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 REPLY BRIEF

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INTRODUCTION

The fundamental flaw in petitioner's post-hearing brief is its failure to accept that it is the Department, and not MMAPS, that is charged with promoting and ensuring the safe delivery of quality health care to the Commonwealth's citizens. And it is the Department, and not MMAPS, that is tasked with administering the Medical Marijuana Act, regulating the "growing, processing, sale, and use of medical marijuana" in the Commonwealth, and "ensuring medical marijuana businesses comply with the Medical Marijuana Act" and do not produce or sell medical marijuana products that pose a risk to patient safety.[1]

The courts are not the proper forum for debating the science of terpene safety, cannabis additives, or vaporized medical marijuana products. When an agency is tasked with administering and enforcing a law and regulating the parties and products governed by that law, it is given substantial discretion to take good-faith steps to carry out its responsibilities. Only when the agency acts contrary to the terms of the law or carries out its duties in bad faith, fraudulently, capriciously, or abusively may a court intervene and reverse the agency's action.[2] Petitioner has not come close to demonstrating that this is the case here.

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

[2] *Malt Beverages Distribs. Ass'n v. Pa. Liquor Control Bd.*, 8 A.3d 885, 892 (Pa. 2010).

At most, petitioner has offered evidence showing that the Department might consider other methods or criteria for ensuring the safety of vaporized medical marijuana products containing externally sourced terpenes that have not been deemed safe for inhalation by the FDA. Those other means of ensuring that these products pose no risk to patient health or safety might be reasonable. They might be effective. But nothing in the Act or its regulations or any other authority on which petitioner relies *requires* the Department to employ petitioner's preferred means.

Petitioner has had a full opportunity to demonstrate its entitlement to the extraordinary remedy of a preliminary injunction—a remedy that is even more extraordinary in this case because it would compel the Department to approve for sale medical products that it believes may pose a risk to patient health or safety and force the Department to remain silent about those concerns. Just two weeks after filing its complaint, petitioner was given an evidentiary hearing at which it could present whatever fact and expert evidence it wished, and it has by now filed two lengthy briefs in support of its application for a preliminary injunction. Yet it has failed entirely to meet its burden of proving all of the requisites for the granting of a preliminary injunction.

ARGUMENT

Petitioner repeatedly refers in its brief to the Department's decision not to put on any witnesses at the preliminary injunction hearing, which, petitioner contends, renders petitioner's evidence "unrefuted."[3] Petitioner is wrong on multiple counts. For one thing, petitioner itself introduced evidence—multiple exhibits—outlining the rationale, the legal basis, and the background to the Department's action, as well as other exhibits supporting the Department's arguments.[4] For another, as outlined in the Department's briefs, much of the testimony of petitioner's witnesses was undermined by cross-examination on numerous critical issues. And finally, petitioner ignores that *it has the burden* to prove that *all six* of the essential requirements for a preliminary injunction are present. It fell far short of meeting that burden on at least three of those requirements.

In its opening brief, the Department detailed at length those shortcomings in petitioner's case, and it will not repeat here those many flaws. In this reply brief, the Department responds only briefly to some of the more egregious misstatements of the record facts or the law in petitioner's opening brief.

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[3] *See, e.g.*, Pet'r Br. 7-8.

[4] *See* Hearing Exhs. S-1, S-3, S-4, S-6, S-7, P-1, P-4.

I. Petitioner is wrong that it and its purported members were not required to avail themselves of available administrative remedies.

Petitioner contends that its members were not required to avail themselves of the Department's appeal procedures (outlined in chapter 1230 of its regulations) because the Department's February 4, 2022 action posed "such a direct and immediate hardship on the Pennsylvania medical marijuana industry that pre-enforcement review is appropriate."[5] Petitioner has not proved, however, that it (or even its members) face "immediate hardship," and thus, there is no reason they could not have filed an appeal from the Department's February 4, 2022 action.[6]

Moreover, this case does not involve "pre-enforcement review," another foundational requirement for immediate judicial review when a party fails to exhaust statutory remedies. There is no new regulation here, yet to go into effect, that petitioner seeks to block to prevent immediate hardship from enforcement of that new regulation. To the contrary, the Department's challenged action—not approving certain vaporized medical marijuana products and requiring any of these products already on the market to be recalled—already has occurred.[7] Petitioner seeks to reverse that action, not prevent it from happening in the future.

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[5] Pet'r Br. 20 (citing *Arsenal Coal Co. v. Dep't of Env't Res.*, 477 A.2d 1333 (Pa. 1984)).

[6] *See* Resp't Br. 25-26.

[7] Petitioner's contention that the February 4, 2022 notice was "issued without warning or grace period" (Pet'r Br. 20) is perplexing, coming as it does immediately after petitioner's lengthy discussion (*id.* at 16-20) of the November 16, 2021 notice on the exact same subject (and containing almost identical language regarding the need to recall certain products).

Finally, as the evidentiary hearing and the parties' briefs make clear, petitioner cannot prevail on its claims without proving certain disputed material factual issues; petitioner's case is far from one that "presents only questions of law presently amenable to judicial review."[8] The question whether the Department's action is authorized by the Act may be a pure question of law, but petitioner's case raises many other fact-bound issues, including, to name just a few, representational standing, the basis for agency action, and the sources and safety of ingredients added to certain medical products. This case falls far outside *Arsenal Coal*'s narrow exception to the administrative exhaustion requirement.

II. Petitioner has not proven that it has standing or the capacity to sue or even that it exists.

Petitioner has the burden of *proving* its representational standing. This is not a proceeding on preliminary objections; it is a request for a preliminary injunction, which requires the movant to present actual evidence to support its burden of proving each of the requirements for entry of an injunction. The primary case on which petitioner relies addressed the issue whether a trial court erred in sustaining *preliminary objections*; this Court held that the trial court had not erred because the plaintiff "failed to plead sufficient facts, whether by identification or description of the allegedly aggrieved members, from which it could be determined that those

[8] *EQT Prod. Co. v. Dep't of Env't Prot.*, 130 A.3d 752, 758-59 (Pa. 2015).

members had standing."[9] This case offers no aid to petitioner, which, at this stage, must do more than simply plead sufficient facts.

Petitioner has failed entirely to offer any *evidence* that it even exists or has members, let alone that those members include the ones it identifies in its brief. Allegations (which, in any event, are absent from the complaint) and arguments of counsel are not sufficient. Actual proof is required. Here, petitioner has offered no proof that it exists, that it may bring suit in Pennsylvania, that it has actual members, or that those purported members are grower/processors, dispensaries, patients, or providers.

III. Petitioner must prove that *it* will face imminent harm without an injunction and, even if it can rely on harm to its members, it has not met its burden.

Petitioner claims that it can meet its burden regarding the injury requirement of the preliminary injunction analysis by relying on injury to its members, but there is no indication in the one case petitioner cites[10] that the respondents contested this issue.[11] Petitioner points to no case in which this Court or the Supreme Court has expressly held, when squarely faced with the issue, that an organization may obtain

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[9] *Ams. for Fair Treatment, Inc. v. Phila. Fed'n of Teachers, Local 3*, 150 A.3d 528, 534 (Pa. Cmwlth. 2016).

[10] *Marcellus Shale Coalition v. Dep't of Env't Prot. of Pa.*, 185 A.3d 985, 997 (Pa. 2018).

[11] *See Marcellus Shale Coalition v. Dep't of Env't Prot. of Pa.*, No. 573 M.D. 2016, 2016 Pa. Commw. Unpub. LEXIS 830, at *7-*8 (Nov. 8, 2016) (discussing respondents' arguments, which focused on harm to the petitioner's members and not to petitioner), *rev'd in part*, 185 A.3d 985 (Pa. 2018).

the extraordinary relief of a preliminary injunction by relying on harm to others, even its supposed members, rather than harm to itself.

In any event, as the Department explained in its opening brief, petitioner failed to *prove* that its purported members would suffer an injury without an injunction.[12] Its damages expert's testimony should be stricken or disregarded entirely because petitioner declined to disclose the actual financial information on which the expert relied, leaving the Court, as the finder of fact, without any basis to credit the expert testimony on which petitioner relies to demonstrate that its members would suffer imminent injury without an injunction.

The Department will not repeat the argument it made regarding petitioner's need to introduce the *facts* on which its expert relied.[13] Petitioner's meager argument on this issue is simply wrong and relies almost entirely on case law pre-dating the adoption of the Pennsylvania Rules of Evidence.[14] Petitioner's claim that the Department "had the opportunity to challenge the reliability of the underlying data" on which Mr. Ahern relied, "including the sources and credibility of that

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[12] As an aside, it is interesting to note that at least one purportedly affected grower/processor—one on which Mr. Ahern relied, Hearing Tr. 342:8-20—recently informed the SEC that it "does not believe that the recall and ban will have a material negative impact on its operations and results in Pennsylvania in the coming year." Curaleaf Holdings, Inc., Form 6-K (Mar. 7, 2022), available at https://sec.report/Document/0001104659-22-031128/.

[13] *See* Resp't Br. 22-24.

[14] Pet'r Br. 22; *see also* Hearing Tr. 340:13-341:1 (petitioner's argument at hearing, also relying on pre-Rules case law).

information,"[15] however, demands a response. As the Court is well aware, petitioner vehemently objected to Mr. Ahern disclosing even the names of the companies that were the sources of his data,[16] and neither he nor any of petitioner's other witnesses disclosed *the underlying data* itself, leaving the Department and the Court completely unable to evaluate the reliability or credibility of the data. Petitioner's contention is not only unsupported but is directly refuted by the undisputed record.[17]

IV. Petitioner's speculation and argument are no substitute for evidence of *imminent* harm.

Petitioner points to its fact witness's testimony that the products "*will expire* on a continuous rolling basis," and some of the products "*could have* already expired" since February 4, and argues that "this litigation and related appeals will certainly extend far beyond" the expiration dates.[18] This is not proof of imminent harm, a critical and core requirement for entry of a preliminary injunction. It is speculation, generalities, and argument of counsel.

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[15] Pet'r Br. 23.

[16] Hearing Tr. 335:3-336:6.

[17] Petitioner relies on a red herring in claiming that the Department argued that "monetary harm cannot constitute irreparable harm." Pet'r Br. 24. It did nothing of the sort. Rather, it simply pointed out that monetary relief for *past* harm is not available in a case such as this: "[T]o the extent that the witness is going to testify about *past damages*, I don't see how that's relevant. We're here today to determine whether the Court is going to enter a preliminary injunction, *not award damages for past wrongdoing*." Hearing Tr. 262:23-263:6 (emphasis added).

[18] Pet'r Br. 4, 25 (emphasis added).

At the evidentiary hearing, petitioner did not point to a single recalled vaporized product with an expiration date in the next few weeks or even months. Not one. The notion that petitioner has shown imminent harm because hundreds of thousands of units *may* expire at some *unknown* date leaves this critical requirement for a preliminary injunction missing.

Moreover, even if the Court considers petitioner's damages expert's testimony, that testimony did not in any way establish that the purported harm to petitioner's members is immediate and irreparable.[19] Petitioner's contrary contention includes no analysis whatsoever and simply summarizes the expert's opinion regarding its members' purported harm and then concludes, in *ipse dixit*: "This harm is immediate. This harm is irreparable."[20] Just saying it is so does not make it so.

Finally, petitioner's attempt to rely on imminent harm to patients is, like much of the rest of its case, based on hearsay, speculation, and a glaring absence of factual evidence. Dr. Sisley's contention that patients who formerly used one of the recalled medicines—which make up only 15-20% of the total medical marijuana market in Pennsylvania—"will *likely* return to using their addictive prescription medications or turn to the illicit market"[21] is speculative, unsupported hyperbole

[19] *Id.* at 28.

[20] *Id.*

[21] *Id.* at 29 (emphasis added).

from a medical marijuana advocate; it is not factual evidence that patients actually will do anything of the sort. In fact, not a single patient testified that he or she could not use one of the thousands of medical marijuana products that remain on the market, including hundreds of vaporized products, following removal of some products from the market. Indeed, petitioner failed to even identify a single patient that is a member of MMAPS.

Petitioner similarly offered no evidence that the recalled products were any particular patient's "medicine of choice."[22] The options for medical marijuana patients are wide and varied, including numerous vaporized medical marijuana products that are still on the market. It is simply implausible that a medical marijuana patient who previously used, for example, PurePenn's Moxie Liquid Peaches & Cream Vape Cartridge will be unable to find any other medical marijuana product—whether vaporized or non-vaporized—now that his or her supposed "medicine of choice" is not available. More to the point, petitioner did not offer a single piece of factual evidence to support this notion.

[22] *Id.* at 2.

V. Petitioner fell far short of presenting sufficient evidence to meet its burden of proving that the Department's action that petitioner challenges constituted a manifest and flagrant abuse of discretion or a purely arbitrary execution of the Department's duties.

Tellingly, petitioner's argument section attacking the substance of the Department's action is titled, "No Evidence Supports The Terpene Recall Mandate."[23] Petitioner then goes on to emphasize, yet again, that there supposedly have been no adverse events from the use of vaporized medical marijuana products using externally sourced terpenes not deemed safe for inhalation by the FDA.[24] But, again, the issue is not whether the evidence supports the Department's action in the way that a plaintiff typically bears the burden of proof in a civil case.[25] The Department does not have the burden of proving that its action was necessary or that it was the best means of ensuring patient health and safety. Rather, petitioner has the heavy burden of proving that it was a "manifest and flagrant abuse of discretion or purely arbitrary execution of the agency's duties or functions."[26]

Petitioner also emphasizes that non-cannabis-derived terpenes are identical to the same cannabis-derived terpenes but ignores the critical fact that the cannabis-

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[23] *Id.* at 30.

[24] *Id.* at 30-32.

[25] *See, e.g.*, *Sutliff v. Sutliff*, 543 A.2d 534, 538 (Pa. 1988) (noting that the evidentiary burden in most civil cases "requires only proof by a preponderance of the evidence"); *see also Commonwealth v. Brown*, 786 A.2d 961, 968 (Pa. 2001) (noting approval for a "greater weight of the evidence" or "tips the scales" definition of preponderance of the evidence).

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

derived terpenes that are permitted under the Act are those derived from Pennsylvania grower/processors and therefore subject to the Department's oversight and regulation.[27] Externally sourced terpenes are *not* subject to the Department's oversight and regulation, and if they have not been deemed safe for inhalation by the FDA, then neither a Commonwealth or federal agency has given (or can give) them a stamp of approval for use in vaporized medical marijuana products.

This plainly is of no concern to the grower/processors, as their authorized representative professed to have no idea what testing was done on the externally sourced terpenes that petitioner wants to force the Department to approve for use in vaporized medical marijuana products.[28] Petitioner's terpene expert was no more helpful, as she similarly had no idea what testing other terpene companies did, admitted that they likely did not employ a Ph.D. scientist such as herself to oversee terpene safety, and could not explain her own company's warnings about using its terpenes in vaping products.[29]

The Department, on the other hand, cannot be so laissez-faire when it comes to the ingredients added to vaporized medical marijuana products. The Act, its

[27] *See, e.g.*, 35 P.S. §§ 10231.702(a)(2.1), .301(a)(3); 28 PA. CODE § 1141.45(a)-(b).

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

[29] *Id.* at 173:13-174:4, 175:8-176:1, 180:3-25.

regulations, and the Department's obligation to ensure the public's health and safety all require the Department to be more vigilant regarding medical marijuana products than grower/processors and terpene suppliers appear to be.[30]

Finally, petitioner claims that the Department "assumed that a terpene not listed in the [FDA] database is unsafe."[31] But this is not true, and the Department never said this was the case. Rather, the Department cannot assume that an externally sourced terpene not listed in the FDA database *is safe* for inhalation. This is so because the Department has not tested and does not regulate such terpenes and the FDA has not deemed them safe for inhalation. Because of its paramount concern for patient safety, and in light of the thousands of alternative medical marijuana products, including vaporized products, still available, the Department has quite reasonably determined that products containing these externally sourced terpenes that neither the Department nor the FDA has deemed safe for inhalation should not be part of the Pennsylvania medical marijuana market.

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[30] As detailed in the Department's opening brief, petitioner's scientific experts greatly overstate the harmlessness of externally sourced terpenes, the dangers of which are apparently serious enough to warrant a warning from petitioner's terpene expert's own company. *See generally* Resp't Br. 34-41. There is no need to restate here the many other problems with these experts' blasé attitude toward externally sourced (and, as far as the record reveals, minimally tested) terpenes. For present purposes, it is sufficient to point out again that the experts' disagreement with the Department's approach to ensuring patient safety does not in any way demonstrate that the Department's action was a "manifest and flagrant abuse of discretion or purely arbitrary execution of the agency's duties or functions." *AT&T*, 737 A.2d at 210 n.9.

[31] Pet'r Br. 5.

That is certainly not a manifest and flagrant abuse of the Department's substantial discretion to regulate medical marijuana and ensure patient health and safety and access to medical marijuana products. Nor is it a purely arbitrary execution of these duties.

VI. Petitioner's remaining legal arguments do not establish its likelihood of prevailing on the merits of its claims.

In its opening brief, the Department addressed the bulk of petitioner's arguments in its post-hearing brief regarding its substantive claims.[32] We make only a few additional points here.

The notion that the testimony of petitioner's *scientific* experts somehow explains the reason for the language used by the legislature in amending the Act last year to authorize the inclusion of certain ingredients in medical marijuana products is fanciful.[33] The plain language of the statute and, to the extent that the language is unclear, such matters as the "occasion and necessity for the statute," the "object to be attained," and the "consequences of a particular interpretation,"[34] determine the meaning of the law, not the subjective views of industry advocates. Petitioner's proffered interpretation is inconsistent with the Act's paramount goal of patient safety and would leave the Department unable to oversee and regulate

[32] *See* Resp't Br. 27-34, 41-45; *see also* Pet'r Br. 35-42.

[33] Pet'r Br. 36.

[34] 1 PA. C.S. § 1921(b), (c)(1), (c)(4), (c)(6).

the ingredients in any medical marijuana products not ingested as food. As the Department explained at length in its opening brief, petitioner has not shown that it is likely to prevail on the merits of this claim, based as it is on an absurd and dangerous interpretation of the Act.[35]

Petitioner has repeatedly contended that all of the recalled products were previously approved by the Department and have been sold for three years, but it offered no evidence at the hearing that all of the products at issue[36] have been on the market for the past three years. As with the remainder of its case, it offered nothing but generalities on this point. With regard to the prior approvals, even assuming (despite the lack of any actual evidence) that all of the products at issue were approved by the Department at some point before November 16, 2021, petitioner's putative members have been on notice for four months now that the Department was reviewing "*all* vaporized medical marijuana products containing additional ingredients."[37] If that review determined that any of these products, even if previously approved, did not meet the requirements of the Act and the regulations for ensuring patient safety, the Department had not only the right, but the obligation, to ensure that they were removed from the market. Petitioner points

[35] Resp't Br. 28-34.

[36] *See* Hearing Exh. P-1.

[37] Hearing Exh. S-3 (emphasis added).

to no legal authority entitling a party to sell a medical product requiring governmental approval *after* that approval has been denied or withdrawn.[38]

Finally, petitioner's attempt to equate the alleged reputational rights of corporations in a heavily regulated industry to parents accused of sexually abusing their children is borderline frivolous.[39] It is one thing for a parent or other individual to seek to expunge a specific accusation of horrific wrongdoing. It is quite another for a corporation to seek to gag a governmental agency from informing the public of the agency's belief that certain medical products that a number of corporations produce and sell may not be safe for their intended use. Petitioner's theory of reputational harm, if accepted, would severely constrict all Commonwealth agencies from carrying out their critical responsibilities and would particularly handcuff the Department in carrying out its duties under the Act to ensure patient safety.

[38] *See also* Resp't Br. 43 & n.154.

[39] Pet'r Br. 42 (citing *R. v. Dep't of Pub. Welfare*, 636 A.2d 142 (Pa. 1994)).

CONCLUSION

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

Respectfully submitted,

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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 16, 2022, this Post-Hearing Reply Brief was filed with the Court and served on the following through the Court's PACFile System:

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