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58 MD 2022

COMMONWEALTH COURT OF PENNSYLVANIA

No. 58 MD 2022

MEDICAL MARIJUANA ACCESS & PATIENT SAFETY, INC.,

Petitioner,

v.

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.

RESPONDENTS' POST-HEARING BRIEF

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INTRODUCTION

Four months ago, the Office of Medical Marijuana ("Office"), the office within the Pennsylvania Department of Health ("Department") that carries out the day-to-day administration of the Medical Marijuana Act ("Act"), notified grower/processors in the Commonwealth that certain medical marijuana products being offered for sale in dispensaries did not comply with the requirements of the Act and the accompanying regulations, and therefore must be recalled.[1] No grower/processor filed an administrative appeal from that action or a lawsuit challenging the action.

Almost three months later, the Office sent a similar notice to grower/processors, confirming that permittees were to initiate a recall of these products from dispensaries, and not offer the products for sale, because the products contained externally sourced ingredients not authorized by the Department for inclusion in vaporized medical marijuana products. As of the hearing in this matter, no grower/processor had filed an administrative appeal from this action either. Instead, a week after the notice was sent, a single petitioner—not a grower/processor, not a dispensary, not a medical marijuana patient, but an entity with apparently no existence outside this litigation—brought this lawsuit.

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[1] The actual respondents here are Keara Klinepeter, the Department's Acting Secretary; John J. Collins, the Office's Director; and Sunny D. Podolak, the Office's Assistant Director and Chief Compliance Officer. For ease of reference, we refer to the Office or the Department throughout this brief instead of referring to the nominal respondents.

That entity, Medical Marijuana Access & Patient Safety, Inc. ("MMAPS" or petitioner), not only challenges the Department's action regarding the vaporized products containing externally sourced ingredients not authorized by the Department, but seeks a preliminary injunction compelling the Department to allow these products to be offered for sale. Although given a full opportunity to be heard at an evidentiary hearing, petitioner has failed to prove that, absent such an injunction, it will suffer any injury—or, for that matter, and assuming it is relevant, that its putative members would suffer any injury—let alone an injury that would occur immediately without an injunction. Nor has petitioner demonstrated that its right to relief is clear. Because petitioner has not met its burden of proof for obtaining the extraordinary relief of a preliminary injunction, its application should be denied.

FACTUAL BACKGROUND

The Medical Marijuana Act. The Medical Marijuana Act became law on April 17, 2016, and was effective one month later.[2] The Act was amended less than a year ago by Act 44 of 2021.[3] While a primary aim of the Act is to offer a "potential therapy that may mitigate suffering in some patients and also enhance quality of

[2] Stipulations ¶ 10 (filed Feb. 25, 2022) ["Stip."]; *see* Act of Apr. 17, 2016, P.L. 84, No. 16.

[3] Stip. ¶ 12; *see* Act of June 30, 2021, P.L. 210, No. 44.

life,"[4] patient safety is a paramount consideration of the Act.[5] Indeed, the first intent of the legislature described in the Act is to 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."[6]

The Department is tasked with implementing and administering the Act.[7] More specifically, it is charged with issuing grower/processor and dispensary permits, as well as "ensuring medical marijuana businesses comply with the Medical Marijuana Act, and registering practitioners; it also has regulatory and enforcement authority over the growing, processing, sale, and use of medical marijuana."[8] The Department's authority, of course, is limited to the Commonwealth.[9]

The Department may conduct announced or unannounced inspections "of a medical marijuana organization's site, facility, vehicles, books, records, papers, documents, data, and other physical or electronic information," as well as "a grower/processor facility's equipment, instruments, tools and machinery that are

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[4] 35 P.S. § 10231.102(1).

[5] *See, e.g.*, *id.* § 10231.102(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.").

[6] *Id.* § 10231.102(3)(i).

[7] *McKelvey v. Pa. Dep't of Health*, 255 A.3d 385, 398 (Pa. 2021).

[8] *Id.*

[9] *See, e.g.*, 35 P.S. § 10231.301(a)(3) ("The department shall … [h]ave regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana *in this Commonwealth*." (emphasis added)).

used to grow, process and package medical marijuana, including containers and labels."[10] Again, this authority is limited to organizations, facilities, equipment, and so forth within the Commonwealth. The Department's other powers include requiring a medical marijuana organization to cease selling or to quarantine certain medical marijuana products.[11]

Under the Act, grower/processors must recall any product that "poses a risk to public health and safety."[12] A medical marijuana organization may challenge an action of the Office of Medical Marijuana by filing an appeal to the Department within 30 days of receiving notice of the action,[13] and if aggrieved by the Department's adjudication of the appeal, the organization may appeal to this Court.[14]

A provision of the Act added by Act 44 authorizes grower/processors to obtain "all unfinished [medical marijuana] plant and plant-derived material," "from another grower/processor *within this Commonwealth* to process medical marijuana."[15] Act 44 also added a provision authorizing grower/processors, "in accordance with department regulations," to add certain ingredients to medical

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[10] 28 PA. CODE § 1141.45(a)-(b).

[11] *Id.* § 1141.47(a)(5).

[12] *Id.* § 1151.42(c).

[13] *Id.* §§ 1230.38, .39; *see also id.* § 1141.47(d).

[14] 2 PA. C.S. § 702.

[15] 35 P.S. § 10231.702(a)(2.1) (emphasis added).

marijuana, so long as those ingredients are "pharmaceutical grade" or "approved by the department."[16] This provision indicates:

> 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 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.[17]

Grower/processors must obtain approval from the Department to add any ingredient to medical marijuana "that alters the dosage level, color, appearance, smell, taste, effect or weight of the medical marijuana."[18]

The Current Dispute. Medical marijuana in Pennsylvania comes in a number of forms, including "a form medically appropriate for administration by vaporization."[19] This form of medical marijuana accounts for about a third of the medical marijuana used in Pennsylvania.[20] Approximately half of the vaporized

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[16] *Id.* § 10231.702(a)(5). The Act actually uses the term "excipients," rather than ingredients. Excipients are defined by the Act as "Solvents, chemicals or materials reported by a medical marijuana organization and approved by the department for use in the processing of medical marijuana." *Id.* § 10231.103.

[17] *Id.* § 10231.702(a)(5).

[18] 28 PA. CODE § 1151.27(f).

[19] 35 P.S. § 10231.303(b)(2)(iv).

[20] Stip. ¶ 11; Hearing Tr. 46:15-19.

products used in Pennsylvania (and thus, roughly 15-20% of the total medical marijuana in use in the Commonwealth) is at issue in this dispute.[21]

On November 16, 2021, the Department wrote to grower/processors, informing them that the Department 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)."[22] The Department required "every grower/processor to submit for approval each vaporized product that contains additional ingredients, even if the product had previously been approved."[23] Because the Department's review was "limited to inhaled products," the Department informed grower/processors that, in submitting products for approval, they did not need to indicate whether an ingredient "is permitted by the United States Food and Drug Administration for use in food or is generally recognized as safe under federal guidelines," under Section 702(a)(5) of the Act.[24]

In the November 16 email, the Department also informed grower/processors that, "[r]egardless of the Department's review, you have a responsibility to ensure patient safety. If you are producing any vaporized medical marijuana products that

[21] Hearing Tr. 47:6-9.

[22] Hearing Exh. S-3.

[23] *Id.*

[24] *Id.*

contain additional ingredients that are not approved by the FDA for inhalation, you MUST recall these products pursuant to 28 Pa. Code 1151.42(c)."[25] No grower/ processor filed an administrative appeal from the Department's initiation of the review of vaporized products with added ingredients or its statement that products containing additional ingredients not approved by the FDA for inhalation must be recalled.[26]

On February 4, 2022, eighty days after sending its initial notice regarding additional ingredients in vaporized products, the Department sent notice to grower/ processors whose products contained additional ingredients that had "not been approved for inhalation by the United States Food and Drug Administration."[27] In those emails, the Department informed these grower/processors that the vaporized products that included these unapproved ingredients "meet the conditions for recall under 28 Pa. Code § 1151.42(c)(1)," and that the grower/processors "MUST follow the mandatory recall procedures outlined in 28 Pa. Code § 1151.42(c)."[28]

The Department explained that the "rationale" for its determination regarding these products was the Act's focus on "patient safety," as well as Act 44's requirement that additional ingredients be either pharmaceutical grade or approved

[25] *Id.* (capitalization in original).

[26] Hearing Tr. 103:19-107:15.

[27] Hearing Exh. S-1.

[28] *Id.* (capitalization in original; bold lettering omitted).

by the Department.[29] In an email sent to patients and caregivers the same day, the Department explained that, following its review initiated in November, "the Department has determined that certain vaporized medical marijuana products containing some added ingredients have not been approved for inhalation by the [FDA]."[30]

The notice to the grower/processors informed them that they could appeal the Department's action in accordance with chapter 1230 of title 28 of the Pennsylvania Code, and it attached a list of the products that were affected by the notice.[31] As of the hearing in this matter, no affected grower/processor had filed an administrative appeal from the Department's February 4, 2022 action.[32] Rather, petitioner MMAPS filed this original action, seeking a preliminary injunction, declaratory relief, and a permanent injunction, that would require the Department to authorize the products subject to recall to be placed back on the market and to allow vaporized products with externally sourced terpenes to be produced and sold in the future.

The Evidentiary Hearing. This Court held an evidentiary hearing on petitioner's application for a preliminary injunction on February 24 and 28, 2022.

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[29] *Id.* (citing 35 P.S. §§ 10231.102(2), (3), .702(a)(5)).

[30] Hearing Exh. S-7.

[31] Hearing Exh. S-1; *see also* Hearing Exh. P-1 (list of withdrawn products).

[32] Hearing Tr. 81:8-17, 102:20-103:7.

As discussed below, petitioner has the burden of proving the existence of all six requirements for a preliminary injunction. In attempting to meet that burden, petitioner offered four witnesses at the hearing—one fact witness and three expert witnesses.

Petitioner's lone fact witness, Trent Woloveck, is the chief commercial director of Jushi Holdings, an entity that does not hold a permit to operate dispensaries or act as a grower/processor in Pennsylvania, but is the parent company of certain permittees.[33] Mr. Woloveck testified that he was "authorized to speak on behalf of MMAPS,"[34] but he did not know whether MMAPS is registered to do business in Pennsylvania, did not know when MMAPS was created, did not know where MMAPS was located, and could offer no specifics on how MMAPS is funded.[35]

Mr. Woloveck testified that the recalled products "have expiration dates," but petitioner did not elicit any details during Mr. Woloveck's direct testimony regarding those expiration dates.[36] Mr. Woloveck later testified on cross-examination that the recalled products have an expiration date one year from "final testing and labeling,"[37] but that he had no information on the actual expiration

[33] *Id.* at 34:5-14, 88:24-89:19.

[34] *Id.* at 37:13-15.

[35] *Id.* at 92:12-15, 93:20-95:17.

[36] *Id.* at 44:12-15.

[37] *Id.* at 98:22-99:15.

dates for any recalled products.[38] He did not know if any of the recalled products expired in one week, in one month, in three or four or five months, or in a year.[39]

Mr. Woloveck also conceded that he had no knowledge whether any patients who may have used the recalled products had switched to other medical marijuana products, whether other vaporized products not included in the recalls or other, non-vaporized products.[40]

Petitioner called two scientific expert witnesses to testify, Dr. Shawna Vreeke, a Ph.D. in chemistry who works for a terpene supplier, and Dr. Suzanne Sisley, a doctor who studies the medical benefits of cannabis.

Dr. Vreeke works for and has an ownership interest in a for-profit terpene company that supplies terpenes to Pennsylvania grower/processors, including for some of the recalled products.[41] Dr. Vreeke testified that her company's products are used in food,[42] but she conceded that an ingredient deemed safe by the FDA for ingestion as food is not necessarily safe for inhalation.[43] Although Dr. Vreeke testified that she considered her company's terpene products "pharmaceutical

[38] *Id.* at 99:16-102:10.

[39] *Id.* at 100:18-101:16.

[40] *Id.* at 89:20-90:11, 91:10-92:1.

[41] *Id.* at 131:18-25, 153:17-155:12.

[42] *Id.* at 132:6-16.

[43] *Id.* at 164:17-23, 167:1-9.

grade," she acknowledged that there is "actually not a clear definition on what pharmaceutical grade is."[44]

Dr. Vreeke testified that her company's terpene products "undergo testing prior to sale to medical marijuana manufacturers,"[45] but she admitted that other terpene companies may not do similar testing and they do not typically have someone such as her employed in a scientific role.[46] Dr. Vreeke also had no explanation for her company's express warning that its terpene products that are safe in food products have "not been evaluated for safe use in e-cigarettes or any vaping application where the product is/are intentionally vaporized and inhaled."[47] As she conceded, this is precisely the use of the products that are at issue here.[48]

Dr. Sisley is an internal medicine physician and cannabis researcher.[49] While Dr. Sisley is required to identify for the FDA all of the terpenes (and their amounts) in the products she studies as part of her FDA-approved cannabis

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[44] *Id.* at 132:17-133:3. Neither the Federal Food, Drug, and Cosmetic Act nor the FDA's regulations define "pharmaceutical grade," although the regulations include guidance regarding good manufacturing practice for drug products. *See* 21 C.F.R. pts. 210, 211.

[45] Hearing Tr. 138:6-13.

[46] *Id.* at 173:13-174:4, 175:8-176:1.

[47] *Id.* at 180:3-25.

[48] *Id.* at 180:18-25. Although the Court took a break to give Dr. Vreeke additional time to review her company's warnings about the use of its terpenes in vaporized products, *id.* at 186:20-187:23, 188:12-189:4, petitioner asked Dr. Vreeke no questions on this subject on re-direct, *id.* at 194:11-20.

[49] *Id.* at 199:4-200:9.

research,[50] she acknowledged that, because the FDA does not regulate the medical marijuana products used by Pennsylvania patients,[51] it does not have any oversight of the terpenes in any vaporized products used by these patients.[52]

Dr. Sisley conceded that a cannabis-derived terpene would have the same alleged medicinal properties as an identical non-cannabis-derived terpene,[53] but some grower/processors prefer the externally sourced terpenes over cannabis-derived terpenes because "it is much less expensive and a reasonable source of terpenes to simply acquire these terpenes … from extracting from citrus peels and things like that … where you can get a much less expensive version."[54]

Petitioner's final witness, Jon Ahern, testified as an "expert in analyzing accounting financial and economic issues, including business valuation and calculating damages."[55] He was "tasked with evaluating the terpene recall mandate vis-à-vis damages to the Petitioner's members."[56] Mr. Ahern conceded that he did

[50] *Id.* at 228:14-229:14.

[51] *Id.* at 230:1-6, 252:18-253:23.

[52] *Id.* at 256:5-11, 258:18-22.

[53] *Id.* at 259:7-21.

[54] *Id.* at 216:1-8.

[55] *Id.* at 277:1-4.

[56] *Id.* at 280:20-22.

not evaluate any alleged "damages" or injury to MMAPS itself, as opposed to its members.[57]

During his direct testimony, Mr. Ahern did not disclose the sources of any of the information on which he purportedly relied in developing his opinions, and, when asked to disclose them on cross-examination, petitioner vehemently objected, calling the information "irrelevant."[58] Although Mr. Ahern eventually was compelled to disclose the companies that provided him with financial information,[59] neither he nor any other witness presented the specific financial information on which his analysis allegedly was based.[60] Rather, he simply testified generally that "I relied upon financial information that was provided to me from five of the MMAPS members," including "summaries and evidence of what they perceived to be harm and how they saw damages or the economic impact," and "sales data and recall data and product data and margin data," and "a little bit

[57] *Id.* at 348:19-349:11.

[58] *Id.* at 334:13-336:1.

[59] *Id.* at 341:21-342:20.

[60] When asked whether he presented any evidence of specific financial information, petitioner's lone fact witness, Mr. Woloveck, testified, "I don't—I don't—I don't recall specifically, but I—*I did talk to general—general statements* around the economic of—of selling medicine to the patients of Pennsylvania." *Id.* at 414:1-9 (emphasis added).

more."[61] He also "had discussions to make sure that I understood the data that I had been provided with from each of the five companies."[62]

Mr. Ahern also opined that petitioner's members suffered reputational harm from the Department's action,[63] though he conceded that he had conducted no consumer survey regarding the members' reputations before and after the Department's action,[64] and he offered no basis for his supposed expertise regarding reputational harm.

Mr. Ahern's ultimate opinion was that the Department's action caused unidentified MMAPS' members "damages between $17 and $18 million," based on undisclosed financial information known only to Mr. Ahern.[65] Because petitioner offered no factual evidence to support Mr. Ahern's opinion regarding petitioner's "damages," respondents moved to strike Mr. Ahern's testimony.[66]

After petitioner rested its case, the hearing was continued on February 28, 2022.[67] Respondents chose not to put on any evidence and, after they rested,[68] and

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[61] *Id.* at 284:8-285:4.

[62] *Id.* at 285:8-11.

[63] *Id.* at 298:15-300:4, 317:3-318:10.

[64] *Id.* at 347:6-348:8.

[65] *Id.* at 292:18-20.

[66] *Id.* at 359:16-360:10.

[67] *Id.* at 359:7-8.

[68] *Id.* at 400:14-401:8.

over their objections,[69] petitioner put Mr. Woloveck back on the stand as a "rebuttal" witness. The basis for petitioner's purported rebuttal testimony was respondents' cross-examination of Mr. Ahern,[70] which obviously occurred before petitioner had rested its case in chief.[71] During the "rebuttal," petitioner asked Mr. Woloveck to identify "some of the other members" of MMAPS besides the five that Mr. Ahern had been forced to identify, but the only one Mr. Woloveck identified was a Jushi subsidiary, Pennsylvania Medical Solutions,[72] that he already had identified in his original testimony.[73]

ARGUMENT

As a threshold matter, this Court does not have jurisdiction over this petition for review and thus, petitioner's request for a preliminary injunction fails at the outset. As the Supreme Court often has noted, "where an adequate administrative process is available, a party may not forgo that process in favor of seeking judicial relief. Instead, the party must first exhaust its administrative remedies before proceeding

[69] *Id.* at 403:25-404:16, 406:13-407:4.

[70] *Id.* at 406:4-9, 408:12-15.

[71] "As a general rule a party cannot claim as a right to give as evidence in rebuttal that which he might have given in chief." *Daddona v. Thind*, 891 A.2d 786, 813 (Pa. Cmwlth. 2006) (internal quotation omitted).

[72] Hearing Tr. 408:12-409:1.

[73] *Id.* at 34:5-8.

to court."[74] As the court has explained, "exhaustion of administrative remedies is a prerequisite to the court's exercise of subject-matter jurisdiction."[75]

The grower/processors affected by the November 16, 2021 and February 4, 2022 actions had a right under the Act and the applicable regulations to appeal to the Department's Secretary within 30 days.[76] In that appeal, they could have raised the same challenge that petitioner seeks to raise here on their behalf—that the Department should not have determined that the affected products do not meet the criteria for approval under the Act and its regulations. If unsatisfied with the results of that administrative appeal, they could have appealed to this Court.[77] Petitioner offered no evidence that any grower/processor availed itself of this opportunity and thus, this Court therefore lacks jurisdiction over this matter. This is sufficient ground alone to deny petitioner's request for a preliminary injunction.

Petitioner may claim that *it* could not have filed an administrative appeal because *it* is not a grower/processor, but such a contention would only highlight other flaws in petitioner's case relating to its lack of standing, which are discussed below. The bottom line is that petitioner cannot, at the same time, claim to

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[74] *SEPTA v. City of Phila.*, 101 A.3d 79, 90 (Pa. 2014) (citation omitted).

[75] *White v. Conestoga Title Ins. Co.*, 53 A.3d 720, 726 n.11 (Pa. 2012) (internal quotation omitted).

[76] 28 PA. CODE §§ 1230.38, .39, 1141.47(d).

[77] 2 PA. C.S. § 702.

represent grower/processors and then disclaim any connection to them when they are challenged for failing to exhaust statutory remedies available to them. In short, the parties directly affected by the action challenged here—the grower/processors who were informed that certain of their products had to be removed from the medical marijuana market and could not be placed back on the market—could have appealed, and were required to appeal, that action before coming to court. This case should be dismissed for this threshold defect, which deprives this Court of jurisdiction over it.

* * * *

If the Court determines that it does have jurisdiction, the request for preliminary injunction still should be denied. Petitioner seeks a court order compelling the Department to authorize grower/processors and dispensaries to sell certain medical marijuana products that, at least as of February 4, 2022, have not been approved for sale by the Department. Petitioner also seeks a court order compelling the Department to remain silent regarding the safety of these products. It thus asks this Court to "command the performance of some positive act," which amounts to the entry of a mandatory injunction.[78] A mandatory preliminary injunction is "an

[78] *Mazzie v. Commonwealth*, 432 A.2d 985, 988 (Pa. 1981).

extraordinary remedy that should be utilized only in the rarest of cases."[79] This is not one of those rare cases.

The requirements for entry of a preliminary injunction are well established:

> First, a party seeking a preliminary injunction must show that an injunction is necessary to prevent immediate and irreparable harm that cannot be adequately compensated by damages. Second, the party must show that greater injury would result from refusing an injunction than from granting it, and, concomitantly, that issuance of an injunction will not substantially harm other interested parties in the proceedings. Third, the party must show that a preliminary injunction will properly restore the parties to their status as it existed immediately prior to the alleged wrongful conduct. Fourth, the party seeking an injunction must show that the activity it seeks to restrain is actionable, that its right to relief is clear, and that the wrong is manifest, or, in other words, must show that it is likely to prevail on the merits. Fifth, the party must show that the injunction it seeks is reasonably suited to abate the offending activity. Sixth and finally, the party seeking an injunction must show that a preliminary injunction will not adversely affect the public interest.[80]

"For a preliminary injunction to issue, *every one* of these prerequisites must be established; if the petitioner fails to establish any one of them, there is no need to address the others."[81] As the Supreme Court reiterated just last year, these six conditions are "essential prerequisites" for issuance of a preliminary injunction.[82]

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[79] *Summit Towne Ctr., Inc. v. Shoe Show of Rocky Mt., Inc.*, 828 A.2d 995, 1005 n.13 (Pa. 2003).

[80] *Id.* at 1001 (citations omitted).

[81] *County of Allegheny v. Commonwealth*, 544 A.2d 1305, 1307 (Pa. 1988) (emphasis in original); *see also Wyland v. West Shore Sch. Dist.*, 52 A.3d 572, 582-83 (Pa. Cmwlth. 2012) ("The Supreme Court consistently holds that 'for a preliminary injunction to issue, *every one* of these prerequisites must be established; if the petitioner fails to establish any one of them, there is no need to address the others.'" (emphasis in original) (citation omitted)).

[82] *Pittsburgh Logistics Sys. v. Beemac Trucking, LLC*, 249 A.3d 918, 934 n.7 (Pa. 2021).

Petitioner's request for a preliminary injunction should be denied because it has not proved, among other things, that (1) *any injury* would result from refusing an injunction; (2) an injunction is necessary to prevent *immediate and irreparable harm*; and (3) petitioner's right to relief is clear—*i.e.*, it is *likely to prevail* on the merits of its claims.[83]

I. Petitioner has not offered any evidence that *it* will suffer any injury without an injunction and it has not demonstrated that its purported members will suffer any injury either.

The Court need not determine whether greater injury would result from refusing an injunction than from granting it, because petitioner has not shown that it will suffer *any* injury. Even if petitioner could meet its burden by relying on injury to its putative members, its request should be denied because it also has not proved that its supposed members would suffer any injury either.

A. Petitioner did not offer any evidence that petitioner itself will suffer any injury without an injunction or, for that matter, that petitioner even exists.

Petitioner failed to prove that it even exists—the most basic requirement for bringing suit—let alone prove that it is entitled to the extraordinary relief it seeks. Its sole fact witness was unable to say whether MMAPS is registered to do business in Pennsylvania, when it was created, where it was located, and how it

[83] The Department does not concede that petitioner has proved that the remaining three requirements for a preliminary injunction are met, but the Court need not address these requirements because petitioner must prove that *each* prerequisite is met. Petitioner has failed to do so with regard to at least three of the prerequisites for a preliminary injunction.

was funded.[84] No evidence was offered regarding its bylaws, corporate purpose, list of members, governance structure, or funding.

Petitioner does not allege in its petition for review whether MMAPS is a domestic or a foreign corporation.[85] There is no evidence that MMAPS has either filed articles of incorporation as a domestic corporation or registered to do business as a foreign association with the Pennsylvania Department of State, one of which is required for it to bring this action.[86] To all appearances, MMAPS does not exist and was invented for the sole purpose of bringing this action. As such, it has no capacity to sue and no standing to seek a preliminary injunction.[87]

In addition to its failure to prove its own existence and capacity to sue, petitioner offered no evidence that *it* will suffer any injury if an injunction is not entered. Neither its authorized representative nor its "damages" expert could point

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[84] Hearing Tr. 92:12-15, 93:20-95:17.

[85] Pet. for Review ¶ 20.

[86] *See* 15 PA. C.S. § 5309(a) (domestic nonprofit corporation has no corporate existence until articles of incorporation are filed with Department of State); *id.* § 5502(a)(2) (domestic nonprofit corporation has power to sue); *id.* § 411(a)-(b) (foreign filing association "may not maintain an action or proceeding in this Commonwealth unless it is registered to do business under this chapter"); *id.* § 102(a) (foreign filing associations include nonprofit corporations); *see also* https://www.corporations.pa.gov/Search/CorpSearch (Department of State business entity search page).

[87] *See, e.g.*, *In re Estate of Sauers*, 32 A.3d 1241, 1248-49 (Pa. 2011) (discussing standing and capacity to sue); *Drake Mfg. Co. v. Polyflow, Inc.*, 109 A.3d 250, 260-61 (Pa. Super. 2015) (foreign corporation that did not prove that it was registered to do business in the Commonwealth lacked capacity to sue).

to any harm that would befall MMAPS itself if an injunction is not granted.[88] Rather, petitioner attempted to prove its case by pointing to supposed harm to *its putative members* if an injunction is not granted. But an entity complaining of an injury "on behalf of its membership" instead of itself is on "a different footing" from its members, in terms of standing to seek a preliminary injunction.[89]

Thus, petitioner's failure to prove that *it* faces injury in the absence of an injunction is another fatal flaw in its request for a preliminary injunction.

B. Even if petitioner could rely on an injury to its members, it still has not demonstrated that any of its purported members would suffer an injury without an injunction.

Even if petitioner could prove the preliminary injunction requirement of an injury by demonstrating that *its members* would suffer such an injury without an injunction, its request for an injunction still would fail.

As an initial matter, petitioner's failure to demonstrate that it has legal existence and standing (discussed above, in Section I.A) obviously dooms its preliminary injunction request, whatever injury its purported members would face. Even aside from this threshold flaw, petitioner presented *no factual evidence* supporting its contentions (or supporting the opinions of its damages expert) regarding the impact of the Department's action on purported MMAPS members.

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[88] Hearing Tr. 95:18-98:21, 348:19-349:11.

[89] *Indep. State Store Union v. Pa. Liquor Control Bd.*, 432 A.2d 1375, 1380 n.* (Pa. 1981).

Petitioner offered only one fact witness, an executive of a holding company that is not itself a permittee.[90] That witness did not offer any specific fact testimony regarding financial harm that any MMAPS member would suffer if an injunction is not granted.[91] Moreover, not a single witness from an actual grower/processor or dispensary affected by the Department's action, let alone any of the putative (but not identified) patient or doctor members, testified at the preliminary injunction hearing.[92]

Instead, petitioner offered expert testimony regarding "damages" and argued that this was sufficient to demonstrate as a factual matter the financial impact of the Department's action.[93] In fact, even petitioner's expert failed to present any details of the alleged financial impact on MMAPS' supposed members[94]—indeed, petitioner resisted disclosing even the *sources* of the financial information on which its expert relied.[95] But even if petitioner's expert *had* disclosed the specific

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[90] Hearing Tr. 34:5-14, 88:24-89:19.

[91] *Id.* at 414:1-9.

[92] *See* 35 P.S. § 10231.103 (defining grower/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 act to grow and process medical marijuana" (emphasis added)); *id.* (defining dispensary as a "person, including a natural person, corporation, partnership, association, trust or other entity, or any combination thereof, *which holds a permit issued by the department* to dispense medical marijuana" (emphasis added)).

[93] Hearing Tr. 335:14-336:6.

[94] *Id.* at 284:8-285:4.

[95] *Id.* at 335:15-336:1 ("I'll remind you that hearsay is admissible for experts to form their opinions. Who gave the information is irrelevant. He's already testified, and you vetted it and found it to be accurate for his purposes. So, whomever—the identity of the entities that gave the

financial information on which he relied, it would not constitute the admissible factual evidence that petitioner was required to present in order to prove that harm would befall its members if an injunction was not issued.[96]

The Supreme Court has repeatedly held that expert testimony, standing alone, is insufficient to support an expert's opinions; rather, the record must contain the actual facts on which the expert relied:

> The salient facts relied upon as the basis of the expert opinion *must be in the record* so that the jury may evaluate the opinion. At the heart of any analysis is *the veracity of the facts* upon which the expert's conclusion is based. *Without the facts*, a jury cannot make any determination as to [the] validity of the expert's opinion.[97]

This admonition is as true here as in a jury trial. The "salient facts" on which petitioner's damages expert relied must be in the record so that this Court can evaluate the expert's opinion. Mr. Ahern testified that "I believe that the data that I—that I reviewed and relied upon was reliable and sufficient."[98] But this is a

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information is largely irrelevant here."). *But see* PA. R. EVID. 705 ("If an expert states an opinion the expert must state the facts or data on which the opinion is based.").

[96] *See, e.g.*, *Commonwealth v. Smith*, 861 A.2d 892, 896-97 (Pa. 2004) (holding that factual information testified to by expert does not constitute "a fact of record"); *McMurdie v. Wyeth*, No. 1386, 2005 Phila. Ct. Com. Pl. LEXIS 336, at *47 (July 14, 2005) ("[C]ounsel may not bootstrap factual material into a case through opinion evidence. Expert opinion itself cannot establish any case specific fact.").

[97] *Lower Makefield Twp. v. Lands of Dalgewicz*, 67 A.3d 772, 776 n.5 (Pa. 2013) (citing *Commonwealth v. Rounds*, 542 A.2d 997, 999 (Pa. 1988)) (emphasis added); *see also City of Phila. v. WCAB (Kriebel)*, 29 A.3d 762, 771 (Pa. 2011) ("While an expert may base his opinion on facts of which he has no personal knowledge, those facts must be supported by record evidence.").

[98] Hearing Tr. 291:6-9.

determination that must be made by the finder of fact, not the expert himself. An expert cannot shield from scrutiny the data or facts on which he relied and then establish their reliability solely on the basis of his own say-so. If the actual facts on which the expert relied are not in the record, the finder of fact—here, the Court—"cannot make any determination as to [the] validity of the expert's opinion."[99] In such circumstances, the expert's opinion has no foundation and should be stricken or given no weight.[100]

While petitioner claims to have patient members and alluded at the hearing to alleged harm to these members, it offered no evidence of such membership, presented no patient witnesses, and introduced no factual evidence regarding the effect of the Department's action on patients.[101] Instead, it once again relied on expert testimony—in this instance, Dr. Sisley's testimony that patients would suffer without the recalled products because they allegedly would not use one of

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[99] *Lower Makefield Twp.*, 67 A.3d at 776 n.5.

[100] At the preliminary injunction hearing, petitioner cited *Bolus v. United Penn Bank*, 525 A.2d 1215 (Pa. Super. 1987), in support of its contention that an expert need not even disclose the sources of the information on which he relied for his opinion. Hearing Tr. 340:13-341:1. In *Bolus*, the business records on which the expert relied *were* admitted into evidence, 525 A.2d at 1226-27, and the court specifically noted that "since these records were admitted into evidence in this case, there is very little chance that [the expert's] reliance on them could have prejudiced the Bank since they were thus available to the jury to use in evaluating the credibility of [the expert's] testimony." *Id.* at 1227. This is the precisely the point: without admission of the underlying business records—none of which were admitted here—the finder of fact cannot evaluate the credibility of the expert's testimony.

[101] Petitioner's sole fact witness conceded that he did not know whether patients who previously used one of the recalled products switched to another vaporized product or a non-vaporized medical marijuana product. Hearing Tr. 89:20-90:11, 91:10-92:1.

the many other vaporized products still on the market or possibly a non-vaporized medical marijuana product.[102] The same law outlined above, however, leads to the same conclusion—petitioner's failure to offer a single stitch of factual evidence of the actual effect of the Department's action on patients renders its expert's vague, generalized testimony foundation-less and irrelevant.

In short, even if petitioner could rely on injury to its purported members to meet this element of the preliminary injunction test, it has failed to offer any such evidence.

II. Petitioner has not demonstrated that it will suffer *immediate and irreparable* harm if an injunction is not granted.

Aside from petitioner's failure to demonstrate *any* injury, it also has not shown that any purported injury would be immediate and irreparable because the recalled products are being quarantined rather than destroyed and petitioner offered no evidence that their expiration date is imminent.

At the hearing, the Department represented that, pending resolution of this litigation, it would not require the grower/processors to destroy the recalled products that they are quarantining.[103] Following the hearing, the Court entered an Order providing that, consistent with the Department's representation, recalled products "may be held in quarantine and destruction will not occur until the

[102] *Id.* at 243:23-247:11.

[103] *Id.* at 369:14-371:10.

conclusion of this matter."[104] Thus, the products remain available for sale if petitioner should ultimately prevail in this litigation.

Petitioner did not even attempt to show that any (let alone all) of the recalled products will expire imminently or before this litigation is concluded. Other than asking its lone fact witness whether the products expire,[105] petitioner offered no evidence on this critical issue. On cross-examination, this witness acknowledged that the products expire one year from their final testing and labeling, but he conceded that he had no information on when any of the products at issue actually expire.[106]

Petitioner thus failed to prove that the recalled products that are the basis for this entire litigation are in danger of being permanently lost in the near future—or at any point shorter than a little less than a year. Petitioner, therefore, cannot meet the requirement for a preliminary injunction that an injunction is necessary to prevent *immediate and irreparable* harm.

III. Petitioner has not demonstrated that it has a clear right to relief, *i.e.*, that it is likely to prevail on the merits of its claims.

The Court can, and should, deny petitioner's request for a preliminary injunction on any one or more of the bases set forth above: (1) the Court lacks

[104] Mar. 1, 2022 Order.

[105] Hearing Tr. 44:12-15.

[106] *Id.* at 98:22-102:10.

jurisdiction because of the failure to exhaust administrative remedies; (2) petitioner lacks the capacity to sue and lacks standing to bring this case and to seek a preliminary injunction; (3) petitioner has not proved that it will suffer an injury if an injunction is not entered; (4) petitioner has not proved that its purported members will suffer an injury if an injunction is not entered; and (5) petitioner has not proved that any alleged injury would be immediate and irreparable.

Should the Court proceed further, however, it also should hold that petitioner has not met the requirement for a preliminary injunction that it prove a clear right to relief—that it is likely to prevail on the merits of its claims. While petitioner raises seven different claims, at the heart of its case is its contention that the Department did not have the authority to take the action it took and that its criteria for not approving certain vaporized products—that they contain externally sourced terpenes not deemed safe for inhalation by the FDA—is improper. Petitioner is wrong, but, at a minimum, it cannot show that it is likely to prevail on this claim (or its other claims).

A. Petitioner cannot show that it is likely to prevail on its foundational claim that the Department's action was not proper.

The Department is charged with the task of administering the Medical Marijuana Act and ensuring, through its regulatory and enforcement authority, that medical marijuana businesses comply with the Act and do not put patient safety at

risk.[107] An agency charged with administering a law is given great discretion in carrying out its duties; as relevant here, an agency's actions in this regard may be reversed by a court only where they are not authorized by law—*i.e.*, the governing statute does not permit the agency's actions or those actions constitute "bad faith, fraud, capricious action or abuse of power."[108] Petitioner cannot show that it is likely to prevail on either point.

1. The Department's action is authorized by the Medical Marijuana Act and its regulations.

The heart of petitioner's argument is that the Medical Marijuana Act does not permit the Department to use the criteria it has relied on to determine that the vaporized medical marijuana products at issue here should not be approved for sale to patients. The Court should reject petitioner's cramped and unreasonable reading of the law.

"The object of all interpretation and construction of statutes is to ascertain and effectuate the intention of the General Assembly."[109] The Supreme Court often has invoked the "well-settled principle that the interpretation of a statute by those charged with its execution is entitled to great deference, and will not be overturned

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[107] *See, e.g.*, *McKelvey v. Pa. Dep't of Health*, 255 A.3d 385, 398 (Pa. 2021); *see also* 35 P.S. § 10231.102(2).

[108] *Malt Beverages Distribs. Ass'n v. Pa. Liquor Control Bd.*, 8 A.3d 885, 892 (Pa. 2010) (quoting *Slawek v. State Bd. of Med. Educ. & Licensure*, 586 A.2d 362, 365 (Pa. 1991)).

[109] 1 PA. C.S. § 1921(a).

unless such construction is clearly erroneous."[110] The Department's interpretation of the Act as permitting it to consider the paramount concern of patient safety when establishing criteria for approval of vaporized products containing additives is not clearly erroneous; indeed, it is eminently reasonable.

First, the legislature's concern for ensuring that patient safety is protected upon the introduction of a brand-new medical product to the Commonwealth is patent: "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."[111]

As discussed below (in Section III.A.2), much of petitioner's case is focused on arguing that the Department has been *too cautious* in acting to ensure patient safety. But petitioner cannot fault the Department for taking steps to ensure patient safety, which is an express and primary goal of the Act. Moreover, applicable regulations (that are not challenged here) require the recall of any product that "poses a risk" to patient health or safety, not simply products that are known with certainty to be unhealthy or unsafe,[112] thus authorizing the Department to be pro-active when it carries out the legislature's intent regarding patient safety.

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[110] *Estate of Wilson v. State Emps. Ret. Bd.*, 219 A.3d 1141, 1151 (Pa. 2019) (internal quotation and brackets omitted).

[111] 35 P.S. § 10231.102(2).

[112] 28 PA. CODE § 1151.42(c).

While providing "access to medical marijuana" is another key goal of the Act,[113] the Department's action that petitioner challenges hardly forecloses such access—about half of the vaporized medical marijuana products on the market prior to the Department's action remain available to patients and approximately 80-85% of all medical marijuana products previously on the market remain available as well.[114]

Second, the specific terms of the Act and its regulations plainly authorize the Department's actions. Petitioner's argument ultimately turns on a single word that petitioner adds to the Act but which the legislature omitted: "only."[115]

Petitioner acknowledges that the Act, as amended by Act 44 last year, addresses the use of excipients in medical marijuana products. Section 702(a)(5) of the Act authorizes grower/processors, "in accordance with department regulations," to include excipients in their products if the excipients are "pharmaceutical grade" or "approved by the department."[116] Petitioner offered no evidence at the evidentiary hearing that any of the terpenes in the products at issue are "pharmaceutical grade." Thus, grower/processors may not add any terpenes to their medical

[113] 35 P.S. § 10231.102(3)(i).

[114] Hearing Tr. 46:15-19, 47:6-9.

[115] *See, e.g.*, Pet. for Review ¶ 90.

[116] 35 P.S. § 10231.702(a)(5).

marijuana products unless they are approved by the Department in accordance with its regulations.

In determining whether to approve terpenes for inclusion in vaporized medical marijuana products, the Department established certain criteria, one of which is at issue here—if a terpene to be added to a vaporized product comes from a source other than a Pennsylvania grower/processor's marijuana plant,[117] it must be deemed safe for inhalation by the FDA. This reasonable criteria is drawn directly from the language of the Act.

Section 702(a)(5) provides that, in determining whether to approve an additive, the Department "shall consider the following"—not, as petitioner would have it, "shall *only* consider the following" or "shall consider *only* the following." The "following" includes two items: "Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under Federal guidelines," and "Whether the added substance constitutes a known hazard such as diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6."

Again, focusing on the first of these, petitioner contends that these are the *only* factors the Department may consider in determining whether to approve the

[117] Act 44 added a separate provision, 35 P.S. § 10231.702(a)(2.1), that authorizes grower/processors to use plant-derived material such as terpenes from other Pennsylvania grower/processors' medical marijuana plants.

addition of a terpene to a medical marijuana product. The plain language of the provision forecloses petitioner's argument, as the Act nowhere commands the Department to consider *only* these factors. "The best indication of legislative intent is the plain language of a statute … When the words of a statute are clear and unambiguous, we must give effect to the plain language, and we cannot ignore the text of the statute in pursuit of its spirit."[118] The Act's plain language requires that, where the listed factors are applicable, the Department *must* consider them. Only petitioner's *sua sponte* amendment of the Act imposes the otherwise absent requirement that the Department must consider *only* them.

Petitioner's interpretation is not only inconsistent with the plain language, but is unreasonable in the extreme, as it construes a statutory provision expressly limited to food products as imposing the only permissible criteria for approval of products *not* ingested as food. Petitioner's terpene expert conceded that a substance deemed safe by the FDA for use in food is not necessarily safe for inhalation in a vaporized product.[119] And apparently, her own company expressly warns users of this precise fact.[120]

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[118] *Commonwealth v. Golden Gate Nat'l Senior Care LLC*, 194 A.3d 1010, 1027-28 (Pa. 2018) (citations omitted); *see also* 1 PA. C.S. § 1921(b).

[119] Hearing Tr. 164:17-23, 167:1-9.

[120] *Id.* at 180:3-25.

The Department's action that petitioner challenges is drawn directly from Act 44's language requiring the Department to consider, *for products ingested as food*, whether an additive has been deemed by the FDA as *safe for use in food*. The challenged criteria similarly asks whether a terpene added to *a vaporized product* has been deemed by the FDA as *safe for inhalation*. Petitioner's contention that the Department cannot apply any criteria except one applicable only to products ingested as food is, again, absurd and inconsistent with the language of the Act and with the Department's obligation to ensure patient safety with regard to *all* medical marijuana products.

The same is true for the second part of the provision at issue here: whether a proposed additive "is Generally Recognized as Safe (GRAS) under Federal guidelines." Petitioner has pointed to no federal guidelines regarding GRAS designation for substances in vaporized products. To the contrary, as petitioner's own hearing exhibit shows, the FDA's Select Committee on GRAS Substances issues "opinions and conclusions" addressing the safety of "food substances," not substances for inhalation.[121] Similarly, all relevant FDA regulations involve identifying substances as GRAS for use as human or animal *food*, not for inhalation.[122]

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[121] Hearing Exh. P-4.

[122] *See* Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960 (Aug. 17, 2016) ("The Food and Drug Administration … is issuing a final rule that amends and clarifies the criteria in

In short, nothing in the plain language of the Medical Marijuana Act prohibits the Department from relying on the criteria that it uses to determine whether to approve a terpene added to a vaporized medical marijuana product. To the contrary, the core purposes of the Act and the language of Section 702 plainly authorize the Department to rely on the reasonable criteria on which it relies, which is drawn directly from the criteria the Department must use in the analogous context of evaluating proposed additives to ingestible medical marijuana products.[123]

2. Petitioner did not prove that the Department's action constituted bad faith, fraud, capricious action or an abuse of the Department's power.

As set forth above, the Department's action that petitioner challenges is authorized by the Act. In addition, petitioner has not shown that the Department's action constituted bad faith, fraud, capricious action, or an abuse of power. At

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our regulations for when *the use of a substance in food* for humans or animals is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act … because the substance is generally recognized as safe (GRAS) under the conditions of its intended use." (emphasis added)); 21 C.F.R. § 170.30 ("Eligibility for classification as generally recognized as safe"); *cf.* 21 U.S.C. § 321(s) (statutory definition of "food additive," which excludes any substance "generally recognized … to be safe under the conditions of its intended use").

[123] Petitioner contends that the vaporized medical marijuana products subject to the recalls were at one time approved by the Department. Hearing Tr. 45:15-17. The Department does not concede that all of the recalled products were at one point approved, but because it chose not to offer any evidence at the preliminary injunction hearing, it accepts this contention for present purposes. Nonetheless, whatever the reasons for the prior approvals, the Department has never considered the externally sourced terpenes in these products authorized for inclusion in vaporized products in Pennsylvania, and, on that basis, it rescinded any approval that the products had previously received. *See* Hearing Exh. S-1.

most, petitioner has presented evidence that the Department might have taken different steps from the action challenged here in its efforts to ensure patient safety and access to medicine. Those alternatives may even be reasonable actions, but the existence of such alternatives does not render the Department's action unreasonable, let alone a "manifest and flagrant abuse of discretion or purely arbitrary execution of the agency's duties or functions."[124]

Petitioner relied on the testimony of its two scientific experts in its attempt to prove that the Department's actions were improper—*i.e.*, a manifest and flagrant abuse of discretion or purely arbitrary execution of its duties. As a threshold matter, while respondents do not challenge these experts' scientific bona fides, they are hardly unbiased witnesses on the matter at hand. Dr. Vreeke, for example, is no disinterested academic. To the contrary, she works for, and has an ownership interest in, a business that supplies terpenes to Pennsylvania grower/processors.[125] It is no surprise that she would testify that externally sourced terpenes—the products she works with and profits from—are safe and should be permitted in Pennsylvania vaporized medical marijuana products. Dr. Sisley is a medical doctor

[124] *AT&T v. Pa. PUC*, 737 A.2d 201, 210 n.9 (Pa. 1999).

[125] Hearing Tr. 131:18-25, 153:17-155:12.

and researcher but her professional life is devoted to demonstrating the medical benefits of marijuana, making her hardly an unbiased witness as well.[126]

But even aside from the two witnesses' interest in the issue here—whether externally sourced terpenes not deemed safe for inhalation by the FDA should be authorized for addition to vaporized products—their testimony fell far short of demonstrating that petitioner is likely to prevail on the claim that the Department's action is a manifest and flagrant abuse of discretion or a purely arbitrary execution of its duties.

First, petitioner's scientific experts did not dispute that an ingredient deemed safe for use in food is not necessarily safe in an inhalation product.[127] Thus, it is entirely reasonable for the Department not to rely on criteria regarding a substance's safety *in food*, but to rely on analogous criteria when determining whether an ingredient is safe *for inhalation*.

Second, although petitioner's scientific experts focused heavily on the fact that the FDA does not regulate medical marijuana, Dr. Vreeke conceded that it does regulate vaporized products such as e-cigarettes.[128] She also acknowledged that the FDA's list of inactive ingredients in approved drug products includes some that are

[126] *Id.* at 199:6-200:9.

[127] *Id.* at 164:17-23, 167:1-9.

[128] *Id.* at 160:20-161:19.

deemed safe for inhalation, as well as some terpenes.[129] Petitioner's experts also made much of the fact that a terpene's absence from the FDA's list of ingredients that are safe for inhalation does not mean "that the FDA has found [it] to be unsafe for inhalation,"[130] but they conceded that they had no idea if the Department conducts its own research on terpene safety.[131]

Notably, Dr. Sisley testified that, for her FDA-approved cannabis research, she must expressly describe for the FDA the identity and quantity of terpenes in the products being researched.[132] Of course, because the FDA does not regulate the medical marijuana products used by Pennsylvania patients,[133] it does not similarly give its stamp of approval to the type, source, or amount of terpenes in any vaporized products on the Pennsylvania medical marijuana market.[134]

Thus, a terpene's absence from the FDA's list of substances safe for inhalation could leave the Department without confirmation from either a federal or state authority of a terpene's safety for inhalation.[135] In these circumstances, the Department's reliance on the FDA as an authoritative source on the safety of

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[129] *Id.* at 134:3-5.

[130] *Id.* at 135:5-12; *see also id.* at 230:17-231:5 ("It means that the FDA simply has not had an opportunity to review data.").

[131] *Id.* at 168:1-15, 238:3-7.

[132] *Id.* at 228:14-229:14.

[133] *Id.* at 230:1-6, 252:18-253:23.

[134] *Id.* at 256:5-11, 258:18-22.

[135] *Id.* at 253:24-254:9.

terpenes in inhalation products, even if it would arguably lead to the prohibition of some potentially benign products, can hardly be deemed a manifest abuse of the Department's discretion.

Third, the contention of petitioner's scientific experts that the terpenes have unique healing powers[136] and that medical marijuana patients cannot substitute other medical marijuana products for the withdrawn products completely undermines their argument that the terpenes are harmless additives, despite not being deemed safe for inhalation by the FDA. In fact, if the terpenes have the medicinal qualities attributed to them by petitioner's experts, they would constitute *active* ingredients, not *inactive* ingredients.[137] The scientific experts' claims also conflict with the only fact testimony petitioner offered—that the terpenes are used in Pennsylvania medical marijuana products only to enhance "the aroma, the taste, the flavor, the smell, the color" of the products.[138]

Fourth, in decrying the purported illogic of the Department's action, petitioner elides the fact that, by its own witnesses' admissions, approximately half of the vaporized products in the Pennsylvania medical marijuana market are *not* subject

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[136] *Id.* at 144:13-145:16, 208:7-209:4, 210:6-212:3, 222:13-223:2.

[137] *Id.* at 151:9-152:13, 153:8-16; *see also* 21 C.F.R. § 210.3(b)(7) (defining active ingredient as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals").

[138] Hearing Tr. 45:2-5.

to the recall requirement because they do *not* contain externally sourced terpenes.[139] This is so because grower/processors have a number of other, permissible options for adding ingredients that purportedly enhance the color, smell, or taste of vaporized products, including using terpenes extracted from their own plants and obtaining terpenes from other Pennsylvania grower/processors.[140] The grower/processors affected by the Department's action *chose* to use non-Pennsylvania, externally sourced terpenes in their products; they were not forced to do so.[141]

Petitioner also ignores that, unlike terpenes derived from medical marijuana plants within Pennsylvania that the grower/processors are free to use,[142] the externally sourced terpenes are not subject to oversight and regulation by the Department.[143] Nor apparently are they subject to any oversight by the medical marijuana organizations, as petitioner's sole fact witness had no idea what testing

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[139] *Id.* at 47:6-9.

[140] *See, e.g.*, 35 P.S. § 10231.702(a)(2.1); *see also* Hearing Tr. 259:7-21 (petitioner's medical expert conceding that a cannabis-derived terpene would have the same medical benefits as an identical non-cannabis-derived terpene).

[141] Hearing Tr. 110:15-111:2; *see also id.* at 216:1-8 ("it is much less expensive and a reasonable source of terpenes to simply acquire these terpenes through extraction, as was mentioned earlier, from extracting from citrus peels and things like that, that—where you can get a much less expensive version").

[142] 35 P.S. § 10231.702(a)(2.1).

[143] *See, e.g.*, *id.* § 10231.301(a)(3); *cf.* 28 PA. CODE § 1141.45(a)-(b) (describing Department's authority to conduct extensive inspections of medical marijuana organizations, facilities, equipment, and the like within the Commonwealth).

for safety purposes terpene suppliers perform on their terpenes.[144] While Dr. Vreeke touted her own company's testing procedures, she conceded that she had no idea what testing other terpene companies performed,[145] acknowledged that her investigatory role at her company was "something that is not typically found" at other terpene companies,[146] and had no explanation for her own company's express warnings that its terpenes had not been "evaluated for safe use" in vaporized products.[147]

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There is no question that petitioner's scientific experts—an employee and part-owner of a terpene company and a medical marijuana researcher—do not agree with the Department's decision to not approve vaporized products containing externally soured terpenes that have not been deemed safe for inhalation by the FDA. Leaving aside the many issues with their testimony, outlined above, they may well be correct that there are other methods the Department could employ—aside from relying on the FDA—to ensure that vaporized products containing externally sourced terpenes are safe for patients.[148] But even if this is so, petitioner

[144] Hearing Tr. 111:22-112:20.

[145] *Id.* at 173:13-174:4, 175:8-17.

[146] *Id.* at 175:18-176:1.

[147] *Id.* at 180:3-25.

[148] *Id.* at 159:17-160:1 ("if a terpene is not on the FDA's inactive ingredient list for approved drugs, … we should look to other areas and other research to assess its safety").

has not come close to proving that the Department's action that petitioner challenges is unauthorized by the Act or a manifest and flagrant abuse of discretion or a purely arbitrary execution of its duties.

B. The Court need not address petitioner's other claims, but petitioner cannot show that it is likely to prevail on any of them either.

Because petitioner's request for a preliminary injunction fails on so many other grounds, we address only summarily the flaws in petitioner's other claims, which all derive to some extent from its core argument that the Department's action was not authorized by law.

Unlawful De Facto Regulation. As explained above (in Section III.A.1), the Department's use of certain criteria for determining whether to approve the use of externally sourced terpenes in vaporized medical marijuana products is expressly authorized by the Act. The Act provides that terpenes that are not pharmaceutical grade may be added to medical marijuana products only if they are approved by the Department and their inclusion complies with the Department's regulations.[149] The Department's implementation of this criteria through its lack of approval for vaporized products containing externally sourced terpenes not deemed safe for inhalation by the FDA is simply the execution of the plain terms of the law and the

[149] 35 P.S. § 10231.702(a)(5).

accompanying regulations, none of which are challenged here.[150] In no way does it constitute the *de facto* creation of a new regulation.

Improper Reliance on Recall Regulation. Nothing in the regulations limits the Department's authority to notify grower/processors or dispensaries that products that are being produced and placed for sale do not have (or no longer have) approval for production and sale in Pennsylvania. The contrary notion is absurd, dangerous, and inconsistent with well-established principles of administrative law.

Most fundamentally, if petitioner's argument were accepted, the Department would be powerless to take steps to remove unsafe products from the market *except* when a grower/processor itself discovered a condition relating to its products that posed a health and safety risk. This absurd and dangerous result is contrary to the well-established principle that "an administrative agency is vested with the implied authority necessary to the effectuation of its express mandates, because the Legislature cannot foresee all the problems incidental to the agency's carrying out its duties and responsibilities."[151] Here, those "express mandates" include providing "a safe and effective method of delivery of medical marijuana to patients."[152]

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[150] *Cf.* Hearing Exh. S-3 (Nov. 16, 2021 email, invoking and quoting the Act and regulations); Hearing Exh. S-1 (same, in Feb. 4, 2022 email).

[151] *Commonwealth v. Ctr. Twp.*, 95 A.3d 354, 369 (Pa. Cmwlth. 2014) (internal citation omitted).

[152] 35 P.S. § 10231.102(3)(ii).

The Court should reject petitioner's troubling suggestion that the Department has no authority to instruct grower/processors to institute the applicable recall procedures when the Department disapproves products that pose a risk to public health and safety.

Vested Right. Petitioner presented no evidence at the evidentiary hearing on most of the elements it contends it must prove to prevail on this claim. For example, petitioner presented no evidence that *each* MMAPS member (whoever they are) received prior approval from the Department to produce and dispense the products at issue, no evidence that *each* MMAPS member complied with the Department's applicable regulations, and no evidence that *each* MMAPS member (none of whom petitioner even wanted to identify, until forced to do so by the Court[153]) expended substantial sums on the products at issue.[154]

Taking. As discussed above (in Section I.A), petitioner presented no evidence that *it* has suffered or will suffer any injury as a result of the Department's action. Put simply, no property of petitioner's has been taken by the Department. Petitioner offers no basis for the notion that it may assert a taking claim on behalf of its members. Even assuming *arguendo* that petitioner can assert *some* claims on

[153] Hearing Tr. 334:13-336:1.

[154] Pet. for Review ¶ 110. This claim fails for the additional reason that the case cited in support of it, *id.* ¶ 109 (citing *Dep't of Env't Res. v. Flynn*, 344 A.2d 720 (Pa. Cmwlth. 1975)), and the principles on which petitioner relies, involve the unique area of land-use rights, not permits to produce and sell a medical product.

its members' behalf, a taking claim, which necessarily involves specifically identifiable property and individualized proof of compensation, is a particularly inapt species of claim for representational standing.[155]

Petitioner's taking claim also relies on its other arguments that the Department's action was not authorized or appropriate,[156] and, because petitioner is wrong on these points, its taking claim fails for this reason as well.

Procedural Due Process. Petitioner acknowledges that an appeal process is provided for under the Act and the Department's regulations, and that the Department informed grower/processors of the process when notifying them that the products at issue were not approved.[157] Petitioner's procedural due process claim is based on its allegations that the recalled products will be destroyed and the Department's appeal process does not provide for a supersedeas.[158] Yet the Department has represented, and the Court has codified in an Order, that the recalled products may be quarantined and not destroyed until the conclusion of this proceeding.[159] Thus, the grower/processors were afforded all of the process they

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[155] *See, e.g.*, *Fumo v. City of Phila.*, 972 A.2d 487, 509 n.7 (Pa. 2009) (noting that a "standing question often turns on the nature and source of the claim asserted, such that its resolution depends on a consideration of the specific allegations made or the relief sought," and holding that a court must address "standing on a claim-by-claim basis").

[156] Pet. for Review ¶ 118.

[157] *Id.* ¶ 125; *see also* Hearing Exh. S-1.

[158] Pet. for Review ¶¶ 124, 126-127.

[159] Hearing Tr. 369:14-371:10; Mar. 1, 2022 Order.

were due; that they declined to take advantage of it constitutes both a failure to exhaust remedies that deprives this Court of jurisdiction and a fatal flaw in petitioner's procedural due process claim.[160]

Damage to Reputation. Petitioner cites no authority for the remarkable proposition that a Commonwealth agency can be sued for damaging a regulated party's reputation by taking good-faith steps to carry out its regulatory mandate to ensure the health and safety of those individuals it is charged with protecting. Even if—contrary to all of the foregoing arguments—the Department was not authorized to take the action petitioner challenges, there is no authority that would permit a regulated party like the grower/processors, let alone their purported representative in MMAPS, to bring a suit against the Department for its efforts to inform the public about what the Department believed was a potential risk to patient health and safety.

The outrageousness of petitioner's damage-to-reputation claim is embodied in its proposed order accompanying its application for a preliminary injunction, in which, in connection with this claim, petitioner asks this Court to gag a Commonwealth agency tasked with assuring the safe delivery of quality health care in the Commonwealth and preclude it from "making further comments

[160] This claim also fails for the same reason as the taking claim—petitioner offers no authority for the notion that it has standing to assert procedural due process claims on behalf of its members.

concerning the safety of the medical marijuana vaporization products" at issue in this case.

Like petitioner's other claims, this one is meritless; petitioner certainly cannot demonstrate that it is likely to prevail on this remarkable claim.

CONCLUSION

Petitioner's application for a preliminary injunction should be denied.

Respectfully submitted,

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March 11, 2022

CERTIFICATE OF COMPLIANCE

Rule 127 Compliance. I certify that this filing complies with the provisions of the *Case Records Public Access Policy of the Unified Judicial System of Pennsylvania* that require filing confidential information and documents differently than non-confidential information and documents.

Service. I certify that, on March 11, 2022, this Post-Hearing Brief was filed with the Court and served on the following through the Court's PACFile System:

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