversely affected to have standing.

Americans for Fair Treatment, Inc. v. Philadelphia Federation of Teachers, Local 3, AFL-CIO, 150 A.3d 528, 533-34 (Pa. Cmwlth. 2016) (internal citations omitted).

Moreover, "[s]tanding may be shown without identification of individual members, but only where the [petition]'s description of the organization's members is sufficient to show that they are aggrieved." *Id.* at 534-35 (citations omitted).

The Court is satisfied that the allegations here are sufficient to establish that Petitioner has standing. Mr. Woloveck testified that he is the Chief Commercial Director of Jushi, the parent corporation of several permitted MMOs, including both grower/processor and dispensary permittees. Given this role, he is familiar with the innerworkings of these permittees, their day-to-day operations, as well as DOH's approval processes for specific medical marijuana products. Mr. Woloveck stated that Jushi's permitted MMOs are directly affected by the Recall because it has forced dispensary members to pull medicine from their shelves and return it to grower/processor members, who in turn have placed the products in quarantine. As Mr. Woloveck explained, all medical marijuana products have expiration dates and while he was not able to provide specific dates on which Jushi's recalled products will expire, it is beyond question that a number of the 670 recalled products, totalling approximately 330,000 units, will expire in quarantine absent a preliminary injunction. Moreover, both Mr. Woloveck and Mr. Ahern testified, in detail, as to the financial and reputational harm MMOs have suffered and will continue to suffer due to the Recall, harm that is unique to these organizations and which surpasses the interest of the general public. This harm includes losses for recalled products that were already on the shelves or somewhere within the production lines, disruption in sales and profits, equipment-related costs, and potential lost sales due to the adverse impact on the reputation of MMOs who sell the recalled products given DOH's statements that the products may be unsafe. Given this uncontested credible

testimony, Respondents' argument that Petitioner's asserted harms are speculative lacks merit and the Court finds that Petitioner has standing to bring this action.

B. Preliminary Injunction

The Court now turns to the merits of Petitioner's Application. A preliminary injunction is an extraordinary remedy, the purpose of which "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 Township v. Coletta*, 133 A.3d 86, 91 (Pa. Cmwlth. 2016). It is well established that a court may grant a preliminary injunction only where a petitioner demonstrates each of the following factors:

> (1) the injunction is necessary to prevent immediate and irreparable harm that cannot be compensated adequately by damages; (2) greater injury would result from refusing the injunction than from granting it, and, concomitantly, the issuance of an injunction will not substantially harm other interested parties in the proceedings; (3) the preliminary injunction will properly restore the parties to their status as it existed immediately prior to the alleged wrongful conduct; (4) the party seeking injunctive relief has a clear right to relief and is likely to prevail on the merits; (5) the injunction is reasonably suited to abate the offending activity; and, (6) the preliminary injunction will not adversely affect the public interest.

SEIU Healthcare Pennsylvania v. Commonwealth, 104 A.3d 495, 502 (Pa. 2014) (citing *Warehime v. Warehime*, 860 A.2d 41, 46-47 (Pa. 2004); *Summit Towne Centre, Inc. v. Shoe Show of Rocky Mount, Inc.*, 828 A.2d 995, 1001 (Pa. 2003)). "For a preliminary injunction to issue, every one of the [] prerequisites must be established; if the petitioner fails to establish any one of them, there is no need to address the

others." *Summit Towne Centre*, 828 A.2d at 1001 (quoting *County of Allegheny v. Commonwealth*, 544 A.2d 1305, 1307 (Pa. 1988)).

Based on the evidence adduced by the parties during the hearing, as well as the pleadings and written and oral argument on the matter, the Court concludes that Petitioner has met its burden for preliminary injunctive relief.

The Court begins with the fourth criteria necessary for a preliminary injunction—whether Petitioner has a clear right to relief and is likely to prevail on the merits. "For a right to be clear, it must be 'more than merely viable or plausible;' however, this requirement is not the equivalent of stating that no factual disputes exist between the parties." *Wolk v. School District of Lower Merion*, 228 A.3d 595, 611 (Pa. Cmwlth. 2020) (quoting *Ambrogi v. Reber*, 932 A.2d 969, 980 (Pa. Super. 2007)). Our Supreme Court has further explained that "[t]o establish a clear right to relief, the party seeking an injunction need not prove the merits of the underlying claim, but need only demonstrate that substantial legal questions must be resolved to determine the rights of the parties." *SEIU Healthcare*, 104 A.3d at 506 (citing *Fischer v. Department of Public Welfare*, 439 A.2d 1172 (Pa. 1982)). *Accord Marcellus Shale Coalition v. Department of Environmental Protection*, 185 A.3d 985, 995 (Pa. 2018) ("In the context of a motion for a preliminary injunction, only a substantial legal issue need be apparent for the moving party to prevail on the clear-right-to-relief prong.").

Here, Petitioner first argues that it has a clear right to relief because the Recall exceeds and is inconsistent with DOH's statutory authority. As Petitioner points out, Act 44 recently amended Section 702(a)(5) of the Act to expressly permit grower/processors to add excipients to their medical marijuana products. This section now provides that in determining whether to approve an added substance,

such as terpenes, DOH shall consider "[w]hether the added substance is permitted by the [FDA] for use in food or is [GRAS] under Federal guidelines." Section 702(a)(5)(i) of the Act, 35 P.S. § 10231.702(a)(5)(i). Notably absent from this newly amended statutory provision is whether the added substance is approved as safe for inhalation by the FDA, the standard DOH used in issuing the Terpene Recall Mandate here. Petitioner observes that in "[a]pplying the rules of statutory construction, the inclusion of a specific matter in a statute implies the exclusion of other matters." *Independent Oil and Gas Association of Pennsylvania v. Board of Assessment Appeals of Fayette County*, 814 A.2d 180, 184 (Pa. 2002). Petitioner has raised a substantial argument that, given the express language of the Act and the specificity of the criteria the General Assembly stated could be considered, DOH may have exceeded its statutory authority by issuing the Recall.

In a related vein, Petitioner further argues that the Recall is an unlawful *de facto* regulation that is void because it was not properly promulgated. Petitioner maintains that the Recall imposes an immediately effective industry-wide rule, namely that terpenes must be approved as safe for inhalation by the FDA in order for DOH to approve them as excipients in medical marijuana vaporization products. According to Petitioner, DOH has created a binding norm through this new mandatory rule and, therefore, DOH was required to engage in the requisite rulemaking processes.

It is well established that while regulations are subject to the formal rulemaking process,[16] "[s]tatements of policy . . . need not be subject to notice and

[16] This Court has also explained the purpose and advantages of formal rulemaking as follows:

> [t]he process by which regulations are issued provides an important safeguard for potentially affected parties against the unwise or

comment because, presumably, they only provide guidance by which administrative agency personnel carry out their power delegated to them by the General Assembly." *Department of Environmental Resources v. Rushton Mining Co.*, 591 A.2d 1168, 1171 (Pa. Cmwlth. 1991). Moreover, "interpretive rules or regulations[] which 'do not in themselves establish binding standards of conduct . . . need not be promulgated . . . to the extent they merely construe a statute and do not improperly expand upon its terms.'" *Victory Bank v. Commonwealth*, 219 A.3d 1236, 1243 (Pa. Cmwlth. 2019) (quoting *Borough of Pottstown v. Pennsylvania Municipal Retirement Board*, 712 A.2d 741, 743 (Pa. 1998)). However, "[i]f an interpre[]tive rule or statement of policy functions as a regulation, then it will be nullified due to the agency's failure to obey the processes applicable to the promulgation of a regulation." *Transportation Services, Inc. v. Underground Storage Tank Indemnification Board*, 67 A.3d 142, 154 (Pa. Cmwlth. 2013) (citing *Rushton Mining Co.*, 591 A.2d at 1171)).

Here, Petitioner raises a colorable argument that the Terpene Recall Mandate goes beyond a statement of policy and instead creates a binding norm.

> improper exercise of discretionary administrative power. This process, which includes public notice of a proposed rule, making a request for written comments by any interested party, giving due consideration to such comments, and holding hearings as appropriate affords the affected parties a democratic process for participation in the formulation of standards which govern their conduct and increases the likelihood of administrative responsiveness to their needs and concerns. Moreover, it gives the administrative agency facts and information relevant to the proposed rule, as well as opens up the agency to alternatives, detrimental effects, criticism and advice, thereby contributing to the soundness of the proposed regulation.

Department of Environmental Resources v. Rushton Mining Co., 591 A.2d 1168, 1171 (Pa. Cmwlth. 1991).

Respondents' February 4, 2022 emails to both grower/processors and medical marijuana patients specifically state that DOH has determined that certain vaporization products containing terpenes may no longer be produced and are subject to recall because they have not been approved for inhalation by the FDA. The email to grower/processors further rescinds DOH's prior approval of the products and mandates that grower/processors "**MUST follow the mandatory recall procedures outlined in 28 Pa. Code § 1151.42(c).**" Stipulation Exhibit 1 (emphasis in original). There is little air in the language used by DOH. Moreover, Respondents do not dispute that failure to follow the Recall may result in sanctions, or that the majority of the recalled products were previously approved for production and distribution by DOH. As such, Petitioner has raised a substantial legal question as to whether the Recall—specifically, Respondents' use of the standard of "approved for inhalation by the FDA"—establishes a binding norm such that DOH was required go through the formal rulemaking process.

Petitioner also raises several constitutional arguments, including that the Terpene Recall Mandate violates the vested rights of Petitioner's grower/processor and dispensary members; constitutes the taking of private property without compensation; violates due process because it went into effect prior to Petitioner's members being afforded adequate notice and an opportunity to be heard; and impugns the constitutionally protected right to reputation of Petitioner's members. Given all of the above, the Court is satisfied that Petitioner has raised several substantial legal questions which fulfill this prerequisite.

Next, Petitioner must demonstrate that an injunction is necessary to prevent immediate and irreparable harm that cannot be compensated adequately by money damages. *Summit Towne Centre, Inc.*, 828 A.2d at 1001-02. To meet this

burden, a petitioner generally must present actual proof of irreparable harm; "speculation and conjecture will not suffice." *Reed v. Harrisburg City Council*, 927 A.2d 698, 706 (Pa. Cmwlth. 2007).

As explained above, Petitioner asserts that its grower/processor and dispensary members will continue to suffer reputational harm given Respondents' statements issued in conjunction with the Terpene Recall Mandate suggesting that the recalled products are unsafe. Moreover, Petitioner argues that its members have suffered and will continue to suffer harm because Respondents' actions violate the Act and are unconstitutional. It is well established that alleged violations of constitutional rights and statutory mandates constitute irreparable harm *per se*. *See, e.g.*, *SEIU Healthcare*, 104 A.3d at 508-09; *Pennsylvania Public Utility Commission v. Israel*, 52 A.2d 317, 321 (Pa. 1947). As such, "[n]o other injury is required for an injunction provided that the other necessary ingredients to relief are present." *Northern Pennsylvania Legal Services, Inc. v. Lackawanna County*, 513 F. Supp. 678, 685 (M.D. Pa. 1981) (citing *Elrod v. Burns*, 427 U.S. 347, 373-74 (1976)).

Even though nothing else is required, Petitioner also argues that its grower/processor and dispensary members will be irreparably harmed absent a preliminary injunction because the Terpene Recall Mandate requires the immediate recall and potential expiration of more than 670 individual medical marijuana vaporization products, totaling approximately 330,000 individual units and representing a collective economic loss of more than $17 million. Petitioner further maintains that it's members invested over $9 million in the development, creation, marketing, and future distribution of the recalled products.

Respondents objected to Mr. Ahern's testimony regarding damages, arguing that such testimony is not appropriate in the context of irreparable harm for

purposes of a preliminary injunction. However, as Petitioner correctly notes, money damages are unavailable to its member entities because Respondents may be immune from such damages. Petitioner's action is one seeking a declaratory judgment. While "sovereign immunity does not bar either mandamus or declaratory judgment actions," *Brimmeier v. Pennsylvania Turnpike Commission*, 147 A.3d 954, 961 (Pa. 2016), it does apply when a party seeks to recover money damages. *Finn v. Rendell*, 990 A.2d 100, 105 (Pa. Cmwlth. 2010). Thus, where Respondents would not be liable for lost revenue, even if sufficiently proven, Petitioner's member entities are irreparably harmed because money damages are unavailable to compensate them for their losses.

For these reasons, the Court finds that Petitioner has demonstrated that a preliminary injunction is necessary to prevent immediate and irreparable harm that cannot be compensated adequately by damages.

Petitioner must also show that greater injury would result from refusing the injunction than granting it, and that issuing an injunction would not substantially harm other interested parties. *SEIU Healthcare*, 104 A.3d at 502. Further, Petitioner must demonstrate that a preliminary injunction will not adversely affect the public interest. *Id.* The Court is satisfied that a balancing of the harms weighs in favor of granting the preliminary injunction.

As discussed above, Petitioner has presented credible evidence of the significant harm its grower/processor and dispensary members have suffered and will continue to suffer if the Recall is not enjoined. Petitioner has also raised substantial constitutional and statutory issues with respect to Respondents' issuance of the Recall. The Court is cognizant of DOH's duty, under the Act, to regulate the Commonwealth's medical marijuana program in a way that enhances and promotes

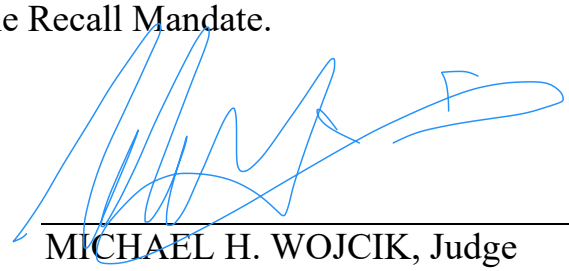
patient safety. *See, e.g.*, Section 102 of the Act, 35 P.S. § 10231.102. However, Respondents, have failed to present any evidence to the Court of potential harm to medical marijuana patients due to the recalled products, or more specifically due to the addition of terpenes to these products. Respondents did not call any witnesses during the preliminary injunction hearing or present any evidence regarding patient complaints or adverse events suffered due to the recalled products containing terpenes. To the contrary, Petitioners' witnesses testified to the lack of such evidence. At this juncture, and given the evidence presented to date, the Court concludes that the balancing of harms weighs in favor of granting the preliminary injunction. *See Summit Towne Centre Inc.*, 828 A.2d at 1003 (upholding trial court's conclusion that balancing of harms weighed in favor of granting preliminary injunction where enjoined party failed to present particular evidence of its own harm).

Further, the Court finds that Petitioner's request would maintain the "status quo," which has been defined for purposes of a preliminary injunction as "the last peaceable and lawful uncontested status preceding the underlying controversy." *Hatfield Township v. Lexon Insurance Co.*, 15 A.3d 547, 556 (Pa. Cmwlth. 2011) (quoting *In re Milton Hershey School Trust*, 807 A.2d 324 (Pa. Cmwlth. 2002)). Here, that would be the parties' status prior to DOH's issuance of the Terpene Recall Mandate. Finally, the Court finds that Petitioner's request that Respondents be enjoined from enforcing the Recall is reasonably suited to abate the offending activity.

V. Conclusion

Upon review of the evidence, the Court concludes that Petitioner has met its burden of establishing all of the necessary prerequisites for a preliminary

injunction.[17] Accordingly, the Application is granted[18] and Respondents are enjoined from enforcing the Terpene Recall Mandate.



MICHAEL H. WOJCIK, Judge

[17] In its Application, Petitioner requested that the bond required by Pa.R.Civ.P. 1531(b) for the issuance of a preliminary injunction be set at the nominal level of $100. The Court grants this request, being satisfied that no entity will sustain reasonably foreseeable damages in the event it is later determined that the requested preliminary injunction was wrongfully granted.

[18] Petitioner further requested that the Court specify in any order granting a preliminary injunction that no appeal from said order would act as an automatic supersedeas under Pa.R.A.P. 1736(b). The Court declines to grant such relief.

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Medical Marijuana Access & Patient Safety, Inc., Petitioner	:	
v.	:	No. 58 M.D. 2022
Keara Klinepeter, Acting Secretary, Pennsylvania Department of Health, John J. Collins, Director of the Pennsylvania Department of Health, Office of Medical Marijuana, and Sunny D. Podolak, Assistant Director and Chief Compliance Officer of the Pennsylvania Department of Health, Office of Medical Marijuana, Respondents	:	

O R D E R

AND NOW, this 2nd day of June, 2022, Petitioner's Application for Special Relief in the Nature of a Preliminary Injunction is GRANTED. Respondents are hereby ENJOINED from enforcing the February 4, 2022 Terpene Recall Mandate.

Pursuant to Pa.R.Civ.P. 1531(b), this Order shall become effective upon Petitioner's filing of a bond or legal tender of the United States with the Court in the amount of one hundred dollars ($100.00).

The Court SUSTAINS Respondents' objection to the rebuttal testimony of Trent Woloveck.

To the extent the Application seeks relief from Pa.R.A.P. 1736(b) pertaining to automatic supersedeas, that request is DENIED.

MICHAEL H. WOJCIK, Judge