IN THE 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*.**

POST-HEARING REPLY BRIEF OF MEDICAL MARIJUANA ACCESS & PATIENT SAFETY, INC.

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INTRODUCTION

DOH's Post Hearing Brief (DOH Br.), hobbled by DOH's failure to articulate in testimony a single justification for the Terpene Recall Mandate, is a paper tiger – all bluster, no muscle. DOH relies as it must on procedural feints and mischaracterizations of MMAPS' witnesses' compelling testimony to claim that MMAPS has not proven that: (1) any injury will result from refusing an injunction; (2) an injunction is necessary to prevent immediate and irreparable harm; and (3) it will likely prevail on the merits. DOH Br. at 18-19. As detailed in this reply brief, DOH is incorrect.

MMAPS meets all the requirements for a preliminary injunction. MMAPS' fact witness Mr. Woloveck testified to the harms of depriving patients of medicine, removing inventory worth millions from shelves, and foreclosing future sales by grower/processors and dispensaries. MMAPS' expert Mr. Ahern quantified the economic harm, and Dr. Sisley confirmed the harm to patients who depend on the recalled medicine. These harms are irreparable. They will continue to grow every day absent court intervention prohibiting DOH's enforcement through the Terpene Recall Mandate of DOH's new, unauthorized, and unsupported "approved for inhalation by the FDA" binding norm on which the recall is based. As Dr. Vreeke explained, science does not support DOH's new standard; it makes no sense. Feb. 24, 2022 Tr. 139:23 (Tr.). Moreover, as she explained and no one contests, the

marijuana vaporization medicines DOH has not recalled contain terpenes identical to those in the medicines subject to recall.

Greater harm will flow from not granting a preliminary injunction than if one is granted because a preliminary injunction will return the parties to the status quo prior to the recall and the threat the recall poses to patients and providers alike. The unrebutted testimony reveals that there never has been an adverse event associated with the recalled medicine in the three years it has been used by Pennsylvania patients, or during the more than ten years it has been used by patients in other states.

MMAPS is likely to prevail on the merits. DOH lacks the power to adopt its new "approved for inhalation by the FDA" standard; a proper construction of the 2021 amendments to the Medical Marijuana Act reveals that in directing DOH to consider FDA approvals of ingredients for use in food, the General Assembly purposefully withheld the power to adopt the FDA's list of ingredients approved for inhalation. MMAPS' unrebutted expert testimony supports this interpretation: (a) the FDA only approves ingredients for inhalation that are present in drugs approved for inhalation; (b) terpenes common to cannabis and many other plants are not generally used in drugs the FDA has approved for inhalation; (c) terpenes are plentiful in cannabis and need to be added back in all marijuana vaporization drugs; and (d) the FDA does not review and approve either cannabis or marijuana vaporization drugs because cannabis is illegal under federal law. Consequently,

inclusion of added terpenes on the FDA's list of ingredients approved for inhalation is a standard that is as meaningless as it is unattainable – a reality the General Assembly understood but DOH ignores. Moreover, even if DOH had the power, the new standard is an illegal *de facto* regulation and thus is void. Likewise, the recall itself is not authorized by the regulation DOH cites.

Finally, a preliminary injunction will benefit the public interest. Patients will benefit. As Dr. Sisley's testimony on cross demonstrated, the negative effect that DOH's recall will cause Pennsylvania patients is widespread and palpable: she has "developed a large base of [Pennsylvania] patients who regularly contact [her]. So it's not a few sparse patients, this is a large number of patients, including military veterans that we have deep ties with the vet community, and they were very disheartened by [the recall]." Tr. 252:5-17. As well, the public interest will benefit by requiring DOH to confine its regulatory reach within the bounds the General Assembly has prescribed and that DOH itself has included within its own regulations.

DOH's litany of procedural defenses (MMAPS has not exhausted its administrative remedy; MMAPS is seeking an unattainable mandatory injunction; MMAPS does not exist so lacks capacity to sue; MMAPS lacks standing to assert the irreparable harm of its members; MMAPS has presented no evidence of harm because Mr. Ahern's testimony must be thrown out), arguments voiced at hearing

that are even less persuasive as written in DOH's brief, are meritless, as exposed in this reply brief.

DOH, in issuing the Terpene Recall Mandate and pursuing the process that led to it, has acted as no government agency has a right to do. It has arrogated to itself power the General Assembly did not confer. It has acted in a manner that is abusive to the entities it regulates and that is devoid of transparency. It has deprived patients of medicine they need that DOH has already approved, without any evidence that there is a safety risk. Indeed, as the briefing closes in this phase of the case, we still have no explanation of why DOH believes the draconian Terpene Recall Mandate is necessary. It is not. The court should prohibit it from proceeding.

ARGUMENT

I. THE COURT HAS JURISDICTION; THE *ARSENAL COAL* EXCEPTION TO EXHAUSTION APPLIES HERE.

DOH argues that the court lacks jurisdiction over MMAPS' petition for review challenging the Terpene Recall Mandate because MMAPS' members have the right to an administrative appeal and have not demonstrated they exhausted that remedy. DOH Br. at 15-17. The exhaustion requirement does not apply here, however, so the court has jurisdiction. As MMAPS argued at hearing, Tr. 26, and already briefed, MMAPS Post Hearing Br. at 20-21, the *Arsenal Coal Co. v. Com, Dep't of Envtl. Res*., 477 A.2d 1333 (Pa. 1984) exception to the exhaustion doctrine applies. "Where …the impact of a regulation on an industry is direct and immediate, pre-enforcement review is appropriate." *Marcellus Shale Coalition v. Dep't of Envtl. Prot.*, 216 A.3d 448, 459 (Pa. Cmwlth. 2019) (Brobson, J.), (citing *Bayada Nurses, Inc. v. Dep't of Labor & Indus*., 8 A.3d 866, 875 (Pa. 2010) (citing *Arsenal Coal*, 477 A.2d at 1333), *appeal quashed*, 223 A.3d 655 (Pa. 2019). Here, DOH has announced for the first time an immediately effective industry-wide standard that has both retrospective and prospective effect, requiring an immediate cessation of production and sale of, and immediate recall of, 670 perishable medicines that represent 15-20% of all medical marijuana medicines produced and sold in Pennsylvania. MAPPS' members represent 80-90% of the grower/processors and dispensaries adversely affected by DOH's new standard.

As in *Arsenal Coal*, absent judicial intervention, the choice MMAPS' members face to avoid the loss imposed by the Terpene Recall Mandate is (a) to refuse to comply and risk sanctions, including permit revocation, to test the new industry-wide standard through an administrative appeal, or (b) to submit. As the *Arsenal Coal* court reasoned in finding exhaustion inapplicable in similar circumstances, "[w]e cannot say that the burden of such a course is other than substantial." *Id*. at 1340. Moreover, DOH's proffered administrative remedy is a separate administrative appeal for each Recalled Medicine. The Jushi permittees alone would need to file 38 separate administrative appeals, Tr. 41:2-3, resulting in an immensely inefficient, piecemeal, and prejudicial appeal process, all the while requiring MMAPS members, a sizable segment of the industry, to choose between permit revocation and unrecoverable economic loss. In these circumstances, Pennsylvania courts have applied *Arsenal Coal* to permit an exception to the exhaustion requirement, explaining:

> The Courts of this Commonwealth have recognized the justiciability of declaratory judgment actions seeking pre-enforcement review of a substantive challenge to the validity of regulations promulgated by administrative agency. *Donahue,* 98 A.3d at 1230; *Arsenal Coal Company v. Department of Environmental Protection*, 477 A.2d 1333, 1338 (Pa. 1984); *PIOGA*, 135 A.3d at 1125. A pre-enforcement challenge to new regulations is permitted where "the regulation itself causes actual, present harm." *PIOGA,* 135 A.3d at 1126 (quoting *Duquesne Light Company, Inc. v. Department of Environmental Protection*, 724 A.2d 413, 417 (Pa. Cmwlth. 1999)).

> Whether the harm is "present" is determined by whether the effect of the challenged regulations is "direct and immediate." *Arsenal*, 477 A.2d at 1339. Conversely, where there is no harm done to the litigant until the agency takes some action to apply and enforce its regulations, the normal post-enforcement review process is deemed an adequate remedy. *Id*.

Hommrich v. Pennsylvania Public Utilities Commission, 2017 WL 3203437 at *4, Util. L. Rep. P 27,411 (Pa. Cmwlth. 2017) (not reported in A. 3d).[1]

Plainly, DOH's new standard and the resulting recall enforcing it causes "actual, present harm" to MMAPS members, and did so from the moment DOH sent out its February 4, 2022 emails. Under these circumstances, going through the motions of the illusory administrative remedy is not required. The court has jurisdiction under the *Arsenal Coal* exception.

II. MMAPS SEEKS A PROHIBITORY INJUNCTION

DOH argues that because MMAPS is seeking a mandatory injunction it carries a heavier burden than a prohibitory injunction. DOH Br. at 17-19. Although MMAPS is entitled to a preliminary injunction in either case, DOH's attempt to raise the bar a bit higher is baseless. MMAPS seeks to prohibit and restrain DOH from carrying through with action that will cost millions in non-compensable monetary

[1] Pursuant to Pa. R.A.P. 126(b)(1)(2), this opinion is cited for its persuasive value. A copy of the unpublished opinion is attached hereto as **Appendix 1**.

losses and deprive patients of medicines they have been using, based on a *de facto* regulation that was improperly promulgated, that goes beyond DOH 's statutory authority, that the evidence shows has no scientific basis, and that was improperly promulgated. "The relevant standard requires that an injunction must address the *status quo* as it existed between the parties before the event that gave rise to the lawsuit, not to the situation after the alleged conduct but before entry of the injunction.". *Ambrogi v. Reber*, 932 A.2d 969, 974 (Pa. Super. 2007) (explaining that prohibitory injunctions preserve the *status quo* by forbidding an act). MMAPS is asking the court to prohibit DOH from carrying through with the Terpene Recall Mandate pending resolution of this case on the merits.

III. MMAPS HAS CAPACITY AND STANDING TO SEEK A PRELIMINARY INJUNCTION BASED ON ITS MEMBERS' HARM

DOH argues that a preliminary injunction should be denied because MMAPS does not exist and that even if it did, it lacks standing to assert only the harm of its members. DOH Br. at 19-21.

MMAPS exists. As DOH recognizes, a domestic non-profit corporation exists upon it *filing* Articles of Incorporation with the Pennsylvania Department of State. DOH Br. at 20, n. 86; 15 Pa.C.S. § 5309(a). MMAPS filed Articles of Incorporation as a domestic non-profit on February 4, 2022 and can be found on the Department of State's Business Entity search page by entering "Medical Marijuana

Access & Patient Safety, Inc.[2] Likewise, as DOH also acknowledges, a non-profit organization has the capacity to sue. DOH Br. at 20, n. 86; 15 Pa.C.S. §5502(a)(2). Therefore, as of February 4, 2022, MMAPS possessed the legal capacity to bring a legal action, and the underlying petition to review (filed February 10, 2022) is a valid exercise of its corporate powers. 15 Pa.C.S. §5502(a)(2). That MMAPS' authorized representative who testified at hearing did not have the details of MMAPS' corporate formalities at his fingertips is not surprising and certainly not material to the issues before the court.

Moreover, MMAPS has standing if any of its members do, as described in greater detail in MMAPS' post-hearing brief. *See* MMAPS Post-Hearing Br. at 9-12 (MMAPS PH Br.). Mr. Woloveck confirmed MMAPS' composition and the harm experienced by MMAPS' members, Tr. 37:3-24, 39:8-14, 43:24-44:10, and specifically testified that the Jushi permittees are MMAPS' members that were harmed by the Terpene Recall Mandate. Tr. 35:5-14, 40:24-41:16.

The much-awaited support for DOH's proposition at hearing that an association must itself be harmed to seek a preliminary injunction on behalf of its harmed members, *Indep. State Store Union v. Pa. Liquor Control Bd.*, 432 A.2d 1375, 1380 n* (Pa. 1981), DOH Br. at 21 n. 89, does not support DOH's desired

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[2] https://www.corporations.pa.gov/search/corpsearch. MMAPS is also attaching hereto as **Appendix 2** its Articles of Incorporation that were filed on February 4, 2022.

proposition. Instead, it expressed the view that associational plaintiffs that did not allege injury to themselves are "[o]n a different footing" than associational plaintiffs that also named some of their members as plaintiffs but concluded that the court "need not reach the issue." Suffice it to say that the court in subsequent cases has reached the issue, and has decided that "an association has standing as representative of its members to bring a cause of action *even in the absence of injury to itself*, if the association alleges that at least one of its members is suffering immediate or threatened injury as a result of the action challenged." *Firearm Owners Against Crime v. Papenfuse*, 261 A.3d 467, 483-84 (Pa. 2021) (emphasis added) (internal citations omitted); *see* MMAPS PH Br. at 9-13.

IV. MMAPS PRESENTED FACTUAL EVIDENCE THAT MMAPS' MEMBERS ARE HARMED

DOH asserts that MMAPS presented no factual evidence to support its allegations of harm, or facts upon which Mr. Ahern could base his expert opinions, such that MMAPS has not shown harm to its members. DOH Br. 21-25. Putting aside the fact that economic harm from the abrupt recall of 670 different medicines that DOH previously approved for production and sale is self-evident and fairly inferred, DOH is wrong on the facts and on the law. MMAPS presented competent factual testimony that proves harm.

MMAPS presented a credible fact witness who demonstrated harm to MMAPS' members. Mr. Woloveck testified that MMAPS is comprised of grower/processors, dispensaries, patients, doctors, and related businesses, Tr. 37:3-8, and that MMAPS' grower/processor and dispensary members are substantially, directly, and immediately affected by DOH's Terpene Recall Mandate because it forced MMAPS' dispensary members to pull medicine from their shelves and return it to MMAPS' grower/processor members. Tr. 37:18-24; 43:24-44:10. Mr. Woloveck explained that the recall required MMAPS' members to recall 670 different medicines that involved over 330,000 individual units of vaporized medicine and that MMAPS' members produced between 80 and 90 percent of the Recalled Medicine. Tr. 39:8-14, 47:12. He explained that the Recalled Medicines have a 12-month shelf life and will expire on a continuous rolling basis because it was produced on a rolling basis. Tr. 98:22-99:15. Some of the Recalled Medicines could have already expired in the weeks during which the mandatory recall has been pending. Tr.113:13-20. For the Jushi permittees alone, the recall will cost "several million dollars of inventory." Tr. 41:12-16. Moreover, approximately 150,000 patients are adversely affected by the recall. Tr. 79:20-80:20.

Mr. Ahern, MMAPS' expert economic witness, relied on Mr. Woloveck's factual testimony as well as his interviews with other MMAPS' members. If the court compares Mr. Woloveck's testimony with Mr. Ahern's it is immediately

apparent that Mr. Ahern's opinion is consistent with Mr. Woloveck's testimony as corroborated and bolstered by the information Mr. Ahern reviewed from other MMAPS' members. However, Mr. Ahern's testimony passes legal muster even without taking Mr. Woloveck's testimony into account.

DOH attempts to paint Mr. Ahern's testimony as insufficient because the information he received from MAAPS' members is not of record. This is not the law. DOH is correct that the general rule regarding expert testimony is that an expert may not express an opinion based upon facts not in evidence. *See, e.g.*, *Murray v. Siegal*, 195 A.2d 190 (Pa. 1963). However, this general rule does not apply to the information relied upon by experts in forming their opinions. Beginning in 1971, Pennsylvania courts began creating an exception through caselaw which permits an expert to rely on reports of others not in evidence if such information is of the type on which the expert customarily relies in the practice of his or her profession. The Supreme Court first articulated the exception in *Commonwealth v. Thomas*, 282 A.2d 693 (Pa. 1971), in the context of expert medical witnesses, and it has been applied since to other experts and codified in Pa. R.E. 703. *See Betters v. Beaver County*, 200 A.3d 1044 (Pa. Cmwlth. 2018) (County court did not err when it admitted expert's testimony regarding his calculations which were based in part on data not in evidence compiled by others who did not testify); *Hooks v. Southeastern*

Pennsylvania Trans. Auth., 2017 WL 3746562 (Pa. Cmwlth. 2017) (unreported)[3] (expert security consultant for transportation industry permitted to testify in SEPTA conductor's negligence suit against SEPTA based in part on six undocumented interviews expert conducted with other SEPTA conductors who were not called as witnesses to form his opinion that SEPTA failed to keep its crews safe); *Al Hamilton Contracting Co. v. Dep't of Env. Res*., 659 A.2d 31, 36 (Pa. Cmwlth. 1995), *allocatur denied*, 670 A.2d 644 (Pa. 1995) (agency's expert hydrogeologist could rely on information submitted by permittee to form his opinion even if that information was not admitted into evidence, citing *Milan v. Commonwealth, Department of Transportation,* 620 A.2d 721, 727, (Pa. Cmwlth. 1993) *petition for allowance of appeal denied,* 633 A.2d 154 (Pa. 1993)); *Steinhauer v. Wilson*, 485 A.2d 477 (Pa. Super. 1994) (construction expert permitted to base a cost estimate upon figures provided by various contractors he consulted that were not in evidence); *Primavera v. Celotex Corp.*, 608 A.2d 515, 520 (Pa. Super. 1992) (summarizing rationale for the rule and explaining the safeguards that are in place to assure fairness such as cross examination on "whether the source material is truly the type ordinarily relied on by similar experts, whether independent or further judgment was brought to bear on particular source material and whether the expert is competent enough to judge

[3] Pursuant to Pa. R.A.P. 126(b)(1)(2), this opinion is cited for its persuasive value. A copy of the unpublished opinion is attached hereto as **Appendix 3**.

the reliability of the sources upon which he relied"); *In re: Glosser Bros.*, 555 A.2d 129 (Pa. Super. 1989) (expert in stock valuation permitted to testify as to the value of certain assets appraised by another person that the expert considered in developing his expert stock valuation opinion, notwithstanding appraisal was not in evidence; appraisal was the type of source information upon which an expert valuing stock would rely in forming an opinion); *see* Pa. R.E. 703.

In short, the law in Pennsylvania is that experts such as Mr. Ahern in forming an opinion may rely on information that is hearsay and not otherwise moved and admitted into evidence so long as that information is of the type upon which the expert would rely in forming the opinion. These conditions are satisfied with respect to Mr. Ahern's testimony. Tr. 269:19-276:20; 283:25-285:23; 345:8-25. The decisions cited by DOH restate the general rule found in *Murray* and otherwise do not directly address this scenario. Mr. Ahern's testimony is competent and admissible to establish the economic damages suffered by MMAPS' members where it fits within the pre-Rule 703 common law exception, the Rule 703 rubric and the post-rule case law. Together with Mr. Woloveck's fact testimony, MMAPS has adduced admissible evidence that MMAPS' members are harmed by the Terpene Recall Mandate. DOH's protestations to the contrary should be disregarded.

V. MMAPS HAS PROVEN IRREPARABLE HARM

DOH argues next that any harm MMAPS' members are suffering has been cured by DOH's concession that the Recalled Medicine need not be destroyed while this case is pending. DOH Br. 25-26. MMAPS has already rebutted this claim. MMAPS PH Br. at 25-26; 27-30. In pointing to the "no destroy" concession, DOH dwells on only one aspect of MMAPS' members' damages claim, and as MMAPS explained in its opening brief, the irreparable harm as to quarantined medicine is not avoided with DOH's concession, because the quarantined medicine will not outlast this case. Moreover, MMAPS consistently has pointed to *the sales lost and other damage categories identified by Mr. Ahern and Mr. Woloveck in their testimony* as the full measure of irreparable harm suffered by its members because of the recall. These harms are not averted by DOH's agreement to hold off on destruction – which itself is akin to telling a dairy farmer that his fresh milk may not be sold but he needn't worry because he can quarantine it while we litigate about whether it must be destroyed.

VI. MMAPS HAS A CLEAR RIGHT TO RELIEF

a. DOH's New "Approved for Inhalation By" the FDA Standard has no Basis in the Act

The new "approved for inhalation by" the FDA standard that DOH adopted as the basis for the Terpene Recall Mandate, Exh. S-1, is unlawful because it is inconsistent with the limits of DOH's statutory authority, as MMAPS has argued in

its prehearing brief in support of this preliminary injunction request at 14-17, and in MMAPS' post hearing brief at 35-36. DOH disagrees, arguing two sets of related points. DOH Br. at 28-34.

First, as preface to focusing on statutory language, DOH asks the court to "trust it" on matters of patient safety. DOH offers that: the object of statutory construction is to ascertain the intent of the General Assembly and the General Assembly's clearly expressed intent in the Act is patient safety; that DOH is entitled to deference in interpreting the statute it is charged with administering and the court must accept DOH's interpretation unless it is clearly erroneous; that DOH has a regulation that requires the recall of any medicine that "poses a risk" to patient health or safety, which thereby empowers DOH to be proactive in matters of safety; and finally that although DOH also is tasked with providing access to medical marijuana, the recall does not affect that goal, because "about half of the vaporized medical marijuana products remain in the market" despite the recall. DOH Br. at 28-30.

There is another side to each of these pronouncements, of course, and it decidedly undermines DOH's "trust me" pitch. As DOH grudgingly concedes, the General Assembly expressed twin goals in the Act: balancing access to medical marijuana, and in particular access to the latest treatments, and effective means of delivering the medicine to patients, on one hand, with, on the other hand, patient

safety.[4] As to the deference due DOH in statutory construction, the Supreme Court recently made clear in a unanimous opinion refusing to accept DOH's interpretation of statutes it administers as the basis to impose a school facemask mandate, that although the agency interpretation of a statute may deserve some deference, it is the primarily the province of the courts to interpret statutes:

> [W]here an agency is authorized to act, it is entitled to some latitude for discretionary matters committed to its expertise-based judgment by statute, such as the Department of Health's power and duty to 'determine and employ the most efficient and practical means for the prevention and suppression of disease.' … *But that does not mean that the courts must defer to an agency on questions of statutory and regulatory construction for deference's sake.* "It is emphatically the province and duty of the judicial department to say what the law is." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177, 2 L.Ed. 60 (1803). By keeping clear the line dividing the judiciary's domain from the executives, we maintain fidelity to the separation of powers.

Corman v. Acting Secretary, Pa. Dep't of Health, 266 A.3d 452, 486 (Pa. 2021) (emphasis added).

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[4] 35 P.S. § 10231.102 provides in part:

> (3) It is the intent of the General Assembly to:
>
> > (i) Provide a program of access to medical marijuana which balances the need of patients to have access to the latest treatments with the need to promote patient safety.
> >
> > (ii) Provide a safe and effective method of delivery of medical marijuana to patients.

As for DOH having a regulation that requires the recall of any medicine that poses a risk to patient health or safety and that authorizes DOH to launch a product recall, the cited recall regulation,[5] as discussed *infra* in Section VI.c.2, does not even provide the means for DOH itself to commence a recall as it has done here; indeed, this is another basis for MMAPS' challenge to the recall. Finally, the unrebutted evidence adduced at hearing directly contradicts DOH's claim that post-recall, "about half" of the vaporized medical marijuana products remain on the market and can satisfy patient needs. The number is closer to 40 percent, Tr. 47:6-9 (i.e., the recalled medicine represents 57 percent of the available medicines), and, more importantly, Dr. Sisley explained in detail that the recalled medicines that contain non-cannabis derived terpenes deliver more consistent and reproducible medicinal effects at a lower cost than can be delivered through cannabis-derived terpenes; the medicines that have not been recalled, she explained, depend on the vagaries of the terpene levels contained in marijuana crops that are harvested. Stated differently, the record reveals that the medicines that have not been recalled are not as helpful as the Recalled Medicines, and they cost patients more. Tr. 210:9-225:15. Dr. Sisley's testimony was unrebutted. These points, taken together with DOH's utter lack of transparency in handling virtually every aspect of the Terpene Recall Mandate, capped off by its failure to offer a single witness at hearing to explain its basis for

[5] 28 Pa. Code § 1151.42(c).

the recall, severely deplete whatever reservoir of trust DOH as an agency is entitled to expect on this issue.

Second, in offering its interpretation of the statutory language, DOH argues that: Act 44 of 2021 authorizes the addition of terpenes that "are pharmaceutical grade" or "approved by" DOH, but there is no evidence that any of the terpenes in the Recalled Medicines are "pharmaceutical grade"; grower/processors may not add terpenes unless they are approved by DOH in accordance with its regulations; MMAPS' reading of the statute depends on reading the word "only" into the statute that the General Assembly did not place there; in determining whether to allow added terpenes, DOH established as a criterion that if a terpene is added from other than Pennsylvania-grown cannabis it must be "approved for inhalation by the FDA, a standard which is "drawn directly from the Act"; the words of Section 702 of the statute as amended by Act 44 of 2021 that require DOH to consider whether an added substance is "permitted by the [FDA] for use in food" plainly also permit DOH to consider whether added terpenes are "approved for inhalation by" the FDA; and finally that MMAPS' interpretation of Section 702 is "absurd and inconsistent with" the language of the Act and DOH's duty to protect patient safety. DOH Br. at 30-34; 35 P.S. § 10231.702.

As with DOH's first set of related points, there is another side to these statutory construction arguments, and it shows the poverty of DOH's points. First,

DOH's observation that the statute provides that terpenes that are pharmaceutical grade do not need to be reviewed and approved by DOH, but that there is no evidence that any of the terpenes in the Recalled Medicines are of "pharmaceutical grade", DOH Br. at 30-31, is directly contradicted by the evidence at hearing. Dr. Vreeke, whose company supplies terpenes to MMAPS' members, Tr. 131:18-25, was asked exactly this question, and explained why they are pharmaceutical grade:

> Q. Would you say that True Terpenes' products are pharmaceutical grade?
>
> A. Yes.
>
> Q. And why is that?
>
> A. Because the concentration level, one definition is the purity of the compound has to match a specific level and we test all our compounds to ensure the highest purity. In addition, the rigorous testing that we perform on all of our isolates and finished blends would easily pass for pharmaceutical grade.

Tr. 132:25-133:13.

DOH's related point that grower/processors may not add terpenes unless they are approved by DOH in accordance with its regulation thus has two answers: first, as Dr. Vreeke testified, because the terpenes her company provides to MMAPS' members are pharmaceutical grade, the statute does not require <u>any</u> approval by DOH, so approval should never have been withdrawn; and second, DOH already approved all of the medicines in question before any of them were produced or sold.

Next, MMAPS' reading of the statute does not depend on reading the word "only" into the statute as DOH contends. Rather, as MMAPS has argued (and DOH thus far has ignored), Section 702 (a)(5)'s directive that DOH must consider whether an added substance is permitted by the FDA for use in food, does not also imply as DOH contends that DOH may require that added terpenes must be "approved for inhalation by" the FDA, or demonstrate that DOH's new standard is "drawn directly from the Act." *See* 35 P.S. §10231.702(a)(5). Interpreting the statute in this way runs afoul of the doctrine of *exclusio unius est exclusio alterius.* "Applying the rules of statutory construction, the inclusion of a specific matter in a statute implies the exclusion of other matters." *Independent Oil and Gas Ass'n of PA v. Board of Assessment Appeals*, 814 A. 2d 180, 184 (Pa. 2002), quoting *Ken R. on behalf of C.R. v. Arthur Z.,* 682 A.2d 1267, 1270 (Pa. 1996). The General Assembly has only amended the Act twice before, and the amendment in question was added a mere nine months ago. Obviously, the General Assembly could have included a directive requiring use of FDA's "approved for inhalation" list, or even a general directive to DOH to adopt whatever judgments the FDA has made, but it was careful to avoid doing so. Instead, the General Assembly was specific and precise in conferring on DOH the power and the duty to consider whether an added terpene is approved by the FDA for use in food but was silent on the issue of FDA approval for inhalation. This silence does not confer tacit approval, as DOH contends, but rather the opposite.

"[T]he more specifically the General Assembly describes what can be done, the more we [the court] must infer that its omission of other exercises of … authority were not merely accidental or due to the expectation that we would understand the specific delineations of authority to tacitly confer much more." *Apartment Ass'n v. Pittsburgh*, 261 A. 3d 1036, 1050 n. 62 (Pa. 2021).

This conclusion is neither "absurd" as DOH contends, nor inconsistent with the language of the Act. Indeed, it flows directly from a plain reading of the Act and is consistent with another important canon of statutory construction that is particularly applicable here: "when interpreting a statute we must listen attentively to what the statute says, but also to what it does not say." *Hanaway v. Parkesburg Group, LP*, 168 A.3d 146, 154 (Pa. 2017) (internal citation omitted). The statute does not say anything about conditioning approval of a medicine containing a botanically-derived terpene on FDA approval of that terpene for administration through inhalation, and with good reason: as the unrebutted hearing testimony made clear, it would make no sense to do so. The FDA database is comprised only of ingredients that the FDA has had cause to review in drugs it approves. Exclusion of an ingredient from the database does not mean the ingredient is unsafe, but rather that the FDA has not had occasion to review it. Tr. 134-135. The reason the FDA has not had that opportunity for virtually all terpenes is that, as it happens, most terpenes are not used as ingredients in drugs approved for inhalation by the FDA.

Terpenes are used in marijuana vaporization medicines, but the FDA does not review and approve marijuana vaporization medicines for inhalation because marijuana is illegal under federal law. Tr. 136:14-137:9, 230:1-231:5. The upshot is that DOH is using a standard that MMAPS' members will never be able to meet until many more terpenes are used in FDA approved drugs, or until marijuana is made legal under federal law.

For all of these reasons, it is DOH's interpretation of the Section 702 (a)(5) as a basis for its Terpene Recall Mandate that is tortured and nonsensical, not MMAPS' interpretation. On the basis of the words of the statute, as placed into context by the unrebutted testimony at hearing, MMAPS' interpretation is the more compelling by far. MMAPS' interpretation thus is likely to succeed on the merits, but at the very least, MMAPS has shown that it has a substantial case on the merits.

b. <u>The Terpene Recall Mandate is an Abuse of DOH's Power</u>

For the reasons stated above and previously stated in MMAPS' brief in support of its preliminary injunction request, at 14-17, and in its post-hearing brief, at 35-36, DOH does not have the statutory authority to adopt its "approved for inhalation" standard, and even if it did, the standard is an illegal *de facto* regulation that was used to initiate an illegal recall, as argued *infra*, so it makes little difference if DOH issued the recall without acting in bad faith, fraud, capriciousness, or an

abuse of power, as DOH argues. DOH Br. at 34-41. But in fact, DOH abused its power in issuing the Terpene recall Mandate.

"To constitute an abuse of discretion the [administrative agency] must have based its conclusion upon wholly arbitrary grounds". *Unified Sportsmen of Pa. ex rel. v. Pa. Game Comm'n*., 18 A.3d 373, 382 (Pa. Cmwlth. 2011). Arbitrary conduct is "based on random or convenient selection or choice rather than based upon reason or nature." *Bd. of Publ. Educ. Sch. Dist. v. Thomas*, 399 A.2d 1148, 1150 (Pa. Cmwlth. 1979). The very fact that DOH has repeatedly failed to justify or explain its Terpene Recall Mandate despite multiple chances to do so is a telltale that it has no reasonable basis and that DOH exercised its power to issue it (assuming it has the power) arbitrarily. This is driven home by what can be divined from the arguments of DOH's lawyers (since DOH presented no testimony) that suggest that DOH is not so much concerned about terpenes as it is about the source of terpenes. DOH Br. at 39 ("unlike terpenes derived from medical marijuana plants … that the grower/processors are free to use" and "[t]he 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." (emphasis in original). Dr. Vreeke and Dr. Sisley both testified without contradiction or rebuttal that regardless of source, terpenes are identical at the molecular level.

Dr. Vreeke testified that the terpene d-limonene is naturally present in both cannabis and citrus peels and that "whether it's extracted from cannabis or a citrus peel, its going to have the exact same chemical property, and so it makes no sense that the DOH is reviewing those two compounds differently based simply on the source of extraction." Tr. 139:15-140:1. Dr. Vreeke, a toxicology and vaporization expert with a doctorate in chemistry and who's primary job is to ensure the safety of non-cannabis derived terpenes, further testified that "non-cannabis-derived botanical terpenes that are also present in cannabis [vaporized products] are going to pose no different risk to the patient" which is why it "makes no sense" that DOH is judging d-limonene differently "simply because [of] the source of the extraction." Tr. 140:3-14, 140:20-141:15.

Dr. Sisley testified that the terpene beta-caryophyllene is found in cannabis and in common cooking ingredients like black pepper, rosemary, and coriander; that beta-caryophyllene is chemically "exactly the same molecule" regardless of whether it is sourced from cannabis or a common cooking ingredients; that beta-caryophyllene extracted from a non-cannabis source poses no greater risk than beta-caryophyllene naturally found in cannabis; and that because beta-caryophyllene is molecularly identical, it will exert the same clinical effect whether it comes from cannabis or a non-cannabis source. Tr. 217:11-219:4, 218:259:7-20.

DOH apparently maintains (without evidence) that it issued the Terpene Recall Mandate for (unidentified) safety reasons but has applied the recall only to externally derived terpenes. DOH Br. at 39; Exh. S-1, S-7. The unrebutted testimony of Dr. Vreeke and Dr. Sisley, however, demonstrates that DOH's distinction is not grounded in science or medicine. A vaporized marijuana medicine that contains d-limonene, beta-caryophyllene, or another terpene is going to pose no different risk nor exert any different clinical effect based on the source from which it is derived. The source of the terpene has no effect on the safety or efficacy of the final vaporized medicine. DOH's decision to make a distinction based on the source of the terpene with zero evidence to support its decision is the quintessential example of arbitrary conduct, and therefore constitutes an abuse of discretion.

Moreover, despite DOH's attempt to paint Dr. Vreeke as a biased witness with a financial stake in the Terpene Recall Mandate and Dr. Sisley as a biased witness because her life is "devoted to demonstrating the medical benefits of marijuana", DOH Br. at 35-36, DOH concedes they are qualified to opine on the underlying science, and the science they have testified to is undisputed. DOH's arguments that it is entitled to rely on criteria other than that which is expressly provided for in 35 P.S. §10231.702(a)(5) (FDA's safe in food and GRAS criteria), DOH Br. at 36-38, and is permitted to conduct its own study of terpenes, is undercut by the fact that DOH has presented no evidence concerning the criteria it does use or the studies it

has conducted. Of course, no MMAPS' witness can assess the efficacy of DOH's process because DOH has never shared what it is. DOH's attempt to show that non-cannabis derived terpenes do not undergo safety testing is likewise unconvincing. Dr. Vreeke provided the only testimony on this point, and her testimony was that True Terpenes' products (which MMAPS' members use) do undergo rigorous safety testing. Tr. 138:13-20. Additionally, Mr. Woloveck testified that all medicines, including those with botanically-derived terpenes are tested, by independent third-party laboratories, prior to being placed on dispensary shelves in their final forms. Tr. 48:22-49:24. The fact that no adverse complaints have occurred that are attributable to non-cannabis derived terpenes over the millions of vaporized medicines consumed nationwide over the last 10-plus years, Tr. 236:2-237:1, underscores MMAPS' testimony that non-cannabis derived terpenes are safe.

In sum, assuming DOH lawfully implemented its new standard (it did not), the record as made compels a finding that DOH's Terpene Recall Mandate is an abuse of discretion and is therefore invalid.

c. <u>MMAPS is Likely to Prevail on the Merits on Its Other Claims</u>

DOH gives short shrift to MMAPS' remaining claims, arguing that all are derivative of MMAPS' argument that DOH lacks statutory authority to issue the Terpene Recall Mandate. DOH Br. at 41-46. DOH indulges this tactic, mere pretext offered to avoid serious engagement with the legal infirmities that beset DOH's

administrative overreach, at its peril. MMAPS has demonstrated a likelihood of success on each of these claims – indeed, some, such as the unlawful *de facto* regulation claim, are dispositive.

1. Unlawful De facto regulation

As detailed in MMAPS' prehearing brief in support of this preliminary injunction request at 17-19, and in MMAPS' post hearing brief at 36-37, DOH's February 4, 2022 Terpene Recall Mandate imposes a new and immediately effective industry-wide rule applicable to existing medicines previously approved by DOH, and to all future medicines, that terpenes added to vaporized marijuana medicines must be "approved for inhalation by" the FDA. *See* Exhibit S-1. The new standard is applicable to all vaporization medicines. DOH has stated that the new standard will be enforced through sanctions, including permit revocation. Because the new rule "establishes a standard of conduct" which DOH purports to apply "in all situations now and in the future, which is the hallmark of a regulation" and because it "establishes a standard of conduct which has the force of law," it is a *de facto* regulation that DOH has failed to properly promulgate, and it thus is "void and unenforceable." *Transportation Services, Inc. v. Underground Storage Tank Indemnification Board*, 67 A.3d 142, 155 (Pa. Cmwlth. 2013):

> The effect of an agency's failure to promulgate a regulation in accordance with the Commonwealth Documents Law is to have the regulation declared a nullity. *Germantown Cab Company v. Philadelphia Parking Authority,* 993 A.2d

> 933, 937 (Pa.Cmwlth.2010), *affirmed,* 614 Pa. 133, 36 A.3d 105 (2012). If an interpretative rule or statement of policy functions as a regulation, then it will be nullified due to the agency's failure to obey the processes applicable to the promulgation of a regulation. *Department of Environmental Resources v. Rushton Mining Company,* 139 Pa. Cmwlth. 648, 591 A.2d 1168, 1171 (1991).[6]

Id. at 154.

Perhaps because the law is so clear on this point and dooms DOH's position, DOH fails to respond, and instead changes the subject. It argues that the Terpene Recall Mandate is not an unpromulgated regulation, but simply implements the Act's express criterion that "terpenes that are not pharmaceutical grade may be added to medical marijuana products only if they are approved by the Department." DOH Br. at 41. This rationale is a *non sequitur*. There is no basis in law or the record for equating "pharmaceutical grade," a term that is undefined in the Act or in DOH regulations, with DOH's new standard of "approved for inhalation by" the FDA. DOH made no reference to "pharmaceutical grade" in issuing the emails that announced its new "approved for inhalation by" the FDA standard, and certainly did

[6] MMAPS' previous filings mistakenly attributed the above quoted statement "If an interpretative rule or statement of policy functions as a regulation, then it will be nullified due to the agency's failure to obey the processes applicable to the promulgation of a regulation" to *Rushton Mining*, but it was actually *Transportation Services Inc.'s* summary of *Rushton Mining's* holding. Petitioner regrets any confusion this may have caused.

not link that term to whether or not an ingredient in a Recalled Medicine has been "approved for inhalation by" the FDA.[7]

The bottom line is that the new standard is a *de facto* regulation that has not been promulgated under even the relaxed temporary regulation authority that DOH enjoys. *See* 35 P.S. §10231.1107. Accordingly, even assuming DOH has the statutory authority to adopt this new industry-wide rule (it does not), the rule as announced is void *ab initio*. That is a basis independent of any other on which to conclude MMAPS is likely to succeed on the merits.

2. Improper Reliance on Recall Regulation

DOH bases the Terpene Recall Mandate on 28 Pa. Code §1151.42. That regulation addresses product recalls but does not identify any circumstance in which DOH itself may initiate a recall, as argued in MMAPS' brief in support of its preliminary injunction request at 19-21, and in MMAPS' post hearing brief at 37-

[7] *See* Exh. S-1 (Feb. 4, 2022 email to grower/processors and dispensaries) ("The Department has reviewed every additive contained in the attached list of products and has determined that additive(s) contained in your product(s) **have not been approved for inhalation by the United States Food and Drug Administration**.") (emphasis added); S-7 (Feb. 4, 2022 email to patients) ("[T]he Department has determined that certain vaporized medical marijuana products containing some added ingredients **have not been approved for inhalation by the United States Food and Drug Administration**.") (emphasis added). In Exh. S-1, DOH quoted Section 702(a)(5) of the Act, which admittedly contains the phrase "[e]xcipients must be pharmaceutical grade," but gave no indication that new "approved for inhalation by the FDA" standard is related, and DOH made no mention of "excipient" at all in Exh. S-7.

38. DOH does not contest this point based on the regulation as written because it cannot. DOH Br. at 42-43. DOH argues instead that nothing in the regulation "limits" DOH's authority to order a recall, opines that DOH's power to initiate a recall is implicit in the Act, and lectures that MMAPS is advocating an "absurd and dangerous result" that is a "troubling suggestion" the court should reject because DOH needs this unbridled power over "products that pose a risk to public health and safety." *Id.*

To be clear, MMAPS is aware that DOH has a mandate to protect patient safety, a goal that MMAPS shares. Here, however, DOH is invoking a regulation that does not address any circumstance in which DOH itself may order a recall, but that does specify circumstances in which a recall is mandatory that are not present: "a complaint made … by a patient, caregiver or practitioner who reports an adverse event from using medical marijuana products." DOH may well have the implicit power under the Act to promulgate a regulation that allows DOH to recall "products that pose a risk to public health and safety," but do date it has not done so. Nor has DOH established that there is a risk to public health and safety posed by the Recalled Medicines based on the criterion that its regulation does establish – a complaint advising of an adverse event from using one of the Recalled Medicines.

DOH is not writing on a blank slate here – it has promulgated a regulation that addresses recalls at length, but that regulation plainly does not provide the

authority DOH ascribes to it. Before DOH can call on alleged implicit powers or ask the court to infer powers from a regulation that on its face does not confer them, DOH has a duty to explain why it believes medicines DOH itself previously approved for inhalation, and that have been used for years without any adverse event, have suddenly become "risk[s] to public health and safety." Even then, DOH's power to institute extraordinary measures of the type adopted here in the "Star Chamber" manner it has done, simply because it says it believes they promote public health and safety, is limited by the Act and DOH's own regulations. *Corman v. Acting Secretary, Pa. Dep't of Health*, 266 A.3d 452, 477 (Pa. 2021) (holding that, despite DOH's broad authority to protect the health of Pennsylvanians during the COVID-19 pandemic, DOH could not "act by whim or fiat" in implementing a school mask mandate that circumvented the formal regulatory process absent a disaster emergency declaration that suspends the agency rulemaking process). Indeed, in stark contrast to the detailed justification that DOH provided for the school mask mandate in *Corman* that nonetheless failed to pass muster,[8] DOH has provided no evidence that justifies its decision that medicines containing terpenes that have not been "approved for inhalation by" the FDA pose a risk to public health and safety. Despite ample opportunity for DOH to present evidence, the only

[8] *See, e,g,*. DOH's school mask mandate rationale, quoted in *Corman v. Acting Secretary, Pa. Dep't of Health*, 267 A.3d 561, 569 (Pa. Cmwlth. 2021) (Wojcik, J. Dissenting).

testimony of record is to the contrary. Under these circumstances, DOH should be held to its own regulation, which does not authorize a recall in these circumstances. This is not a "troubling suggestion." It is simply the law that DOH itself promulgated and now is attempting to sidestep.

3. Vested Right

MMAPS has alleged its members have a vested right in DOH's previous approvals of the Recalled Medicines because MMAPS' members meet all the elements needed to prevail, and DOH has failed to produce any evidence that the recall is required to protect public health, safety or welfare. *Dep't of Envtl. Res. v. Flynn*, 344 A.2d 720, 725 (Pa. Cmwlth. 1975) (reciting elements of vested right claim). Accordingly, as argued in MMAPS' brief in support of its preliminary injunction request at 21-23, and in MMAPS' post hearing brief at 38, MMAPS is likely to prevail on the claim.

DOH responds that MMAPS failed to prove that each MMAPS' member had prior approval or that each MMAPS' member expended substantial sums on the Recalled Medicines. DOH Br. at 43.[9] DOH is wrong on both counts. As Mr. Woloveck testified, the Jushi permittees received prior DOH approval for each

[9] MMAPS notes that DOH has "accepted", at least for purposes of any ruling on MMAPS's preliminary injunction request, all the Recalled Medicines were previously approved by DOH. *See* DOH Br. at 34 n 123. MMAPS assumes that the same concession applies as to this issue.

recalled medicine. Tr. 45:15-16. The same is necessarily true for each of the other MMAPS' members because, by definition, under DOH's strict regulatory regime, no marijuana medicine can be produced or sold in Pennsylvania absent DOH's prior approval. Tr. 48:8-51:8. Indeed, DOH is only aware of the existence of the medicines that have been recalled because DOH previously approved their production and sale. Similarly, Mr. Woloveck testified that the Jushi permittees will lose several million dollars as a result of the recall, Tr. 41:12-16, and Mr. Ahern estimated the total loss for all MMAPS members at between $17 and $18 million. Tr. 319:5-8. These are "substantial" losses by almost any measure. Indeed, to establish that MMAPS members expended substantial sums on the Recalled Medicines and related costs, little more needs to be said than that the recall involves 670 product types totaling 330,000 individual product units. Tr. 39:8-14.

4. Taking

There can be no doubt that the recall interferes with MMAPS' members' "distinct investment-backed expectations," such that it gives rise to a Takings claim, *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978) as argued in MMAPS' brief in support of its preliminary injunction request at 23-25, and in MMAPS' post hearing brief at 39. MMAPS need not establish that MMAPS itself suffers the taking, as DOH argues, DOH Br. at 43, and DOH has offered no authority for the proposition that the claim cannot be asserted by MMAPS but only by

individual MMAPS' members. DOH Br. at 44. MMAPS agrees that success of the Takings claim may depend on the likelihood of success of MMAPS's other claims that DOH has no lawful basis to order the recall, *id.,* but as pointed out elsewhere in this reply brief, DOH has no lawful basis for the recall.

5. Procedural Due Process

It is hornbook law that due process requires a pre-deprivation hearing where, as here, the circumstances demonstrate a high risk of the erroneous deprivation from MAAPS' members of millions of dollars' worth of medicine previously approved by DOH about which there have been no known complaints, adverse effects or risk to public health and safety *and the attendant lost sales*, and the injunction sought will restore the last lawful *status quo ante*. *Fuentes v. Shevin*, 407 U.S. 67, 81-82 (1972) ("If the right to notice and a hearing is to serve its full purpose, then, it is clear that it must be granted at a time when the deprivation can still be prevented."); *Friends of Danny DeVito v. Wolf*, 227 A.3d 872, 897 (Pa. 2020) (reciting the three-part test to determine the appropriate procedural safeguards and holding that the appropriateness of a pre-deprivation hearing depends largely on the last two prongs: private interest affected, the risk of an erroneous deprivation, and whether that risk can be minimized with additional safeguards).

DOH does not address this controlling law in its brief. Its failure to do so cannot be ascribed to surprise as these and other decisions were cited in MMAPS'

Petition for Review, Application for Special Relief in the Nature of A Preliminary Injunction and supporting brief. Rather, this failure is consistent with DOH's gross oversimplification of MMAPS' members' due process claim. While MMAPS consistently has pointed to the loss of the currently quarantined medicine, *as well as the sales lost and other damage categories identified by Mr. Ahern in his testimony*, DOH instead predictably focuses solely on its sudden reversal and last-minute concession that the Recalled Medicines need not be destroyed pending the outcome of this lawsuit. But the concession does not cure the due process violations inherent in DOH's appeal regime.

DOH cites to its barest of bare bones process at 28 Pa. Code §§ 1230.38 and 1230.39, and 1141.47(d) as being sufficient to address its deprivation of MMAPS' members' property, but conveniently omits any reference to the lost sales and other economic damages suffered as a result of the Terpene Recall Mandate. The appeals procedures are careful to make sure that filings are in the prescribed format but neglect to provide any sort of opportunity for a supersedeas hearing.[10] That DOH's

[10] As noted in MAAPS' Petition for Review, resort to GRAPP is equally futile. Compare DOH's appeal process to that of the Environmental Hearing Board which provides for the full panoply of due process protections including a process for obtaining both a temporary supersedeas (25 Pa. Code § 1021.64) pending a requested supersedeas hearing and a supersedeas (25 Pa. Code §§ 1021.61-.64), as well as an opportunity to assert financial inability to prepay civil penalties where required by statute (25 Pa. Code §1021.54a(d)), and a hearing on the asserted inability to prepay (25 Pa. Code § 1021.55).

regulations are temporary provides no excuse for the failure to provide required due process protections.

6. Damage to Reputation

DOH dismisses MMAPS' right to reputation claim as "remarkable" and "outrageous[]". DOH Br. at 45-46. Yet there is no question that Pennsylvania's Constitution protects the right to reputation, Pa. Const. Art. I, §1; Pa. Const. Art. I, §11, as detailed in MMAPS' brief in support of its preliminary injunction request at 30-32, and MMAPS' post hearing brief at 42. DOH's action in recalling the medicines as unsafe without explanation or apparent justification obviously damages the reputations of MMAPS' members. Tr. 298:15-300:4. Although requiring DOH to refrain from taking similar action in the future, as could be suggested by MMAPS proposed order, may be viewed as a prior restraint on speech and thus unavailable as a remedy, requiring DOH to publicly retract its condemnation of the Recalled Medicines upon a decision on the merits in MMAPS' favor is a remedy the court could and should order and as to which MMAPS members are entitled.

CONCLUSION

WHEREFORE, for the reasons stated above, Petitioner's application for a preliminary injunction should be granted.

Respectfully submitted,

/ s / Judith D. Cassel

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APPENDIX 1

2017 WL 3203437

See Pa. Commonwealth Court Internal Operating Procedures, Sec. 414 before citing.

Commonwealth Court of Pennsylvania.

David N. HOMMRICH, Petitioner
v.
Commonwealth of Pennsylvania, PENNSYLVANIA PUBLIC UTILITIES COMMISSION, Respondent

No. 674 M.D. 2016
|
Submitted: April 13, 2017
|
FILED: July 28, 2017

BEFORE: HONORABLE ROBERT SIMPSON, Judge, HONORABLE MICHAEL H. WOJCIK, Judge, HONORABLE DAN PELLEGRINI, Senior Judge

MEMORANDUM OPINION

JUDGE WOJCIK

***1** Before this Court in our original jurisdiction are the preliminary objections of the Commonwealth of Pennsylvania, Public Utility Commission (PUC) to the "Amended Petition for Review in the Nature of a Complaint for Declaratory and Injunctive Relief" (Amended Petition) filed by David N. Hommrich (Hommrich). [1]

Hommrich, proceeding *pro se*, filed the Amended Petition challenging certain PUC regulations pertaining to net metering, adopted on November 19, 2016, as unauthorized under the Alternative Energy Portfolio Standards Act (AEPS Act). [2] Hommrich seeks declaratory relief under the Declaratory Judgments Act (DJA). [3] Specifically, Hommrich requests a declaration that: (I) the challenged regulatory provisions are unenforceable under the AEPS Act; (II) the regulations cannot be retroactively applied to projects that were eligible or approved for net metering prior to promulgation of the regulations; and (III) Hommrich's proposed solar projects qualify for customer-generator status under the AEPS Act and are eligible for net metering. [4]

In support, Hommrich alleged the following, in relevant part. Hommrich is a resident of Pennsylvania and President of Sunrise Energy, LLC (Sunrise Energy), a solar power development company located in Pittsburgh, Pennsylvania. Hommrich seeks to develop alternative renewable energy assets, specifically photovoltaic power (solar) facilities, for his own use and for the benefit of himself and his heirs. The planned projects are separate and distinct from any assets owned by Sunrise Energy. Sunrise Energy will not be involved in the construction or operation of the projects. Sunrise Energy does not own a financial interest in the proposed projects. Amended Petition, ¶¶ 22, 26.

Hommrich intends to build the proposed facilities over the next three years. Hommrich will personally build and operate the planned solar facilities. The timeline for construction is one facility per year between 2017 and 2019 for a total of three new facilities. Each system will have a nameplate capacity of 3,000 kilowatts in size. The solar facilities will be on working sheep farms. Some of the power will be used onsite to offset multiple loads including a barn with lights and electrical outlets, an electric water pump to water the livestock, an electric fence to deter predators, and the electricity required by the renewable energy system to operate. Amended Petition, ¶¶ 23, 25, 27.

***2** Pre-construction activities for the 2017 project include, but are not limited to the procurement of an option to lease property for the project, solar system design, and configuration of the barn and fencing. The proposed projects are within the service territory of Pennsylvania's electric distribution companies (EDCs). Hommrich does not seek to build his facilities in any service territory where net metering is not available pursuant to the AEPS Act. After 2019, Federal Investment Tax Credits (tax credits) begin to expire and future projects will not be economically feasible for him. Amended Petition, ¶¶ 23–25, 27.

Hommrich plans to fund his projects through a combination of long-term debt and tax-equity investments. The tax credits only become available after a project is "live" and is producing electricity. If a construction project is not live when projected, it creates serious tax repercussions for the investor. Amended Petition, ¶¶ 68, 70, 72, 76.

The General Assembly authorized the PUC to develop "technical and net metering interconnection rules" under Section 5 of the AEPS Act, 73 P.S. § 1648.5. Thereafter,

the PUC promulgated regulations, which are the subject of this litigation. Amended Petition, ¶¶ 5–7.

Hommrich claims that the PUC exceeded its statutory authority and contravened *Sunrise Energy, LLC v. FirstEnergy Corp.*, 148 A.3d 894 (Pa. Cmwlth. 2016), *appeal denied*, —— A.3d —— (Pa. 2017), in which this Court held that the PUC has only narrow statutory authorization to impose "technical and net metering interconnection rules." According to Hommrich, the PUC does not have authority to decide eligibility for net metering, which is established in the AEPS Act. Under the AEPS Act, the General Assembly authorized "customer-generators" [5] to "net meter" [6] and defined both terms.

Hommrich asserts that his proposed projects qualify for net metering under the AEPS Act, but could be disapproved under the PUC's regulations. Amended Petition, ¶¶ 27–28. Specifically, Hommrich challenges Sections 75.1 (definition of utility and customer-generator), [7] 75.12 (definition of virtual meter aggregation), [8] 75.13(a)(1) and 75.13(a)(5), [9] 75.16, [10] and 75.17 [11] of Title 52 of the Pennsylvania Code. The PUC revised the definition of customer-generator to incorporate the term "retail electric customer" and added a definition for "utility" to make it clear that the definition applies to retail electric customers and not electric utilities, such as EDCs and so-called "merchant generators" that are in the business of providing electric services. The term "merchant generator" does not appear in the AEPS Act or regulations. The PUC does not define the term, but seeks to prevent "merchant generators" from net metering because of concerns regarding alleged ratepayer harm. The PUC created a secondary review for all renewable energy systems that are greater than 500 kilowatts in size. Amended Petition, ¶¶ 36, 37, 46, 49.

***3** Hommrich alleges that the PUC's imposition of new regulatory definitions and a review process creates uncertainty and insecurity with respect to Hommrich's qualifications under the AEPS Act and jeopardize his ability to secure financing for or otherwise proceed with his proposed solar projects. The regulatory threat to net metering rights prevents investors and lenders from even participating in the due diligence phase, which can take three months to complete, and is an expenditure of significant time and resources on behalf of an investor. If a project does not appear to be viable, the investor will not waste its time or resources. So long as the threat of the PUC enforcement of its new regulations looms, Hommrich cannot obtain funding for his personal projects. Hommrich must secure financing before ordering building materials to construct the facilities. Given the anticipated expiration of the tax credits, the time window for building his projects is both well-defined and closing. The tax credits will be phased out after 2019, which means that Hommrich only has three years to capture the full benefit of them. Once the tax credits diminish, so too will the tax equity investment opportunities. If a given year's project is not completed within that calendar year, Hommrich will be unable to make up for the lost construction opportunity in subsequent years. The threat of a protracted appeal process makes the remedy afforded through the administrative approval process inadequate. Amended Petition, ¶¶ 62–67, 76–79, 81–89. On these grounds, Hommrich seeks declaratory relief to settle and afford relief from uncertainty and insecurity with respect to his status as a customer-generator and his ability to net meter under the AEPS Act.

In response, the PUC filed preliminary objections. First, the PUC asserts that Hommrich's counts are legally insufficient with respect to his challenge to the PUC's regulations pursuant to Pa. R.C.P. No. 1028(a)(4) because the regulations have no direct and immediate effect on him. Next, the PUC objects because Hommrich fails to join the EDC as a necessary party pursuant to Pa. R.C.P. No. 1028(a)(5). The PUC also asserts that this Court lacks jurisdiction under Pa. R.C.P. No. 1028(a)(1) because Hommrich failed to exhaust available administrative remedies. In addition, the PUC contends the Amended Petition does not conform to law or rule of court pursuant to Pa. R.C.P. No. 1028(a)(2) because his pleadings are factually and legally insufficient to justify pre-enforcement review of the PUC's regulations. In addition, the PUC objects on the basis that Hommrich lacks capacity to sue the PUC under Pa. R.C.P. No. 1028(a)(5) because he has not established how he has been personally aggrieved by the regulations. Finally, the PUC seeks dismissal on the ground that Hommrich's Amended Petition seeks an impermissible advisory opinion. The PUC directed each objection to all three counts of Hommrich's Amended Petition. [12]

The PUC and Hommrich filed briefs in support of their positions. In addition, Pennsylvania Independent Oil and Gas Association (Amicus) filed an amicus curiae brief in opposition to the PUC's preliminary objections. This Court has directed expedited consideration of the matter. Commonwealth Court Orders, 2/14/17 and 3/23/17.

PO No. 1—Rule 1028(a)(4)—Legal Insufficiency of Pleading—Demurrer

First, the PUC contends that Hommrich's Amended Petition is legally insufficient because the challenged regulations have no direct and immediate effect on him. The PUC maintains that Hommrich's challenge is purely speculative. According to the PUC, Hommrich does not allege any facts that demonstrate an actual case or controversy because he does not provide details regarding the location of his alleged projects, identify the EDCs or investors, or allege a direct or indirect consequence of the PUC's regulations.

***4** "In ruling on preliminary objections, the courts must accept as true all well-pled facts that are material and all inferences reasonably deducible from the facts." *Pennsylvania Independent Oil & Gas Association v. Department of Environmental Protection*, 135 A.3d 1118, 1123 (Pa. Cmwlth. 2015) (*PIOGA*), *affirmed*, —— A.3d —— (Pa. 2017) (quoting *Guarrasi v. Scott*, 25 A.3d 394, 400 n.5 (Pa. Cmwlth. 2011)). "However, we 'are not required to accept as true any unwarranted factual inferences, conclusions of law or expressions of opinion.' " *Id*. (quoting *Guarrasi*, 25 A.3d at 400 n.5). "To sustain preliminary objections, 'it must appear with certainty that the law will permit no recovery' and '[a]ny doubt must be resolved in favor of the non-moving party.' " *Id*. (quoting *Guarrasi*, 25 A.3d at 400 n.5).

Section 7533 of the DJA states:

> Any person interested under a deed, will, written contract, or other writings constituting a contract, *or whose rights, status, or other legal relations are affected by a statute*, municipal ordinance, contract, or franchise, *may have determined any question of construction or validity arising under the* instrument, *statute*, ordinance, contract, or franchise, and obtain a declaration of rights, status, or other legal relations thereunder.

42 Pa. C.S. § 7533 (emphasis added). The DJA was enacted "to curb the courts' tendency to limit the availability of judicial relief to only cases where an actual wrong has been done or is imminent." *Bayada Nurses, Inc. v. Department of Labor and Industry*, 8 A.3d 866, 874 (Pa. 2010). The purpose of the DJA is "to settle and to afford relief from uncertainty and insecurity with respect to rights, status, and other legal relations" and, accordingly, the DJA should "be liberally construed and administered." 42 Pa. C.S. § 7541(a); *accord* *Office of Governor v. Donahue*, 98 A.3d 1223, 1229 (Pa. 2014) (citation omitted); *Funk v. Wolf*, 144 A.3d 228, 251 (Pa. Cmwlth. 2016), *affirmed*, 158 A.3d 642 (Pa. 2017).

Notwithstanding, "the availability of declaratory relief is limited by certain justiciability concerns." *Donahue*, 98 A.3d at 1229; *accord* *Funk*, 144 A.3d at 251. "In order to sustain an action under the [DJA], a plaintiff must allege an interest which is direct, substantial and immediate, and must demonstrate the existence of a real or actual controversy...." *Funk*, 144 A.3d at 251 (quoting *Donahue*, 98 A.3d at 1229); *accord* *Stilp v. Commonwealth*, 910 A.2d 775, 782 (Pa. Cmwlth. 2006), *affirmed*, 974 A.2d 491 (Pa. 2009). "A matter is ripe for judicial review if the issues are adequately developed and a party will suffer hardship by a delay of review." *Sewer Authority of City of Scranton v. Pennsylvania Infrastructure Investment Authority of Commonwealth*, 81 A.3d 1031, 1038 (Pa. Cmwlth. 2013) (citing *Bayada Nurses*, 8 A.3d at 874).

The Courts of this Commonwealth have recognized the justiciability of declaratory judgment actions seeking pre-enforcement review of a substantive challenge to the validity of regulations promulgated by administrative agency. *Donahue*, 98 A.3d at 1230; *Arsenal Coal Company v. Department of Environmental Protection*, 477 A.2d 1333, 1338 (Pa. 1984); *PIOGA*, 135 A.3d at 1125. A pre-enforcement challenge to new regulations is permitted where "the regulation itself causes actual, present harm." *PIOGA*, 135 A.3d at 1126 (quoting *Duquesne Light Company, Inc. v. Department of Environmental Protection*, 724 A.2d 413, 417 (Pa. Cmwlth. 1999)). Whether the harm is "present" is determined by whether the effect of the challenged regulations is "direct and immediate." *Arsenal*, 477 A.2d

at 1339. Conversely, where there is no harm done to the litigant until the agency takes some action to apply and enforce its regulations, the normal post-enforcement review process is deemed an adequate remedy. *Id*.

***5** Here, Hommrich alleged specific immediate harm if the challenged regulations remain in effect. Hommrich alleged that his inability to obtain financing for his proposed personal projects is a direct consequence of the PUC's regulations. Amended Petition, ¶¶ 77, 85. Hommrich needs funding and tax credits to build his proposed solar projects. In order to obtain funding, he must qualify for net metering under the law. Although he maintains that he qualifies under the AEPS Act, he alleged that his facilities could be disapproved under the regulations. Amended Petition, ¶ 28. He explained that the uncertainty as to whether he qualifies as a customer-generator under the regulations makes his projects too risky for investors and lenders. Moreover, the tax credits are only available until 2019. Without the aid of third-party funding and the benefit of the tax credits, his solar projects are not financially feasible. The window on his opportunity to build his solar projects is closing.

Additionally, Hommrich alleged that he will suffer hardship by the delay of review through an application and appeal process. Even at a brisk pace, the timeline for an appeal before the PUC is indeterminate. Such delay would likely deprive him of the opportunity to build the solar facility in 2017, at the very least. Once the construction window is missed, Hommrich will have lost potential income from that project.

Although Hommrich has not provided detailed information, such as the identity of the banks, investors, insurance companies, or EDCs, he has asserted sufficient information upon which to conclude that the regulations are causing him actual, present harm warranting pre-enforcement review in that he cannot obtain financing to build his new projects because of the threat of regulatory enforcement. Accepting Hommrich's well-pled allegations as true,[13] we believe that the asserted impact of the challenged regulations in this case is sufficiently direct and immediate to render the issue appropriate for judicial review. A DJA action is the appropriate means to settle and afford relief from uncertainty and insecurity with respect to the regulations and his putative status as a customer generator. We therefore overrule the PUC's preliminary objection as to Counts I and III.

However, insofar as Hommrich also seeks a declaration that the regulations cannot be retroactively applied to projects that were eligible or approved for net metering prior to the promulgation of the regulations, his claims fall short. Hommrich filed the Amended Petition in his personal capacity, not on behalf of Sunrise Energy. Hommrich has not alleged sufficient facts regarding Sunrise Energy's existing projects. He does not allege that the PUC enforced or intends to enforce its regulations against Sunrise Energy's existing projects retroactively. Significantly, he does not allege how the application of the regulations against these existing projects would cause him present harm to justify bypassing the normal post-enforcement review process. Thus, we sustain the PUC's preliminary objection to Count II of the Amended Petition for legal insufficiency.

PO No. 2—Rule 1028(a)(5)—Nonjoinder of a Necessary Party

Next, the PUC contends that Hommrich's Amended Petition should be dismissed because Hommrich failed to join the EDC as a necessary party. Hommrich asserts that his proposed projects and Sunrise Energy projects will "create excess energy that is sold to [an] EDC." Amended Petition, ¶ 58. The EDC provides net metering as a service and purchases excess energy at a retail rate. Therefore, the PUC claims the affected EDC has an interest in this matter that is not merely incidental. However, Hommrich does not identify the EDC to which he intends to interconnect and who would be obligated to purchase excess energy he produces. He does not join any EDC as a party.

***6** A party is considered indispensable when its rights are "so directly connected with and affected by litigation" that no decree can be made without impairing those rights. *CRY, Inc. v. Mill Service, Inc.*, 640 A.2d 372, 376 (Pa. 1994) (quoting *Scherbick v. Community College of Allegheny County*, 387 A.2d 1301, 1303 (Pa. 1978)). An indispensable party must be made party to protect such rights and a court should not adjudicate a case in the absence of an indispensable party. *Id*. The absence of an indispensable party "renders any order or decree of court null and void for want of jurisdiction." *Id*. (quoting *Scherbick* 387 A.2d at 1303).

We consider the following guidelines in determining whether a party is indispensable:

(1) Do absent parties have a right or interest related to the claim?

(2) If so, what is the nature of the right or interest?

(3) Is that right or interest essential to the merits of the issue?

(4) Can justice be afforded without violating due process rights of the absent parties?

CRY, Inc., 640 A.2d at 375 (quoting *Mechanicsburg Area School District v. Kline,* 431 A.2d 953, 956 (Pa. 1981)). The basic inquiry is whether justice can be done in the absence of a third party. *Id*. For an accurate analysis, the court must "refer to the nature of the claim and the relief sought." *Id*. at 376.

Here, according to the PUC, the identity and joinder of the EDC is necessary because the challenged regulations would not apply to customers served by rural electric cooperatives and municipal electric systems. However, the PUC's assertion fails to accept as true Hommrich's well-pled allegation that the proposed projects "are within the service territory of Pennsylvania EDCs." Amended Petition, ¶ 24. Hommrich also alleges that he "does not seek to build his facilities in any service territory where net metering is not available pursuant to the AEPS Act." *Id*. Hommrich seeks a declaration regarding the validity of the PUC's regulations. His challenge is a question of law that is not dependent on the location of his planned projects in a particular EDC service territory or the identity of the EDC to which Hommrich's alternative energy systems would interconnect and to which he would sell his excess energy. Although an EDC is the entity responsible for approving or denying an application for net metering depending if the applicant qualifies under the law, the EDCs do not have a right or interest regarding the validity of the regulations or who qualifies as a customer-generator. The EDCs merely apply the law in effect when ruling on the applications. Thus, we conclude that the EDC is not an indispensable party to this litigation and overrule this objection.

PO No. 3—Rule 1028(a)(1)—Lack of Jurisdiction

Next, the PUC contends that this Court lacks jurisdiction because Hommrich has not pled facts demonstrating that he has applied to net meter any solar project. Therefore, none of the regulations he seeks to enjoin the PUC from enforcing have been enforced against him or his projects. The PUC maintains that filing an application to net meter to an EDC is a prerequisite to this action. Only if the EDC denies his application may Hommrich seek review with the PUC under Section 701 of the Public Utility Code, 66 Pa. C.S. § 701 or 52 Pa. Code § 75.17. Only then may Hommrich file an appeal to this Court. Thus, the PUC claims that this Court lacks subject matter jurisdiction because Hommrich has not exhausted available administrative remedies. [14]

***7** As discussed above, this Court may invoke its original equitable jurisdiction to resolve a pre-enforcement challenge to the validity of regulations promulgated by administrative agency. *Arsenal*, 477 A.2d at 1338. "Administrative agencies are not empowered to make rules and regulations which are violative of or exceed the powers given them by the statutes and the law, but must keep within the bounds of their statutory authority in the promulgation of general rules and orders." *Pennsylvania Association of Life Underwriters v. Department of Insurance*, 371 A.2d 564, 566 (Pa. Cmwlth. 1977), *affirmed*, 393 A.2d 1131 (Pa. 1978). "An agency cannot confer authority upon itself by regulation. Any power exercised by an agency must be conferred by the legislature in express terms." *Sunrise Energy*, 148 A.3d at 907.

Notwithstanding, the courts must refrain from exercising equity jurisdiction when there exists an adequate statutory remedy. *Id*. The doctrine of exhaustion of administrative remedies is intended to prevent the premature interruption of the administrative process, which would restrict the agency's opportunity to develop an adequate factual record, limit the agency in the exercise of its expertise, and impede the development of a cohesive body of law in that area. *Bucks County Services, Inc. v. Philadelphia Parking Authority*, 71 A.3d 379, 388 (Pa. Cmwlth. 2013).

However, the exhaustion doctrine is not so inflexible as to bar legal or equitable jurisdiction where the remedy afforded through the administrative or statutory process is inadequate, such as an action challenging the scope of an agency's powers. *Bucks County*, 71 A.3d at 388 (non-medallion taxicab operators seeking declaratory and injunctive relief against Philadelphia Parking Authority alleging taxicab regulations were invalid did not have to exhaust statutory remedy); *see also* *Hoke v. Elizabethtown Area School District*, 833 A.2d 304 (Pa. Cmwlth. 2003), *appeal denied*, 847 A.2d 59 (Pa. 2004) (student challenging school district's enrollment policy requiring an expulsion hearing did not have to exhaust administrative remedy of having the hearing); *Spooner v. Secretary of Commonwealth*, 539 A.2d 1 (Pa. Cmwlth.

1988), *affirmed*, 574 A.2d 600 (Pa. 1990) (pool owners and swimmers seeking declaration that the Department of Environmental Resources (DER) did not have authority to enforce regulation requiring lifeguards at any public pool licensed by DER did not have to exhaust statutory remedy in the nature of an appeal of an enforcement order). Significantly, in *Bucks County*, we noted that the Philadelphia Parking Authority cannot rule upon the legality of its own regulations or its power to issue them. Similarly, in *Hoke*, the school board could not rule on the legality of the school district's policy, which is what the student sought. In *Spooner*, we noted that it would not be proper for the agency promulgating a regulation to determine whether it had authority to do so. Additionally, the review process is inadequate if the regulation's effects would result in piecemeal litigation or uncertainty in the industry. *Arsenal*, 477 A.2d at 1340.

Here, the General Assembly tasked the PUC "to develop technical and net metering interconnection rules for customer-generators...." Section 5 of the AEPS Act, 73 P.S. § 1648.5. Whether the PUC exceeded this statutory authority is the crux of the Amended Petition.

Hommrich readily admits that he did not apply for and was not denied an interconnection request for his proposed projects. Hommrich's Answer to Preliminary Objections, ¶ 25. Instead, Hommrich seeks pre-enforcement review of a substantive challenge to the validity of regulations promulgated by the PUC. In this regard, Hommrich alleged sufficient facts in his Amended Petition to establish that pre-enforcement review is appropriate in this case. Hommrich asserts that the PUC exceeded its statutory authority by redefining terms and imposing additional restrictions on net metering violative of the AEPS Act and case law. Hommrich alleged that the imposition of these regulations would have a substantial and immediate impact on his ability to net meter and generate alternate energy under the AEPS Act. In addition, Amicus, a trade association representing oil and natural gas interests in Pennsylvania whose members are impacted by these regulations, advances similar concerns for the need for pre-enforcement review of the regulations for the industry.

***8** We agree with Hommrich that there is no adequate administrative remedy available with regard to Count I of his Amended Petition because the PUC cannot rule upon the legality of its own regulations or its power to issue them. *See Bucks County; Hoke; Spooner*. Absent pre-enforcement review, piecemeal litigation of this issue is inevitable. Conversely, determining whether the PUC's regulations are violative of or exceed the scope of statutory authority would resolve any ongoing uncertainty in the alternative energy industry and promote the goals of the AEPS Act. *See Arsenal*. For these reasons, we overrule the PUC's lack of jurisdiction objection as to Count I of his Amended Petition.

However, insofar as Hommrich seeks a declaration from this Court that his proposed solar projects qualify for customer-generator status under the AEPS Act and are eligible for net metering in Count III of his Amended Petition, Hommrich has not exhausted administrative remedies or alleged sufficient facts that the review process is deficient or too time-consuming.

Under the regulations, the EDC is charged with approving or denying net metering applications to enable a generator to interconnect onto its distribution system in accordance with the AEPS Act and regulations. 52 Pa. Code § 75.13(a). The EDC must determine whether proposed facilities meet the criteria, which includes criteria beyond whether an applicant is a customer-generator. *See id*. Whether a project qualifies for net metering is fact specific. *See id*. [15] It is for the EDC, not this Court, to determine whether an applicant qualifies for net metering or whether there are any potential deficiencies ancillary to the issue of net metering. *Id*. Hommrich has not provided this Court with sufficient details regarding his proposed projects to even attempt such a determination. Hommrich must file an application with the EDC for his proposed projects to obtain the approval to net meter that he seeks here.

To the extent Hommrich claims this administrative remedy is inadequate because of the length of time involved, Hommrich's claims are speculative at best. Under the challenged regulation, the EDC submits a completed application to the PUC's Bureau of Technical Utility Services (Bureau) with a recommendation on whether the system complies with regulatory provisions for net metering and the EDC's net metering tariff "*within 20 days of receiving the completed application*." 52 Pa. Code § 75.17(b) (emphasis added). If the EDC recommends approving an application, the Bureau has 10 days to approve or disapprove the net metering application. 52 Pa. Code § 75.17(e). The Bureau must describe in detail the reasons for disapproval. *Id*.

If the EDC recommends rejecting an application, the applicant has 20 days to submit a response to the Bureau.

52 Pa. Code § 75.17(c). The Bureau then has 5 days from an applicant's response to approve or disapprove the application, "*but no more than 30 days* after an EDC submits an application with a recommendation to deny approval, whichever is earlier." 52 Pa. Code § 75.17(e) (emphasis added). All told, the timeline for approval or denial is relatively short.

Thereafter, both the applicant and the EDC may appeal the Bureau's determination to the PUC within 20 days pursuant to Section 5.44, which relates to petitions for reconsideration from actions of the staff. 52 Pa. Code §§ 5.44(a), 75.17(g). Although neither the AEPS Act nor the regulations provide a time limit within which the PUC must act on the petition for reconsideration, administrative agencies are entitled to a presumption that they will act in good faith in discharging their duties. *See* *Donahue*, 98 A.3d at 1239. Failing that, there are other avenues of relief, such as mandamus. But, until he applies, it is unknown whether this administrative remedy is inadequate. Thus, we sustain the PUC's preliminary objection to Count III.

PO No. 4—Rule 1028(a)(2)—
Pleading Fails to Conform to Law

***9** Next, the PUC objects on the ground that Hommrich's pleadings are insufficient pursuant to Pa. R.C.P. No. 1019. On this basis, the PUC claims the Amended Petition fails to conform to law or rule of court pursuant to Pa. R.C.P. No. 1028(a)(2).

"Pennsylvania is a fact-pleading state." *Brimmeier v. Pennsylvania Turnpike Commission*, 147 A.3d 954, 967 (Pa. Cmwlth. 2016), *affirmed*, —— A.3d —— (Pa., No. 104 MAP 2016, filed May 25, 2017) (quoting *Bricklayers of West Pennsylvania Combined Funds, Inc. v. Scott's Development Co.*, 90 A.3d 682, 694 n.14 (Pa. 2014)). Rule 1019 of the Pennsylvania Rules of Civil Procedure governs the contents of pleadings and provides, in relevant part:

> (a) The material facts on which a cause of action or defense is based shall be stated in a concise and summary form.
>
> * * *
>
> (f) Averments of time, place and items of special damage shall be specifically stated.
>
> (g) Any part of a pleading may be incorporated by reference in another part of the same pleading or in another pleading in the same action. A party may incorporate by reference any matter of record in any State or Federal court of record whose records are within the county in which the action is pending, or any matter which is recorded or transcribed verbatim in the office of the prothonotary, clerk of any court of record, recorder of deeds or register of wills of such county.
>
> (h) When any claim or defense is based upon an agreement, the pleading shall state specifically if the agreement is oral or written.
>
> Note: If the agreement is in writing, it must be attached to the pleading. See subdivision (i) of this rule.
>
> (i) When any claim or defense is based upon a writing, the pleader shall attach a copy of the writing, or the material part thereof, but if the writing or copy is not accessible to the pleader, it is sufficient so to state, together with the reason, and to set forth the substance in writing.

Pa. R.C.P. No. 1019. For pleadings to suffice, they must: "adequately explain the nature of the claim to the opposing party so as to permit the preparation of a defense," and "be sufficient to convince the court that the averments are not merely subterfuge." *Martin v. Lancaster Battery Co., Inc.*, 606 A.2d 444, 448 (Pa. 1992).

Here, Hommrich alleged that he personally plans to build solar facilities. The projects will be working sheep farms that will not provide distribution services, like an EDC does, or sell power and capacity to end users, like an Electric Generation Supply company does. Amended Petition, ¶ 27. He described the proposed projects as similar to those built by his company, Sunrise Energy. Amended Petition, ¶ 58. He alleged that his proposed solar facilities will have a nameplate capacity of 3,000 kilowatts. Amended Petition, ¶ 27. A portion of the electricity generated by his solar facilities will be used to offset part of the farms' multiple electrical loads, including a barn with lights and outlets, water pump, fence, and electricity required to operate the renewable energy system. Amended Petition, ¶ 27. The proposed projects will be located within a Pennsylvania EDC's service area. Amended Petition, ¶ 24.

In addition, he averred the harm that he would suffer of a lost opportunity to construct these projects if the PUC's

regulations remain in effect. Specifically, Hommrich alleged that potential investors will not finance his projects because of the regulations and the uncertainty of Hommrich's status as a customer-generator.

***10** The PUC takes issue with the fact that Hommrich did not provide further details regarding the proposed projects, including the location of the projects, the name of the EDC that will serve the location, whether the working sheep farms currently exist or are planned, and the identity of the electrical service provider. The PUC also points out that Hommrich has not attached plans for the projects or any lease agreements. The PUC maintains that without this information, it is impossible for it to determine whether the projects exist as described and whether the PUC's regulations would actually affect Hommrich. The PUC contends it will be incapable of investigating or defending against Hommrich's claims without this information.

The additional details the PUC seeks are not critical for ruling on the remaining count challenging the validity of the regulations. For purposes of this stage of the proceeding, Hommrich has sufficiently alleged his plan to build the proposed solar facilities and how his plans are affected by the PUC's regulations. Upon review, Hommrich has sufficiently pled facts to state his case and survive this objection. Thus, we overrule this preliminary objection.

PO No. 5—Rule 1028(a)(5)—Lacks Capacity to Sue

Next, the PUC objects on the basis that Hommrich lacks capacity to sue the PUC because he did not establish how he has been personally aggrieved by the PUC's regulations from which he seeks declaratory judgment. According to the PUC, the regulations do not directly and immediately affect Hommrich. The PUC contends that it can be reasonably inferred that Hommrich is not personally contracting in the solar power facilities because he is the President of Sunrise Energy. The PUC maintains this allegation "is dubious in light of the fact that [ ] Hommrich admits he has sought the legal benefits of a limited liability company for his solar power developing venture, Sunrise Energy." Respondent's Brief at 38. The PUC advances that "this Court is not required to believe that he now wants to put his personal assets at risk doing the same activities he created Sunrise Energy to perform." *Id*.

In adjudicating preliminary objections alleging a lack of capacity to sue, we must consider the party's standing. *PG Publishing Co., Inc. v. Governor's Office of Administration*, 120 A.3d 456, 461 (Pa. Cmwlth. 2015), *affirmed*, 135 A.3d 578 (Pa. 2016). Our Supreme Court has explained that the hallmark of standing is that "a person who is not adversely affected in any way by the matter he seeks to challenge is not 'aggrieved' thereby." *William Penn Parking Garage, Inc. v. City of Pittsburgh*, 346 A.2d 269, 280 (Pa. 1975). An individual is aggrieved if he has a "substantial, direct and immediate interest in the outcome of the litigation." *Fumo v. City of Philadelphia*, 972 A.2d 487, 496 (Pa. 2009).

Our Supreme Court recently addressed standing in declaratory judgment actions in *Donahue*, 98 A.3d at 1229, explaining:

> In Pennsylvania, the doctrine of standing ... is a prudential, judicially created principle designed to winnow out litigants who have no direct interest in a judicial matter. *In re Hickson*, ... 821 A.2d 1238, 1243 ([Pa.] 2003). For standing to exist, the underlying controversy must be real and concrete, such that the party initiating the legal action has, in fact, been "aggrieved." *Pittsburgh Palisades Park, LLC v. Commonwealth*, ... 888 A.2d 655, 659 ([Pa.] 2005). As this Court explained in *William Penn Parking Garage*, "the core concept [of standing] is that a person who is not adversely affected in any way by the matter he seeks to challenge is not 'aggrieved' thereby and has no standing to obtain a judicial resolution to his challenge." 346 A.2d at 280–81. A party is aggrieved for purposes of establishing standing when the party has a "substantial, direct and immediate interest" in the outcome of litigation. *Johnson [v. American Standard*, 8 A.3d 318, 329 (Pa. 2010)] (quoting *Fumo*[, 972 A.2d at 496]). A party's interest is substantial when it surpasses the interest of all citizens in procuring obedience to the law; it is direct when the asserted violation shares a causal connection with the alleged harm; finally, a party's interest is immediate when the causal connection with the alleged harm is neither remote nor speculative. *Id*.

***11** Here, although Hommrich identifies himself as the President of Sunrise Energy, he clearly sets forth that he is pursuing the proposed projects in his individual capacity for *his personal use*, not in a corporate capacity. Simply because Hommrich shared with this Court his corporate

status and prior experience in solar development does not negate his well-pled allegations that the proposed projects are personal and independent of the corporation. Hommrich alleged that he will "personally operate and maintain" the project. Amended Petition, ¶ 23. "The planned projects are separate and distinct from any assets owned by Sunrise [Energy]." Amended Petition, ¶ 22. "Sunrise Energy will not be involved in the construction or operation of the projects, nor does Sunrise [Energy] own a financial interest in them." Amended Petition, ¶ 26. For purposes of ruling on preliminary objections, we accept as true all well-pled allegations and all reasonable inferences deducible therefrom. *PIOGA*, 135 A.3d at 1123. The fact that the PUC finds Hommrich's allegations "dubious" is of no moment at this stage of the proceeding. *See id*.

Although Hommrich has not yet filed an interconnection application with an EDC and the PUC has not enforced the regulations against him, Hommrich claims he is aggrieved by the regulations because they are impeding his ability to obtain necessary funding for his projects. He is seeking pre-enforcement review to establish that he is qualified to net meter as a customer-generator under the AEPS Act. As a putative customer-generator, his interest in challenging the regulations surpasses that of other citizens procuring obedience to the law. *See* *Donahue*, 98 A.3d at 1229. Upon review, Hommrich has sufficiently alleged an interest in challenging the regulations, which is direct, substantial and immediate, and has shown the existence of a real or actual controversy that he has an interest in the outcome of the litigation. Thus, we overrule the PUC's preliminary objection challenging his capacity to sue.

PO No. 6—Advisory Opinion

Lastly, the PUC contends Hommrich's Amended Petition must be dismissed because it seeks an advisory opinion based on a purely hypothetical situation. The PUC asserts that Hommrich failed to plead facts demonstrating that the PUC enforced its regulations against his projects. He has not pled facts showing that he personally has an existing renewable energy system that was approved by the PUC as eligible for net metering prior to the promulgation of the regulations. He has not pled that his proposed projects will otherwise meet the statutory requirements for customer-generator and net metering status under the AEPS Act.

As discussed above, in order to sustain a declaratory judgment action, a plaintiff must demonstrate the existence of a real or actual controversy, "as the courts of this Commonwealth are generally proscribed from rendering decisions in the abstract or issuing purely advisory opinions." *Funk*, 144 A.3d at 251 (quoting *Donahue*, 98 A.3d at 1229). "[D]eclaratory judgment must not be employed ... as a medium for the rendition of an advisory opinion which may prove to be purely academic." *Id*. at 251 (quoting *Gulnac by Gulnac v. South Butler County School District,* 587 A.2d 699, 701 (Pa. 1991)). "Courts generally should refuse to grant requests for declaratory judgment where it would not resolve the controversy or uncertainty which spurred the request." *Id*. (quoting *Rendell v. Pennsylvania State Ethics Commission*, 938 A.2d 554, 559 (Pa. Cmwlth. 2007)).

Although Hommrich's proposed projects have not been reviewed or denied under challenged regulations, the remaining issue is whether Hommrich may seek pre-enforcement review of a substantive challenge to the validity of the PUC's regulations. Hommrich alleged that the regulations are causing actual and present harm in that they are thwarting his ability to finance his proposed solar facilities. Under the facts and harm alleged, we believe Hommrich is entitled to seek pre-enforcement relief. *See PIOGA*. We overrule this objection.

In conclusion, we overrule the PUC's multiple preliminary objections to Count I. We sustain the PUC's objection to Count II on the basis of legal insufficiency and its objection to Count III for lack of jurisdiction.

ORDER

***12** AND NOW, this 28th day of July, 2017, the Pennsylvania Public Utility Commission's (PUC) preliminary objections to Count I of Petitioner's Amended Petition for Review in the Nature of a Complaint for Declaratory and Injunctive Relief (Amended Petition) are OVERRULED; the preliminary objections to Counts II and III of the Amended Petition are SUSTAINED. PUC is hereby directed to file an answer to the Amended Petition within thirty (30) days of this order.

All Citations

Not Reported in Atl. Rptr., 2017 WL 3203437, Util. L. Rep. P 27,411

Footnotes

1 We note that the proper designation for the PUC is the "Public Utility Commission," not "Utilities" as designated in Hommrich's Amended Petition and in the caption. *See* 66 Pa. C.S. § 301.

2 Act of November 30, 2004, 73 P.S. §§ 1648.1–1648.8.

3 42 Pa. C.S. §§ 7531–7541.

4 Hommrich also sought injunctive relief to prevent the enforcement of the regulations during the pendency of this matter. He then filed a motion for stay, which this Court dismissed as unauthorized without prejudice to seek preliminary injunctive relief. Commonwealth Court Order, 1/5/17. Thereafter, Hommrich filed an application for expedited special relief in the nature of a preliminary injunction, which he later withdrew. Commonwealth Court Order, 3/16/17.

5 Section 2 of the AEPS Act defines "Customer-generator" as:

> A nonutility owner or operator of a net metered distributed generation system with a nameplate capacity of not greater than 50 kilowatts if installed at a residential service or not larger than 3,000 kilowatts at other customer service locations, except for customers whose systems are above three megawatts and up to five megawatts who make their systems available to operate in parallel with the electric utility during grid emergencies as defined by the regional transmission organization or where a microgrid is in place for the primary or secondary purpose of maintaining critical infrastructure, such as homeland security assignments, emergency services facilities, hospitals, traffic signals, wastewater treatment plants or telecommunications facilities, provided that technical rules for operating generators interconnected with facilities of an electric distribution company, electric cooperative or municipal electric system have been promulgated by the Institute of Electrical and Electronic Engineers and the [PUC].

73 P.S. § 1648.2.

6 Section 2 of the AEPS Act defines "Net metering" as:

> The means of measuring the difference between the electricity supplied by an electric utility and the electricity generated by a customer-generator *when any portion of the electricity generated by the alternative energy generating system is used to offset part or all of the customer-generator's requirements for electricity*. Virtual meter aggregation on properties owned or leased and operated by a customer-generator and located within two miles of the boundaries of the customer-generator's property and within a single electric distribution company's service territory shall be eligible for net metering.

73 P.S. § 1648.2 (emphasis added).

7 Section 75.1 defines "utility" as:

> (i) A business, person or entity whose primary purpose, character or nature is the generation, transmission, distribution or sale of electricity at wholesale or retail.
>
> (ii) The term excludes building or facility owners or operators that manage the internal distribution system serving the building or facility and that supply electric power and other related power services to occupants of the building or facility.

52 Pa. Code § 75.1. It defines "customer-generator" as:

> A retail electric customer that is a nonutility owner or operator of a net metered distributed generation system with a nameplate capacity of not greater than 50 kilowatts if installed at a residential service or not larger than 3,000 kilowatts at other customer service locations, except for customers whose systems are

above 3 megawatts and up to 5 megawatts who make their systems available to operate in parallel with the electric utility during grid emergencies as defined by the regional transmission organization or where a microgrid is in place for the primary or secondary purpose of maintaining critical infrastructure, such as homeland security assignments, emergency services facilities, hospitals, traffic signals, wastewater treatment plants or telecommunications facilities, provided that technical rules for operating generators interconnected with facilities of an EDC, electric cooperative or municipal electric system have been promulgated by the institute of electrical and electronic engineers and the Commission.

52 Pa. Code § 75.1.

8 Section 75.12 defines "Virtual meter aggregation" as:

The combination of readings and billing for all meters regardless of rate class on properties owned or leased and operated by a customer-generator by means of the EDC's billing process, rather than through physical rewiring of the customer-generator's property for a physical, single point of contact. Virtual meter aggregation on properties owned or leased and operated by the same customer-generator and located within 2 miles of the boundaries of the customer-generator's property and within a single EDC's service territory shall be eligible for net metering. Service locations to be aggregated must be EDC service location accounts, held by the same individual or legal entity, receiving retail electric service from the same EDC and have measureable electric load independent of the alternative energy system. To be independent of the alternative energy system, the electric load must have a purpose other than to support the operation, maintenance or administration of the alternative energy system.

52 Pa. Code § 75.12.

9 These sections provide:

(a) EDCs and [default service providers (DSPs)] shall offer net metering to customer-generators that generate electricity on the customer-generator's side of the meter using Tier I or Tier II alternative energy sources, on a first come, first served basis. To qualify for net metering, the customer-generator shall meet the following conditions:

(1) Have electric load, independent of the alternative energy system, behind the meter and point of interconnection of the alternative energy system. To be independent of the alternative energy system, the electric load must have a purpose other than to support the operation, maintenance or administration of the alternative energy system.

* * *

(5) An alternative energy system with a nameplate capacity of 500 kW or more must have Commission approval to net meter in accordance with § 75.17 (relating to process for obtaining Commission approval of customer-generator status).

52 Pa. Code §§ 75.13(a)(1), (5).

10 Section 75.16 provides:

(a) This section applies to distributed generation systems with a nameplate capacity above 3 MW and up to 5 MW. The section identifies the standards that distributed generation systems must satisfy to qualify for customer-generator status.

(b) A retail electric customer may qualify its alternative energy system for customer-generator status if it makes its system available to operate in parallel with the grid during grid emergencies by satisfying the following requirements:

(1) The alternative energy system is able to provide the emergency support consistent with the [regional transmission organization (RTO)] tariff or agreement.

(2) The alternative energy system is able to increase and decrease generation delivered to the distribution system in parallel with the EDC's operation of the distribution system during the grid emergency.

(c) A retail electric customer may qualify its alternative energy system located within a microgrid for customer-generator status if it satisfies the following requirements:

(1) The alternative energy system complies with Institute of Electrical and Electronics Engineers, Inc. (IEEE)] Standard 1547.4.

(2) The customer documents that the alternative energy system exists for the primary or secondary purpose of maintaining critical infrastructure.

52 Pa. Code § 75.16.

11 Section 75.17 establishes the process for obtaining the PUC approval of customer-generator status, providing:

(a) This section establishes the process through which EDCs obtain Commission approval to net meter alternative energy systems with a nameplate capacity of 500 kW or greater.

(b) An EDC shall submit a completed net metering application to the Commission's Bureau of Technical Utility Services with a recommendation on whether the alternative energy system complies with the applicable provisions of this chapter and the EDC's net metering tariff provisions within 20 days of receiving a completed application. The EDC shall serve its recommendation on the applicant.

(c) The net metering applicant has 20 days to submit a response to the EDC's recommendation to reject an application to the Bureau of Technical Utility Services.

(d) The Bureau of Technical Utility Services will review the net metering application, the EDC recommendation and applicant response, and make a determination as to whether the alternative energy system complies with this chapter and the EDC's net metering tariff.

(e) The Bureau of Technical Utility Services will approve or disapprove the net metering application within 10 days of an EDC's submission recommending approval. If disapproved, the Bureau of Technical Utility Services will describe in detail the reasons for disapproval. The Bureau of Technical Utility Services will serve its determination on the EDC and the applicant.

(f) The Bureau of Technical Utility Services will approve or disapprove the net metering application within 5 days of an applicant's response to an EDC's recommendation to deny approval, but no more than 30 days after an EDC submits an application with a recommendation to deny approval, whichever is earlier. The Bureau of Technical Utility Services will serve its determination on the EDC and the applicant.

(g) The applicant and the EDC may appeal the determination of the Bureau of Technical Utility Services in accordance with § 5.44 (relating to petitions for reconsideration from actions of the staff).

52 Pa. Code § 75.17.

12 Thereafter, the PUC filed an application for summary relief seeking to dismiss the action on the basis that Hommrich lacks standing to proceed, which this Court stayed pending disposition of the PUC's preliminary objections. Commonwealth Court Orders, 3/23/17 and 4/11/17.

The PUC also filed a motion to compel discovery. Hommrich responded by filing an application for stay of discovery and an application for *in camera* review of the documents requested in discovery. This Court granted Hommrich's application for stay of discovery pending disposition of the PUC's preliminary objections; denied his application for *in camera* review, without prejudice to refile, if necessary, following the disposition of the preliminary objections; and, denied the PUC's motion to compel discovery, without prejudice to refile, if necessary, following the disposition of the preliminary objections. Commonwealth Court Order, 4/11/17.

Thereafter, Hommrich filed an application for summary relief. The PUC responded by filing an answer and an application to quash on the ground that there are material issues of fact related to Hommrich's asserted claims; alternatively, the PUC requested a stay. This Court stayed the application for summary relief and motion to quash pending disposition of the PUC's preliminary objections. Commonwealth Court Order, 7/10/17.

13 The fact that the PUC does not believe these allegations is not an appropriate consideration when ruling on preliminary objections as we must accept as true all well-pled allegations as fact. *PIOGA*, 135 A.3d at 1123.

14 We note that the PUC did not specifically object under Pa. R.C.P. No. 1028(a)(7) (failure to exhaust a statutory remedy) or Pa. R.C.P. No. 1028(a)(8) (full, complete and adequate non-statutory remedy at law). Rather, the PUC asserted Pa. R.C.P. No. 1028(a)(1) (lack of jurisdiction) as the sole basis for this objection.

15 We note Hommrich only challenges Section 75.13(a)(1) and (a)(5), not the other conditions listed in subsection (a) to qualify for net metering.

End of Document

APPENDIX 2

Entity# : 7450243
Date Filed : 02/04/2022
Pennsylvania Department of State

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

☐ **Return document by mail to:**

Micah Bucy
Name

100 North Tenth Street,
Address

Harrisburg	**PA**	**17101**
City	State	Zip Code

☐ Return document by email to: _____

Articles of Incorporation-NonProfit

(15 Pa.C.S.)

(rev . 2/2017)

5306

Read all instructions prior to completing. This form may be submitted online at https://www.corporations.pa.gov/.

Fee: $125.00 ☐ I qualify for a veteran/reservist-owned small business fee exemption (see instructions)

Check one: ☒ **Domestic Nonprofit Corporation (§ 5306)** ☐ **Nonprofit Cooperative Corporation (§ 7102B)**

In compliance with the requirements of the applicable provisions (relating to articles of incorporation or cooperative corporations generally), the undersigned, desiring to incorporate a nonprofit/nonprofit cooperation corporation, hereby state(s) that:

1. The name of the corporation is:

Medical Marijuana Access & Patient Safety Inc.

2. Complete part (a) or (b) – not both:

(a) The address of this corporation's current registered office in this Commonwealth is: *(post office box alone is not acceptable)*

100 N. Tenth Street,	Harrisburg	PA	17101	Dauphin
Number and Street	City	State	Zip	County

(b) The name of this corporation's commercial registered office provider and the county of venue is:

c/o: _____

Name of Commercial Registered Office Provider — County

3. The corporation is incorporated under the Nonprofit Corporation Law of 1988 for the following purpose or purposes.

To advocate for medical marijuana patient safety and patient access to medical marijuana treatments.

4. The corporation does not contemplate pecuniary gain or profit, incidental or otherwise.

5. ***Check and complete one:***

☒ The corporation is organized on a non-stock basis.

☐ The corporation is organized on a stock share basis and the aggregate number of shares authorized is:

6. For unincorporated association incorporating as a nonprofit corporation only. Check if applicable:

_____ The incorporators constitute a majority of the members of the committee authorized to incorporate such association by the requisite vote required by the organic law of the association for the amendment of such organic law.

7. ***For Nonprofit Corporation Only:***

Check one: ____ *The corporation shall have no members.*

X *The corporation shall have members.*

8. ***For Nonprofit Cooperative Corporation Only:***

Check one of the following:

___ The corporation is a cooperative corporation and the common bond of membership among its members is:

___ The corporation is a cooperative corporation and the common bond of membership among its shareholders is :

9. The name(s) and address(es) of each incorporator(s) is (are) (all incorporators must sign below):

Name	**Address**
Micah R Bucy	100 N. Tenth Street , Harrisburg , Dauphin , PA , United States , 17101

10. The specified effective date, if any, is:

month day year hour, if any

11. Additional provisions of the articles, if any, attach an 8½ x 11 sheet.

IN TESTIMONY WHEREOF, the incorporator(s) has/have signed these Articles of Incorporation this

04 day of February , 2022 .

Micah R Bucy

Signature

APPENDIX 3

2017 WL 3746562
Only the Westlaw citation is currently available.

See Pa. Commonwealth Court Internal Operating Procedures, Sec. 414 before citing.

Commonwealth Court of Pennsylvania.

Nicole HOOKS,
v.
SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY, Appellant

No. 946 C.D. 2016
|
ARGUED: February 7, 2017
|
FILED: August 31, 2017

BEFORE: HONORABLE ROBERT SIMPSON, Judge HONORABLE ANNE E. COVEY, Judge HONORABLE JULIA K. HEARTHWAY, Judge

MEMORANDUM OPINION

JUDGE HEARTHWAY

***1** The Southeastern Pennsylvania Transportation Authority (SEPTA) appeals from the April 26, 2016 order of the Court of Common Pleas of Philadelphia County (trial court), denying SEPTA's post-trial motions seeking a new trial. SEPTA's appeal is based on a challenge to the admissibility of testimony by an expert witness on behalf of Nicole Hooks. Discerning no abuse of discretion, we affirm.

Hooks was working as an assistant conductor on SEPTA's Wilmington train line during the early morning hours of July 5, 2011, when she was struck in the head and injured by an unruly passenger. Hooks brought suit against SEPTA for negligence.[1] At trial, Hooks called George Frazier as an expert witness on transportation safety and security.

Frazier is a security consultant for the transportation industry. The trial court described Frazier's qualifications as follows:

> Captain Frazier has spent twenty-four (24) years working in transportation security for the AMTRAK Police Department, including ten (10) years as AMTRAK's Chief of Police... He has approximately two thousand (2000) hours of training including specific training in areas such as railroad operations, railroad safety, management of incidents, criminal investigations, and records management... He further testified that he had specific independent knowledge and experience with the Wilmington line from his work with AMTRAK and his later work as Director of Public Safety for New Castle County, Delaware...

(Trial Court Opinion, 8/11/16, at 4) (citations omitted). SEPTA did not object to Frazier's qualification as an expert.

However, SEPTA did object to Frazier's testimony insofar as it was based on six interviews of SEPTA conductors. The conductors were referred to Frazier by Hooks' counsel. The interviews were not transcribed or documented. The interviewees were not called as witnesses for Hooks at trial. Outside the presence of the jury, the trial court conducted a hearing pursuant to Pa.R.E. 104 to determine whether Frazier's expert testimony, based at least in part on these six interviews, was admissible.

At that hearing, Frazier testified that in this case he followed the methodology typically used by experts in his field of expertise. He acquired and reviewed the available pleadings and discovery. (Notes of Testimony (N.T.), 12/15/16, at 100–01.) He then conducted interviews "just [to] try to get to the bottom line on what had happened in terms of that particular incident and to form an opinion on what the circumstances were that surrounded it." (N.T., 12/15/16, at 101.) After counsel for Hooks and SEPTA had questioned Frazier, the trial court engaged in the following exchange:

> THE COURT: Let me just clarify, you said that many times you and others in the field rely on deposition testimony; is that correct?

THE WITNESS: Yes.

THE COURT: But there are times that you and others in the field rely on witness interviews?

***2** THE WITNESS: Yes, Your Honor.

THE COURT: And you're not the only one who does this; other experts do this as well?

THE WITNESS: Yes, Your Honor.

THE COURT: And there was no deposition testimony that was available to you in this case; is that correct?

THE WITNESS: Yes, Your Honor.

THE COURT: Are there other cases that you prepared expert reports where there was no deposition testimony that was available?

THE WITNESS: Yes, Your Honor.

THE COURT: And in those cases, do you also rely upon witness interviews that you conduct?

THE WITNESS: Yes, Your Honor.

THE COURT: Do other experts in the field when they don't have deposition testimony available also customarily rely upon witnesses to interview?

THE WITNESS: Yes, Your Honor.

(N.T., 12/15/16, at 12–13.)

SEPTA objected to Frazier's testimony on the bases that the interview subjects were not under oath; the interviews were not reduced to writing; and that the credibility of the interviewees could not be tested. SEPTA also alleged that Frazier's expert opinion was based solely on the contents of the challenged interviews, and that Frazier was simply acting as a conduit for that content. In response to SEPTA's objection, the trial court further questioned Frazier:

THE COURT: In preparing your... 14–page report as part of your methodology, did you rely exclusively on what those approximately six people said to you, or did your investigation go beyond just those interviews with those six people?

THE WITNESS: I formed my opinion based on much more than those six people.

(N.T., 12/15/16, at 120.) Frazier then elaborated on other sources of information that informed his opinion in this case, including the depositions of Hooks and SEPTA police and safety personnel, and SEPTA policies and records.

The trial court overruled SEPTA's objection to Frazier's testimony. However, the trial court did deliver a special instruction [2] to the jury immediately after accepting Frazier as an expert witness:

Ladies and gentlemen of the jury, before we proceed further, let me explain to you that as part of Mr. Frazier's testimony you will be hearing testimony... regarding statements made to him by various SEPTA employees who may or may not be coming in as witnesses to testify later in the trial.

It is important to recognize that these statements regarding those SEPTA employees—regarding the statements that the SEPTA employees made to Mr. Frazier are admitted to you only for a limited purpose, and that is to explain the bases or part of the bases of Mr. Frazier's testimony.

The statements are not admissible and should not be considered by you as substantive evidence of the truth that they assert.

(N.T., 12/15/16, at 146.)

***3** Frazier testified that, in his opinion based on his experience, training and all of the information available to him: (1) SEPTA failed to ensure the safety of its crews; (2) SEPTA failed to adequately train its crew members to deal with unruly passengers; and (3) SEPTA failed to provide sufficient police or security coverage in the Wilmington line. At the conclusion of the trial, the jury found in favor of Hooks on the issue of negligence and awarded her $229,000 in damages.

On appeal, SEPTA argues that the trial court erred by allowing Frazier to present his opinion to the jury because it was based on impermissible hearsay and "lacked the requisite factual underpinnings, independent analysis and reliability." (SEPTA's brief, 11/23/16, at 3.) SEPTA seeks a new trial. However, this Court will award a new trial on appeal "only if the trial court abused its discretion or committed an error of law that controlled the outcome of the case." *Cummings v. State System of Higher Education,* 860 A.2d 650, 654 (Pa. Cmwlth. 2004) (citation omitted). "The

admission of evidence is committed to the sound discretion of the trial court and will not be reversed absent an abuse of discretion." *Commonwealth v. Chamberlain,* 731 A.2d 593, 595 (Pa. 1999). "Discretion is abused when the law is not applied." *Id.*

The boundaries and admissibility of expert testimony are controlled by Article VII of the Pennsylvania Rules of Evidence. Rule 703 provides as follows:

> An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted.

Pa.R.E. 703. In applying Rule 703, the Superior Court has held as follows:

> It is well-established that an expert may express an opinion which is based on material not in evidence, including other expert opinion, where such material is of a type customarily relied on by experts in his or her profession. *Collins v. Cooper,* 746 A.2d 615, 618 (Pa. Super. 2000); *Primavera v. Celotex Corp.*, 608 A.2d 515 (Pa. Super. 1992). Such material may be disclosed at trial even though it might otherwise be hearsay... Such hearsay is admissible because the expert's reliance on the material provides its own indication of the material's trustworthiness: "The fact that experts reasonably and regularly rely on this type of information merely to practice their profession lends strong indicia of reliability to source material, when it is presented through a qualified expert's eyes." *Primavera,* 608 A.2d at 520.

In re D.Y., 34 A.3d 177, 182 (Pa. Super. 2011).

Though SEPTA complains that the trial court erred by permitting the jury to hear expert testimony based on inadmissible hearsay, the express language of Rule 703 and case law permit such expert testimony where "experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." *Id.* The critical inquiry is not whether the information underlying an expert's opinion would be admissible standing alone. Rather, it is whether the information is of the type that experts in a field reasonably rely upon when forming opinions.

In *In re Adoption of R.K.Y.*, an expert in child psychology opined that a mother was unable to safely parent her children. 72 A.3d 669, 673 (Pa. Super. 2013). The expert's opinion was informed in part by a review of reports of psycho-sexual evaluations of four children who did not testify at trial. *Id.* The expert did not conduct the interviews of the children; the evaluations were conducted by the expert's colleagues. *Id.* The expert testified that "reliance on interviews when preparing a psycho-sexual evaluation, including interviews conducted by colleagues, is 'common practice in our field.' " *Id.* at 677. The Superior Court ruled that, under those circumstances, the expert's reliance on interviews in forming her opinion "[satisfied] the basic prerequisites for admission under Rules 703 and 705." *Id.* In this case, the trial court accepted Frazier's testimony that experts in his field rely on information obtained in interviews when forming opinions. The trial court did not abuse its discretion in refusing to exclude Frazier's testimony on the ground that it was in part based on out-of-court interviews.

***4** SEPTA also argues that Frazier's testimony "lacked the requisite factual underpinnings, independent analysis and reliability" for expert testimony. Rule 702 sets forth the criteria for expert testimony:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge is beyond that possessed by the average layperson;
>
> (b) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; and
>
> (c) the expert's methodology is generally accepted in the relevant field.

Pa.R.E. 702. SEPTA's challenge to the "factual underpinnings, independent analysis and reliability" of Frazier's testimony relates to the requirement set forth in Rule 702(c) that an expert's methodology be generally accepted in the relevant field. However, Frazier testified to the satisfaction of the trial court that his methodology

was consistent with the methodology of experts in his field, and SEPTA has not identified any evidence in the record that Frazier's methodology was inconsistent with accepted practice in his field.

Citing *Luzerne County Flood Protection Authority v. Reilly*, SEPTA argues that an expert "is not permitted to merely restate another's conclusions without espousing his own expertise and judgement." 825 A.2d 779, 784 (Pa. Cmwlth. 2004). However, in this case the trial court found that:

> In addition to his knowledge, training, and experience, Captain Frazier also relied upon the following: (1) records produced by [SEPTA] in discovery, including police records for the Wilmington line and [SEPTA's] Passenger Operations Manual; and (2) his review of deposition testimony of witnesses such as [Hooks], Ms. Deidra Rich from [SEPTA's] Training Department, and Captain Charles Lawson from [SEPTA's] Police Department.

(Trial Court Opinion, 8/11/16, at 4) (citation omitted). The record does not support SEPTA's premise that Frazier merely parroted the opinions of others.

In *Luzerne County*, this Court stated:

> The applicability of the rule permitting experts to express opinions relying on extrajudicial data depends on the circumstances of the particular case and demands the exercise, like the admission of all expert testimony, of the *sound discretion of the trial court.* Where, as here, the expert uses several sources to arrive at his or her opinion, and has noted the reasonable and ordinary reliance on similar sources by experts in the field, and has coupled this reliance with personal observation, knowledge and experience, we conclude that the expert's testimony should be permitted.

825 A.2d at 784 (citation omitted) (emphasis in original). We cannot conclude that the trial court abused its discretion in ruling that Frazier's testimony was admissible where the record supports the trial court's conclusion that Frazier relied on multiple sources of information of the types reasonably relied upon by experts in his field, and where he also applied his own personal observation, knowledge and experience in the formulation of his opinion.

The Superior Court's discussion in *Primavera v. Celotex Corporation* of the role, significance and limits of expert testimony in contemporary litigation is highly instructive:

> ***5** In noting the necessity and value of permitting experts to rely on extrajudicial reports and sources, it is important to stress that it is actually the testifying expert's opinion which is being presented and which is subject to scrutiny, cross-examination and credibility determinations. Hence, it is often the case, as it was here, that experts are questioned concerning whether relied-upon sources are "authoritative" or generally accepted, whether the source material is truly the type ordinarily relied on by similar experts, whether independent or further judgment was brought to bear on particular source material and whether the expert is competent enough to judge the reliability of the sources upon which he relied. These are the safeguards which assure that the experts' opinions are not being offered based on inherently untrustworthy data or data which is not commonly used by other professionals. If an expert has made faulty assumptions or leaps of judgment in relying on certain sources or in forming conclusions based on those sources, these issues are the proper subject of cross-examination.
>
> The relative roles of jury and expert in this context have been described as follows:
>
> > In a sense, the expert synthesizes the primary source material—be it hearsay or not—into properly admissible evidence in opinion form. The trier of fact is then capable of judging the credibility of the witness as it would that of anyone else giving expert testimony. This rule respects the functions and abilities of both the expert witness and the trier of fact, while assuring that the requirement of witness confrontation is fulfilled.

> *United States v. Sims,* 514 F.2d 147, 149 (9th Cir.1975), *cert. denied* 423 U.S. 845, 96 S.Ct. 83, 46 L.Ed.2d 66 (1975).
>
> As this court has indicated, the crucial point is that the fact-finder be made aware of the bases for the expert's ultimate conclusions, including his partial reliance on indirect sources. "The adverse party then has the opportunity... to present its own countervailing facts and figures and/or expert testimony to convince the factfinder that the weight to be given to the other side's expert testimony should be little or none". *In re Glosser Bros., Inc.,* 382 Pa. Super. 177, 202, 555 A.2d 129, 142 (1989).

608 A.2d 515, 520–21 (Pa. Super. 1992)

In this case, the trial judge had a basis in the record from which to conclude that Frazier's testimony was based on data of the type that experts in his field customarily rely upon. Additionally, SEPTA had the opportunity to challenge the bases of Frazier's opinions and offer evidence to rebut Frazier's testimony. We find no error here.

For these reasons, we affirm the trial court's order.

ORDER

AND NOW, this 31st day of August, 2017, the order of the Philadelphia County Court of Common Pleas is affirmed.

All Citations

Not Reported in Atl. Rptr., 2017 WL 3746562

Footnotes

1 The Federal Employers' Liability Act, 45 U.S.C. §§ 51–60, authorizes railroad workers to sue employers for negligence.

2 "When an expert testifies about the underlying facts and data that support the expert's opinion and the evidence would be otherwise inadmissible, the trial judge upon request must, or on the judge's own initiative may, instruct the jury to consider the facts and data only to explain the basis for the expert's opinion, and not as substantive evidence." Pa.R.E. 703 cmt.

CERTIFICATE OF COMPLIANCE WITH PUBLIC ACCESS POLICY

I certify that this filing complies with the provisions of the Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts that require filing confidential information and documents differently than non-confidential information and documents.

Respectfully submitted,

/ s / Judith D. Cassel

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Counsel for Petitioner

DATED: March 16, 2022

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

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	:	No. 58 MD 2022
Respondents.	:	

CERTIFICATE OF SERVICE

I hereby certify that I am on this day serving a true and correct copy of the foregoing Post-Hearing Reply Brief of Medical Marijuana Access & Patient Safety, Inc. upon the persons and in the manner indicated below, which service satisfies the requirements of Pa.R.A.P. 121.

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Date: March 16, 2022