Received 3/11/2022 11:52:15 AM Commonwealth Court of Pennsylvania

Filed 3/11/2022 11:52:00 AM Commonwealth Court of Pennsylvania
58 MD 2022

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 BRIEF OF MEDICAL MARIJUANA ACCESS & PATIENT SAFETY, INC.

Judith D. Cassel I.D. No. 209393
Kevin J. McKeon, I.D. No. 30428
Dennis A. Whitaker, I.D. No. 53975
Micah R. Bucy, I.D. No. 320196
Hawke McKeon & Sniscak, LLP
100 North Tenth Street
Harrisburg, PA 17101
Telephone: 717-236-1300
Facsimile: 717-236-4841

March 11, 2022

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Regulations

Constitutional Provisions

INTRODUCTION AND SUMMARY

On February 4, 2022, the Department of Health, Office of Medical Marijuana (DOH), via emails to grower/processors, dispensaries, and patients in Pennsylvania's medical marijuana program, announced a recall of hundreds of DOH-previously-approved medical marijuana vaporization medicines that contain non-cannabis derived terpenes (Terpene Recall Mandate), costing the industry tens of millions of dollars and depriving patients of one of the most important forms of medical marijuana. The recall is based on a new, never-before announced standard -- that non-cannabis derived terpenes must be "approved as safe for inhalation by" the United States Food and Drug Administration (FDA). Exh. S-1. Petitioner Medical Marijuana Access & Patient Safety, Inc. (MMAPS) seeks a preliminary injunction to halt and reverse the recall. A non-profit association of industry stakeholders including permitted grower/processors and dispensaries that produce and sell 80-90% of the medicine subject to recall, certified patients that use the medicine, and terpene suppliers, MMAPS has standing to bring this lawsuit and to seek a preliminary injunction.

The recall is unlawful for all the reasons detailed in MMAPS' petition for review filed February 10, 2022, its brief in support of preliminary injunctive relief filed February 23, 2022, and as summarized later in this brief: MMAPS is likely to succeed on its claims that DOH has no legal basis to issue the Terpene Recall

Mandate, or to issue it in the way that it has done. The unrebutted expert testimony at hearing confirms the illegality of and the lack of a scientific or even a factual basis for DOH's recall, and proves up the other elements required for a preliminary injunction:

- the new standard lacks a scientific, medical, or public health foundation or purpose and makes no sense from that perspective;
- non-cannabis-derived terpenes are identical to, just as safe as, and pose no greater risk for inhalation than cannabis-derived terpenes that are in the vaporization inhalation products DOH has not recalled;
- the recalled medicines have been approved by DOH, manufactured and sold by MMAPS' members, and used by Pennsylvania patients for three years without any adverse events or patient complaints;
- non-cannabis-derived terpene-infused inhalation medicines have been used in other jurisdictions for more than a decade without a single adverse event;
- the recalled medicines provide significant benefits that the non-recalled products do not provide in more consistent therapeutic effect and lower cost;
- MMAPS' members that produce and sell the recalled medicines are suffering irreparable economic harm because of the recall; and
- patients, including MMAPS' members, will suffer irreparable harm because the recall deprives them of their medicine of choice without affording realistic alternatives.

DOH has yet to provide any explanation for its decision to adopt the new standard. It abruptly announced its decision to revisit the previous approvals of the

now-recalled medicines by emails sent on November 16, 2021, rebuffed or ignored all attempts by the industry and patients to inquire as to the reason for the re-review, and then simply "passed" on its opportunity at the preliminary injunction hearing to explain itself or to rebut MMAPS' expert testimony. Indeed, DOH did not even offer the lay testimony of DOH officials it had included in its witness list to explain, support, or justify its new "approved as safe for inhalation by" the FDA standard or otherwise provide a coherent rationale for the recall. Other than stipulating to the emails and attachments it sent and some basic facts, DOH presented no evidence at all.

MMAPS' unrebutted testimony established that the Terpene Recall Mandate has caused and will continue to cause irreparable harm to the affected patients, grower/processors, and dispensaries, effectively destroying over 330,000 units of MMAPS' member-produced vaporized medicines accounting for millions of dollars, without any identified health or safety concern and without any scientific or medical justification.

Mr. Woloveck, the authorized representative of MMAPS, testified that the recall required MMAPS' members to recall and destroy over 330,000 units of vaporized medicine and that MMAPS' members produced between 80 and 90 percent of the Recalled Medicine. Tr. 39:12-14, 47:12. He explained that in its communications DOH has not identified a single adverse event, customer complaint,

or risk to public health and safety as the reason for the mandatory recall, and that MMAPS' members were unaware of any adverse event, complaint, or risk that could justify a recall. Tr. 65:1-6, 67:4-10, 69:5-8, 72:23-75:15. Mr. Woloveck also testified that the Recalled Medicines have a 12-month shelf life and that the Recalled Medicine 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.

Dr. Vreeke, a chemist and the Head Researcher at True Terpenes, a supplier of non-cannabis derived terpenes, was submitted as an expert witness in vaporization chemistry and terpene toxicology. Tr. 125:22-126:2. She testified that terpenes are chemical compounds that are found in all plants and provide the aroma, taste, and effects of the plant. Tr. 118:24-119:2. She testified that she is familiar with the FDA Inactive Drug Database that DOH used here, that the database is comprised only of ingredients that the FDA has had cause to review, and that 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, she explained, is that most terpenes are not used as ingredients in drugs approved for inhalation by the FDA, and are used in marijuana vaporization medicines, but the FDA does not review and approve marijuana inhalation medicines

because marijuana is illegal under federal law. Tr. 136:14-137:9, 230:1-231:5. Dr. Vreeke testified that DOH misapplied the FDA's inactive ingredient database because it assumed that a terpene not listed in the database is unsafe. Tr. 136:14-137:9. She further testified that, at the molecular level, a terpene such as d-limonene is chemically identical regardless of its source, so that there is no different risk in consuming a terpene derived from cannabis versus one derived from another plant. Tr. 138:22-141:15. Dr. Vreeke also testified that "no other state uses that [DOH's standard for recalled products] criterion for cannabis products." Tr. 191:4-5.

Dr. Sisley, MMAPS' third witness, is a practicing physician, researcher, and FDA-approved manufacturer of medical marijuana with an emphasis on inhalation medications; she was offered as an expert witness in medical marijuana research, the FDA approval process, and patient impact. Tr. 199-204, 205:21-206:2, 219:24-220:22. Dr. Sisley is one of only a handful of researchers that has both a United States Drug Enforcement Agency (DEA) and FDA license to grow and process cannabis for use in federally approved research. Dr. Sisley provided testimony that research on terpenes has shown that they provide tangible medical benefits to patients, including promoting the entourage effect and enabling consistent patient outcomes. Tr. 211:13-213:5. She also provided compelling testimony that a terpene is identical regardless of its source. Tr. 218:14-19. Significantly, she explained that vaporization products that use non-cannabis-derived terpenes (the Recalled

Medicines) deliver a more consistent and reproducible medicinal effect than medicines that use cannabis-derived terpenes (the products DOH has not recalled) because the terpene levels in marijuana crops vary from harvest to harvest, whereas producers of non-cannabis-derived terpene infused medicines are able to precisely control and replicate terpene levels, all at a lower cost to patients. Tr. 210:9-225:4-15. As a volunteer medical director for more than 30 growers and manufacturers of medicinal marijuana nationwide over the last 10-plus years, Dr. Sisley testified that she is unaware of any adverse event or risk to health that has been attributed to vaporized medicinal marijuana that contained non-cannabis derived terpenes, and that other states affirmatively permit the use of non-cannabis derived terpenes. Tr. 219:24-222:9, 231:22-232:2. Dr. Sisley further testified that patients who use the Recalled Medicine are typically suffering from both physical and psychological conditions, that sometimes a patient can go years before finding a medical treatment that works, and that DOH's abrupt ban on products that were previously available can be destabilizing and represents a break in a patient's continuity of care. Tr. 243:23-244:24. A patient's inability to obtain her preferred medication, Dr. Sisley testified, will likely force the patient to revert to addictive pharmaceuticals or drive the patient to procure her medicine from the illicit market. Tr. 245:4-246:11.

Mr. Jon Ahern was MMAPS' economic harm expert and was offered as an expert in analyzing accounting, financial, and economic damage issues, including

business valuation and calculating damages. He has substantial experience evaluating damages to cannabis-related entities and markets. Tr. 276:23-277:7. Mr. Ahern provided testimony that he collected and reviewed sales, recalled product, and margin data from, and conducted interviews with, MMAPS' grower/processor and dispensary members to form his opinions as to the economic losses to MMAPS' members caused by the Terpene Recall Mandate. Tr. 284-285. Upon collecting and synthesizing this information, Mr. Ahern was able to conclude that MMAPS' grower/processor and dispensary members have conservatively suffered approximately $18 million in damages. Tr. 319:5-24. He broke down total damages into the following categories: lost value of the Recalled Medicines, Tr. 293:4-294:12, 300:5-305:13; lost future profits, Tr. 294:13-295:8, 305:14-312:10; equipment costs, 295:9-296:9, 312:11-313:18; and reputational harm to the grower/processors that has resulted because DOH has accused them of producing unsafe medicines. Tr. 298:15-300:4, 317:3-318:10.

At the close of this testimony and after DOH's opening statement, the hearing was continued until February 28, 2022. DOH stated in its opening that it would present two witnesses of the three previously identified in its prehearing filing, which were named respondents Klinepeter, Collins and Podolak. At the reconvened hearing, however, DOH advised the court that DOH did "not intend to put on any evidence" and that it would "not be presenting any witnesses." Tr. 400:24-401:1.

DOH's continued refusal, or more likely, inability to provide any justification whatsoever for its Terpene Recall Mandate, leaves MMAPS' competent, credible, and compelling evidence unrefuted. Where, as here, the government takes an action that impacts an entire industry and causes irreparable harm, its utter failure to provide a legal and factual basis for that action that can be tested by the evidence and considered by the court should weigh heavily against it.

ARGUMENT

I. DOH'S EXCLUSIVE RELIANCE ON PROCEDURAL DEFENSES IS TELLING AND MERITLESS

Apparently unable to defend its Terpene Recall Mandate based on science, medicine or public policy, DOH has chosen instead to rely exclusively on its counsel's illusory procedural hurdles to the grant of a preliminary injunction. These procedural defenses are ineffective, and the tactic and resulting evidentiary void simply underscores the perplexingly secretive, unsupportable, and arbitrary nature of DOH's action in issuing the Terpene Recall Mandate.

a. MMAPS Has Standing

1. MMAPS has associational standing

An association is a proper plaintiff and has standing to sue even in the absence of injury to itself if at least one of its members has standing. *Firearm Owners Against Crime v. Papenfuse*, 261 A.3d 467, 483-484 (Pa. 2021); *Robinson Township v. Commonwealth*, 83 A.3d 901, 922 (Pa. 2013); *North–Central Pennsylvania Trial Lawyers Association*, 827 A.2d 550, 554 (Pa. Cmwlth. 2003); *Pennsylvania Social Services Union, Local 668 v. Department of Public Welfare, Office of Inspector General*, 699 A.2d 807, 810 (Pa. Cmwlth. 1997); *Parents United for Better Schools, Inc. v. School District of Philadelphia*, 646 A.2d 689, 690, 692 (Pa. Cmwlth. 1994); *National Solid Wastes Management Association v. Casey*, 580 A.2d 893, 899 (Pa. Cmwlth. 1990); *Concerned Taxpayers of Allegheny County v. Commonwealth*, 382

A.2d 490, 493–94 (Pa. Cmwlth. 1978); *accord Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 342-43 (1977) ("Even in the absence of injury to itself, an association may have standing solely as the representative of its members … The association must allege that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brough suit…"). The plaintiff organization must only allege sufficient facts to show that at least one of its members has a substantial, direct and immediate interest. *Pennsylvania Social Services Union, Local 668*, 699 A.2d at 810; *National Solid Wastes Management Association*, 580 A.2d at 899; *Concerned Taxpayers of Allegheny County*, 382 A.2d at 493–94.

MMAPS more than meets this test and thus has standing to seek declaratory and injunctive relief against DOH's Terpene Recall Mandate. At the preliminary injunction hearing, Mr. Woloveck, MMAPS' authorized representative, Tr. 37:13-15, testified that he is Chief Commercial Director of Jushi, the parent corporation of medical marijuana permit holders Pennsylvania Medical Solutions, LLC, Pennsylvania Dispensary Solutions, LLC, Total Agape Health Care, LLC, Franklin BioScience—Penn, LLC, Franklin BioScience SW, LLC, Franklin BioScience NE, LLC, and Franklin BioScience SE, LLC, Tr. 34:5-14. [1] He explained that MMAPS

[1] DOH identifies on its website each of these entities as permitted medical marijuana organizations. Pennsylvania Medical Solutions, LLC is identified as a grower/processor permittee. *See* Phase 1 Grower-Processor Permittee Facility

is comprised of grower/processors, dispensaries, patients, doctors, and related businesses, Tr. 37:3-8, and that MMAPS' grower/processor and dispensary members, including the Jushi permit holders, Tr. 40:24-41:16, 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. The Terpene Recall Mandate, he further explained, affected over 670 different vaporization medicines that required pulling over 330,000 individual units of Recalled Medicine produced by MMAPS' members. Tr. 39:8-14. Mr. Woloveck testified that the recall would cost "several million dollars of inventory" to the Jushi permit-holder affiliates. Tr. 41:12-16. Mr. Woloveck also testified that approximately 150,000 patients were adversely affected by the recall. Tr. 79:20-80:20.

Locations by Region, *available at* https://www.health.pa.gov/topics/Documents/Programs/Medical%20Marijuana/Phase%201/Phase%201%20Grower-Processor%20Permittee%20Facility%20Locations%20By%20Region.pdf (last visited Mar. 3, 2022). The remaining entities are dispensary permittees. *See* DOH Phase 1 Dispensary Permittee Facility Locations by Region, City, County, *available at* https://www.health.pa.gov/topics/Documents/Programs/Medical%20Marijuana/Phase%201/DOH%20Phase%201%20Dispensary%20Permittee%20Facility%20Locations%20By%20Region_City_County.pdf (last visited Mar. 3, 2022); Phase II Dispensary Permittee Facility Locations by Region, *available at* https://www.health.pa.gov/topics/Documents/Programs/Medical%20Marijuana/PA%20DOH%20Phase%20II%20Dispensary%20Permittee%20Facility%20Locations%20by%20Region.pdf (last visited Mar. 3, 2022).

Mr. Woloveck established early in his testimony without objection that references to "Jushi" should be interpreted as references to all of Jushi's Pennsylvania permittees, Tr. 34:15-18, and he used that shorthand throughout the duration of his testimony, including during cross-examination. Tr. 99:24-25. Mr. Woloveck testified that Jushi – meaning Jushi's seven Pennsylvania medical marijuana permittees – are members of MMAPS. Tr. 37:9-12. He further testified that Jushi's Pennsylvania operations are being adversely affected by the Terpene Recall Mandate, that they were harmed by the removal of 38 different types of products, and the inability to sell the recalled products to patients. Tr. 41:2-16; 77:21-78:14; 40:24-41:16. This testimony, alone, conclusively establishes that more than one member of MMAPS has a substantial, direct and immediate interest in this litigation, and therefore MMAPS has standing to pursue this action on behalf of its members. Indeed, his testimony goes beyond the showing that is required. *See Americans for Fair Treatment, Inc. v. Philadelphia Federation of Teachers*, 150 A.3d 528 (Pa. Cmwlth. 2016) ("Standing may be shown without identification of individual members, but only where the complaint's description of the organization's members is sufficient to show that they are aggrieved."). At the reconvened hearing, Mr. Woloveck specifically testified that Pennsylvania Medical Solutions, LLC is a MMAPS' member. Tr. 408:22-409:1. Mr. Woloveck's testimony on February 28, 2022 simply confirmed what his February 24, 2022

testimony already had established. Moreover, as detailed below, MMAPS' Petition for Review establishes that its members are aggrieved by the recall mandate.

2. <u>There is no heightened standing requirement for a preliminary injunction</u>

DOH concedes that MMAPS has standing to seek declaratory and injunctive relief against DOH's Terpene Recall Mandate. Tr. 363:1-9; 365:16-20 ("Sure, they can represent their members in terms of a declaratory judgment, challenging government action, getting a permanent injunction."). DOH contends, however, that MMAPS is not entitled to a preliminary injunction because the only petitioner is MMAPS and MMAPS has not alleged irreparable harm to itself. Tr. 362:13-25, 365:5-15. To the extent DOH's point is that, even though MMAPS has standing to represent its members for purposes of seeking final declaratory and injunctive relief on the merits, it somehow lacks standing to secure a preliminary injunction because "the only petitioner here is MMAPS," Tr. 362:13-14, and that MMAPS itself as an entity does not allege irreparable harm, DOH's argument has no basis. As discussed above, an association satisfies the standing requirement if a single member could pursue the action. Indeed, courts correctly assume that it is usually, if not always the case, that the plaintiff association's members, and not the association itself, are the ones "actually injured." When an "association seeks a declaration, injunction, or some other form of prospective relief, it can reasonably be supposed that the remedy,

if granted, will inure to the benefit of those members of the association *actually injured*." *Hunt*, 432 U.S. at 343 (emphasis added).

MMAPS is aware of no precedent that supports the notion that the law imposes a heightened standing requirement that bars an association acting as the sole petitioner from seeking a preliminary injunction based on the harm suffered by its members. In *Marcellus Shale Coalition v. Dep't of Envir. Protection of the Com*., 185 A.3d 985 (Pa. 2018), this court granted a preliminary injunction to the sole petitioner, the nonprofit Marcellus Shale Coalition, based on irreparable economic harm that the Coalition's members would experience in order to comply with challenged regulations, and the Pennsylvania Supreme Court affirmed. In affirming, the Supreme Court observed that the association had satisfied the immediate and irreparable harm component of the preliminary injunction standard when evidence was submitted of *costs that would be borne by the association's members* if the regulation was permitted to stand and which could not be recovered because of sovereign immunity. *Id*. at 997. There was no discussion that the association itself was required to satisfy the immediate and irreparable harm component, only that its members did. *Id*. Logic dictated that result there, and compels the same result here: if MMAPS has standing to bring the underlying lawsuit as DOH concedes, it has

standing to seek a preliminary injunction as ancillary relief pending final disposition of the case on the merits.[2]

3. MMAPS has demonstrated harm required for the grant of a preliminary injunction, which admittedly is a higher bar than the harm needed to demonstrate standing

To the extent DOH's point (Tr. at 363:10-364:4) is the uncontroversial proposition that the harm needed to secure a preliminary injunction is greater than the harm needed to demonstrate standing, MMAPS agrees, and has demonstrated that it meets both standards. Asserting the interest of its members as it is entitled to do, MMAPS has shown that the interests of its members that are adversely affected by the Terpenes Recall Mandate are substantial, direct and immediate, *Pennsylvania Social Services Union, Local 668*, 699 A.2d at 810, thereby conferring on MMAPS'

[2] Following affirmance of the grant of a preliminary injunction in *Marcellus Shale*, this court granted partial summary relief to the Coalition, *Marcellus Shale Coalition v. Department of Environmental Protection*, 193 A.3d 447 (Pa. Cmwlth. 2018) (en banc), observing that the Coalition as sole petitioner "describes itself as a non-profit membership organization whose members explore, produce, transmit, and distribute natural gas from the Marcellus and Utica Shale formations. *See* Petition for Review ¶¶ 3-4." *Id*. at 454 n. 1. MMAPS describes itself similarly: "Petitioner is a 501(c)(6) non-profit association consisting of a cross-section of industry stakeholders from *permitted grower/processors and dispensaries*, to certified patients that use the medical marijuana vaporization products that are subject to DOH's terpene recall mandate, and terpene suppliers. Upon information and belief, *Petitioner's members account for approximately 75% of the medical marijuana operations in Pennsylvania and produce more than approximately 90% of the vaporization products that are subject to DOH's Terpene Recall Mandate*." Petition for Review ¶ 20 (emphasis added, footnote omitted).

standing to bring suit. In seeking a preliminary injunction on behalf of its members as it likewise has standing to do, *Marcellus Shale*, *supra*, MMAPS has proven that the Terpene Recall Mandate will cause MMAPS' members immediate and irreparable harm, as shown at hearing and discussed *infra*, Section II. There is no authority of which MMAPS is aware, however, that the association petitioner (as distinguished from the association's members represented by the association) must itself suffer irreparable harm to secure a preliminary injunction for the benefit of the petitioner association's members.

b. <u>MMAPS Did Not Delay In Seeking Court Intervention</u>

DOH's procedural theory that MMAPS could and should have taken an administrative appeal or sought court intervention based on DOH's November 16, 2021 email, Tr. 366:2-367:14, does not square with either the law or the facts. The law is clear: under the Administrative Agency Law, 2 Pa.C.S. §101, only an "adjudication" can be the proper subject of an administrative appeal from a subordinate agency officer to the agency head. *NHS Human Services of PA v. Dep't of Pub. Welfare*, 985 A.2d 992, 995 (Pa. Cmwlth. 2009) (affirming agency's decision dismissing administrative appeal because email that did not convey finality of action, but rather invited resubmission of documentation, was not final action affecting rights and thus not an appealable adjudication). MMAPS and its members could not have challenged DOH's November 16, 2021 email because on its face the email

merely initiated an administrative review process of vaporization medicines; it took no final action to disapprove any medicine, initiate a recall, or otherwise affect MMAPS' members' rights.

Factually, DOH's November 16 email is analogous to the email at issue in *NHS*. There, the Department of Public Welfare emailed a notice of violation to a private contractor advising it that its expenditure submissions were insufficient and that it would not be reimbursed until the submissions met the Department's requirements; the email concluded by instructing the provider to "[p]lease rectify these issues and resubmit immediately." *Id*. The provider characterized the email as an adjudication and sought review, but this court affirmed the agency's dismissal of the appeal because the Department's email *invited* the provider to submit additional documentation to *avoid* an adverse decision and that unless and until the Department rendered an adverse decision no appeal could issue. *Id*. Like the email in *NHS*, DOH's November 16 email invited grower/processors to submit information and *threatened* an adverse decision upon a failure to comply:

> The Department is conducting a review of all vaporized … products containing additional ingredients … the Department is requiring every grower/processor to submit for approval each vaporized product that contains additional ingredients, even if the product had previously been approved … please use the attached forms to submit each product … submissions must be received no later than November 30, 2021 … failure to comply with any part of this communication may result in the Department

> suspending the sale of your entire line of vaporized products."

Exh. S-3. DOH's November 16 email concedes in the first sentence that this email is not a final decision that affects MMAPS' members' rights but rather institutes a review of certain vaporized medicines from which a final decision will issue in the future. The email goes on to require grower/processors to submit documentation so that DOH can complete its review. The email concludes with the threat of suspending a grower/processor's line of vaporized products for failing to comply with the November 16th email—as *NHS* instructs, this future threatened DOH-action, if taken by DOH, is what would have been an adjudication subject to review. MMAPS is not contesting the threatened action under the November 16 email. Instead, it is aggrieved by the Terpene Recall Mandate, an action not directed at non-compliance with the November 16 email, but rather issued and directed on February 4, 2022, at the majority of suppliers of vaporized products.

Any doubt that DOH had not reached a final determination in the November 16 email about MMAPS' members' continued sale of the now-recalled products while DOH was conducting its review is dispelled by the plain language of DOH's December 13, 2021 email, which requested:

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

> artificial terpenes[3] or flavorings, used in your vaporized products.
>
> If you are using additives, including artificial terpenes or flavorings, in other states, please provide the product name and the state in which it is approved.

Exh. S-6. Obviously, from the face of the email, as of December 13 DOH conveyed that it was "continu[ing] our review," viewed MMAPS' members use of non-cannabis derived terpenes in their products as an ongoing activity, and had yet to arrive at a final decision concerning approval or recall.

Additionally, DOH plainly has the practice of advising those it regulates of their appeal rights when DOH takes final action amounting to an adjudication: it omitted such language from the November 16 email but included it in the February 4 email. *Compare* Exh. S-3 *with* Exh. S-1. Its litigation-inspired argument that the November 16 email was a final adjudication is entitled to no weight for that reason alone.

In sum, it is clear from DOH's own words in its November 16 and December 13 emails that DOH did not consider any of its actions in either adopting its "approved by the FDA for inhalation" standard or recalling products via application

---

[3] As the testimony at hearing revealed, there is nothing "artificial" about the terpenes that MMAPS' members use in the medicines they produce; they are derived from plant sources other than cannabis; and are chemically identical to the same terpenes found in cannabis, but are superior to cannabis-derived terpenes from the perspective of product cost and consistency of dosage. Tr.45:8-14, 58:2-59:25, 118:24-119:2, 139:9-140:1, 218:14-19, 225:4-15, 214:25-215:16.

of that new standard, as a final action until it issued its February 4 Terpene Recall Mandate. As the docket reveals and the court is well aware, MMAPS filed its petition for review and request for preliminary injunction four business days later, on February 10, 2022. Contrary to DOH's revisionist history, the February 4 email *did* create an emergency for patients and permittees, and MMAPS acted promptly to seek judicial intervention to address it.

c. MMAPS Satisfies The *Arsenal Coal* Criteria

DOH's Terpene Recall Mandate poses such a direct and immediate hardship on the Pennsylvania medical marijuana industry that pre-enforcement review is appropriate. *Arsenal Coal Co. v. Com, Dep't of Envir. Res*., 477 A.2d 1333 (Pa. 1984). "[T]he pertinent inquiry in determining whether there is standing to bring a pre-enforcement action is whether the administrative process causes a petitioner to suffer immediate and actual harm *prior* to the actual enforcement of the challenged regulation or application of the interpretation." *Pa. Indep. Oil & Gas Ass'n v. Com., Dep't of Envir. Protection*, 135 A.3d 1118, 1126-27 (Pa. Cmwlth. 2015) (emphasis in original).

Here, the harm suffered by MMAPS' members is direct and immediate. Effective as of DOH's February 4 email, issued without warning or grace period and still without justification, MMAPS' members were no longer permitted to produce or sell vaporized medicines that contain non-cannabis derived terpenes, Exh. S-1,

despite DOH previously approving each now-recalled product for production and sale. Tr. 48:8-18. MMAPS' members' harm was experienced immediately on February 4, 2022 and grows daily. The Terpene Recall Mandate requires the immediate cessation of sales and ultimate destruction of more than 670 individual vaporized medicines, of which MMAPS' members produce 80 to 90 percent, totaling more than 330,000 units of MMAPS' members-produced medicine. Exh. S-1; Tr. 45:21, 47:12, 39:11-14. The recall is based on a new, never-before announced standard ("approved as safe for inhalation by" the FDA, Exh. S-1) that is applicable to the entire industry as a binding norm with immediate effect. Because the Terpene Recall Mandate immediately prohibits the sale of more than 330,000 units of already-produced medicines and future production and sale of previously DOH-approved vaporized medicines that required millions of dollars of investments to develop and produce, MMAPS satisfies the *Arsenal Coal* criteria: MMAPS suffers immediate, irreparable, and growing harm *prior* to any actual enforcement steps that DOH may take.

d. <u>MMAPS' Irreparable Economic Harm Evidence Is Competent, Credible, Relevant, and Uncontroverted</u>

DOH seeks to eliminate or minimize the evidence of the clear economic harm the Terpene Recall Mandate is causing in three ways: (1) by seeking to strike Mr. Ahern's expert testimony quantifying the Terpene Recall Mandate's economic harm

to MMAPS on grounds that it is based on data not in the record; (2) by arguing that a preliminary injunction will not issue where the alleged irreparable harm is monetary; and (3) by offering a last-minute concession that the recalled and quarantined products do not need to be destroyed pending a ruling in this case. But the irreparable harm MMAPS' members face as the result of the Terpene Recall Mandate would be evident even without the robust proof that MMAPS has adduced; the court should reject each of these attempts to discount it.

1. The Court should deny DOH's motion to strike Mr. Ahern's testimony

At the close of Mr. Ahern's testimony, DOH moved to strike it in its entirety arguing that Mr. Ahern's expert testimony is inadmissible "when the entirety of the data on which he relied is not in the record." Tr. 359:16-360:10. DOH is simply wrong on the law. Rule 703 of the Pennsylvania Rules of Evidence codified a long-standing evidentiary principle: experts are permitted to rely on source material that is not admitted into evidence and which would otherwise constitute hearsay, if it is the type of information an expert in that particular field reasonably relies upon when forming opinions. Pa. R.E. 703; *Collins v. Cooper*, 746 A.2d 615 (Pa. Super. 2000); *Primavera v. Celotex Corp*., 608 A.2d 515 (Pa. Super. 1992); *Com. v. Thomas*, 282 A.2d 693 (Pa. 1971). As *Primavera* explains, it is the expert's opinion that is being presented, "which is subject to scrutiny, cross-examination and credibility determinations" that operate as "safeguards [to] assure that the experts' opinions are

not being offered based on inherently untrustworthy data or data which is not commonly used by other professionals" or simply parroting another's opinion. 608 A.2d at 520—521.

Here, Mr. Ahern was offered and accepted as an expert in "analyzing accounting, financial, and economic issues, including business valuation and calculating damages, with an emphasis here on damages to cannabis-related entities and markets." Tr. 276:23-277:7; 277:24-278:1. Mr. Ahern testified that in forming his opinions he relied upon information that he would normally expect to rely upon in calculating damages, including the legal filings, initial summaries of damages collected by MMAPS' members, sales, recall, product, and margin data from MMAPS' members, follow-up interviews with MMAPS' members, publicly issued data posted by DOH itself to ensure proper use of the data MMAPS' members provided, and independent research on MMAPS' members and the Pennsylvania medical marijuana industry. Tr. 284:3-292:5. DOH conducted cross-examination of Mr. Ahern and in so doing had the opportunity to challenge the reliability of the underlying data, including the sources and credibility of that information, that Mr. Ahern used to form his opinions. DOH also had the opportunity to present its own expert witness as to harm to show that Mr. Ahern's testimony was not credible; DOH eschewed that opportunity. The procedural safeguards required by Pa. R.E. 703 and applicable caselaw have been met. The court, as fact-finder, may assess Mr. Ahern's

credibility and give his testimony the weight it deserves. DOH's motion to strike the testimony is without merit and should be denied.

2. MMAPS' members' monetary harm is irreparable

DOH's suggestion that monetary harm cannot constitute irreparable harm is wrong. Tr. 262:15-264:6. When, as is the case here, sovereign immunity forecloses a plaintiff's ability to seek and collect monetary damages, "[t]he inability to be adequately compensated by an award of damages constitutes irreparable harm." *Marcellus Shale Coalition v. Dep't of Envir. Protection of the Com*., 185 A.3d 985 (Pa. 2018) citing *Boykins v. City of Reading*, 562 A.2d 1027, 1029 (Pa. Cmwlth. 1989). As in *Marcellus Shale*, DOH is immune to a claim for damages that arise from the imposition of new rules and regulations that affect a regulated industry. Mr. Ahern's testimony concerning the millions of dollars lost because of the Terpene Recall Mandate is thus highly relevant (and competent) on the issue of MMAPS' irreparable harm. Further, MMAPS presented testimony as to the reputational damages of its members because of DOH's unjustified recall. In essence, DOH has led the public to believe that these products are not safe. DOH has no proof or evidence that this is so. The reputational damage that MMAPS' members are incurring gets worse every day that the recall stands and the resulting monetary damages cannot adequately be determined since it could result in permanent loss of market share even if reinstatement is granted.

3. *DOH's last-minute concession that products do not need to be destroyed does not diminish MMAPS' irreparable harm*

At the close of the February 24 hearing, DOH stated through counsel for the first time, and in direct conflict with DOH's answer to MMAPS' preliminary injunction request, that the Recalled Medicine did not need to be destroyed pending the outcome of this case, such that there is no need for a preliminary injunction. Tr. 369:14-371; DOH Ans. ¶15 ("The Department denies that the terpenes should be held in quarantine. The product should be destroyed."). DOH is wrong. The Recalled Medicines have a limited shelf-life of 12-months from the date the products passed their second round of testing when labeling is affixed, whereas this litigation and related appeals will certainly extend far beyond that time. Rather than enforcing active destruction, DOH is content to allow the short shelf life to take its natural toll – having been pulled off the shelves, the products will now be destroyed through atrophy – the only way (some of them) can be salvaged is through the grant of preliminary injunction reversing the effect of the recall so that dispensaries can sell and patients can consume the products now. Moreover, as set forth *infra* in Section II, concerning the other irreparable harms MMAPS faces, the Terpene Recall Mandate would cause irreparable harm even if the products had an infinite shelf life, because patients are deprived of their benefits, and because MMAPS' members that are grower/processors and dispensaries will suffer from the inability to sell these

products and from other significant economic harms that will never be compensated. Tr. 283:1-24.

II. DOH'S ILLEGAL AND STILL-UNEXPLAINED RECALL CAUSES IRREPARABLE HARM

The factual record in this case weighs heavily in favor of granting MMAPS' request for a preliminary injunction because DOH failed to present any evidence justifying its Terpene Recall Mandate. The court has before it an ***unrebutted*** record of credible testimony that demonstrates that MMAPS' members are immediately and irreparably harmed, and that there is no scientific or medical basis for DOH's abrupt about-face on prior approvals of these recalled products. The upshot is that the balancing of harms weighs heavily in favor of granting a preliminary injunction. As Dr. Sisley testified, there is observational data from over 40-plus legal states that have allowed the same products now recalled by the DOH and they have never "seen an adverse event arise in any of these legal markets" which amounts to tens of millions of "patients and millions of dosages administered …and none of them have been associated with adverse events." Tr. 236:2-237:1. Given DOH's lack of statutory authority to impose its new standard, DOH's lack of regulatory authority to order the recall in the manner it has (*i.e.*, without any evidence of a single patient complaint or an adverse event connected to the use of the recalled medicine in Pennsylvania or elsewhere in the country over the last ten years), DOH's failure to

promulgate its new standard as the disguised regulation it is, and given the valid due process, takings, vested rights, and reputational claims MMAPS has raised, MMAPS is likely to prevail on the merits. Under these circumstances, the public interest favors enjoining DOH's recall and allowing the return of the quarantined products to dispensary shelves for patient purchase and the continued production and sale of the medicine that is subject to recall.

a. The Recall Causes Immediate and Irreparable Harm To Patients And MMAPS[4]

MMAPS presented substantial, credible and uncontroverted evidence that DOH's Terpene Recall Mandate is causing, and absent a preliminary injunction by this Court will continue to cause, immediate and irreparable harm to its grower/processor, dispensary, and patient members alike. Grower/processors and dispensaries have suffered and will continue to suffer monetary and reputational harms. Patients have lost their preferred medicines and the continuity of their care. As discussed above, the harms experienced by MMAPS' members are no less irreparable despite DOH's illusory attempt to portray the harm as less imminent by offering that the Recalled Medicines need not be destroyed pending the outcome of this case. The lost sales that grow daily coupled with the very real fact that these

[4] Not discussed here is the *per se* harm that MMAPS and its members suffer because the Terpene Recall Mandate violates the Medical Marijuana Act and is unconstitutional. *See* MMAPS' Br. In Support of Preliminary Injunction at p. 33-34.

medicines lose potency as time passes (rendering them useless and thus effectively destroyed long before this case can be resolved on the merits), makes the harm MMAPS' members experience from DOH's recall immediate and irreparable.

As discussed *supra*, monetary damages qualify as irreparable harm when sovereign immunity forecloses the ability to ever be compensated for loss of value. *Marcellus Shale Coalition v. Dep't of Envir. Protection of the Com*., 185 A.3d 985 (Pa. 2018). Mr. Ahern provided extensive competent testimony related to the many monetary harms MMAPS' members suffer as a result of DOH's Terpene Recall Mandate: the lost value of the Recalled Medicines, Tr. 293:4-294:12, 300:5-305:13; lost future profits, Tr. 294:13-295:8, 305:14-312:10; sunk equipment costs, 295:9-296:9, 312:11-313:18; and reputational harm to the grower/processors that has resulted because DOH has accused them of producing unsafe medicines. Tr. 298:15-300:4, 317:3-318:10. Through his analysis, Mr. Ahern concluded that MMAPS' grower/processor and dispensary members have suffered approximately $18 million in damages. Tr. 319:5-24. This harm is immediate. This harm is irreparable.

Dr. Sisley, an expert that DOH has relied on in the past, Tr. 202:17-204:25, provided testimony as to the harm the Terpene Recall Mandate causes patients. She presented testimony that the use of non-cannabis derived terpenes enables replicability and consistency in medications that are invaluable to patients battling serious medical conditions. Tr. 214:8-215:16. The importance to a patient who

suffers from physical and psychological debilitation of finding a medication that works is significant and should not be undervalued. Tr. 243:23-244:12. To then abruptly, and without a coherent public health safety basis, prohibit access to a medicine that has effectively treated a patient's symptoms can be destabilizing and demoralizing. Tr. 244:12-24. And as Dr. Sisley testified, patients who can no longer access their preferred medications will likely return to using their addictive prescription medications or turn to the illicit market to attempt to replicate their preferred medications that have been recalled. Tr. 245:4-247:11. The irreparable harm to patients is the break in their continuity of care by introducing unpredictability into their medical regimen without any basis in science or medicine.

At the close of the hearing, DOH reversed its stated position that the Recalled Medicine could not be quarantined but must be destroyed. DOH Ans. ¶15; Tr. 369:14-371. Portrayed as a dramatic concession to show that emergency relief is no longer needed, DOH's ploy has no more value than the proverbial "giving the sleeves from one's vest." Make no mistake, absent a preliminary injunction, the Recalled Medicines are effectively destroyed. All Recalled Medicines have a shelf-life of 12 months that begins running when the product passes final testing and the labeling process is complete. Tr. 98:22-99:15. Once the Recalled Medicines' expiration date expires it has no value because it cannot be sold or consumed. Forcing grower/processors to store a substantially increased amount of medical

marijuana products over an unanticipated length of time, increases the risk of unlawful diversion which violates both the Act and the regulations. 35 P.S. §10231.613(1); 28 Pa. Code §§ 1141.47(a)(1)(i) and (5)(ii). Practically, it is very likely that a final order will not issue from this court on the underlying petition for review before the Recalled Medicines expire. If an appeal were to be taken by either party, then it is a near certainty that the Recalled Medicines will be long expired before a final resolution is reached. Therefore, the reality is that the issuance of a preliminary injunction that reverses the Terpenes Recall Mandate and permits the sale of the previously DOH-approved medicines that have been sold for years in Pennsylvania and more than a decade nationwide without incident is the only way to ensure that MMAPS' grower/processor and patient members are not irreparably harmed.

b. <u>No Evidence Supports The Terpene Recall Mandate</u>

MMAPS presented a fact witness and two highly qualified expert witnesses that credibly testified there has been no adverse event related to the Recalled Medicine that could have prompted the Terpene Recall Mandate nor any scientific or medical basis for DOH's recall. This evidence stands unchallenged. Dr. Sisley testified that in Arizona, after ten years of the cannabis program allowing external terpenes, the data from the Poison Control Centers confirms that "not a single case" has ever "been associated with terpenes that have been added back into a vape

cartridge." Tr. 231:11-232:25. MMAPS' witnesses testified that there has not been a single adverse reaction to a patient that used the Recalled Medicines. Tr. 104:22-105:9 (Woloveck), Tr. 147:23 – 148:2 (Vreeke), Tr. 219:5-9 (Sisley). On the other hand, there was substantial testimony of the harm to patients that has occurred, and will continue to occur, from the DOH recall. Dr. Sisley testified as follows:

> We definitely saw harm in patients who, you know --- keep in mind these are sick, debilitated patients who often have co-occurring depression, anxiety, terminally ill patients who are dealing with fear of death and end of life anxiety. And when a medication that they've come to rely on, that they have spent years titrating, finding --- you know, adjusting the dose to find that best fit that works for them --- often these patients have tried multiple vape cartridges until they found that right fit. And to have that yanked out from under them abruptly is --- can be very damaging to their morale, to their sense of stability, their peace of mind, to know that --- when you're sick you just want a stable medical regime. You can't have a situation where suddenly things are up in the air. That can totally destabilize you. And I think this action represents a complete, you know, severing of the continuity of care.

Tr. 243:23-244:24.

The regulation DOH cites to support its Terpene Recall Mandate, 28 Pa. Code § 1151.42, requires an identification of an adverse event, customer complaint, or risk to public health and safety before a mandatory recall can be issued. Mr. Woloveck, who is charged with overseeing production and sale of the Recalled Medicine for multiple Pennsylvania medical marijuana operators, testified that he is unaware of any adverse event related to the Recalled Medicine. Tr. 74:16-75:15. The record

reveals that, to date, DOH, though provided many opportunities to do so, has failed to identify a single adverse event, customer complaint, or an identified risk to public safety that can be attributed to the Recalled Medicine. Exh. S-1; S-3; S-4, S-6, S-7; Tr. 65:1-6, 67:4-10, 69:5-8, 72:23-73:10. The uncontroverted evidence demonstrates that there was no factual justification for DOH's Terpene Recall Mandate.

Dr. Vreeke, a trained chemist tasked with analyzing the toxicological risk of terpenes added to medicinal vaporization products, was offered as an expert in vaporization chemistry and terpene toxicology. Tr. 125:22-126:2. Dr. Vreeke testified that although all substances potentially pose some risk, non-cannabis derived terpenes pose no greater risk than terpenes derived from cannabis – the very vaporized products DOH chose not to recall. Tr. 130:20-131:1, 139:9-141:15. Dr. Vreeke also testified that her employer, True Terpenes, supplies pharmaceutical-grade terpenes to Pennsylvania grower/processors, including MMAPS' members, and that those supplied terpenes undergo rigorous safety testing. Tr. 131:18-25, 132:25-133:13, 138:13-20. Additionally, Dr. Vreeke opined that DOH's new "safe for inhalation" standard is a misapplication of the FDA's inactive ingredient database, Tr. 136:14-137:9, that "makes no sense." Tr. 139:23. Her unrebutted testimony is that just because the FDA has not approved a terpene as being "safe for inhalation" does not mean it is unsafe, but simply means that the FDA has not had an opportunity to review the given terpene in an FDA-approved drug. Tr. 137:4-9.

As she explained, "[s]ince a vast majority of terpenes that we sell that get inhaled are found in cannabis products, and cannabis is a Schedule I drug, the FDA would not even be able to review nor approve it …as a drug for inhalation." Tr. 135:15-21. Because DOH has presented no evidence to rebut Dr. Vreeke's credible testimony, the record is devoid of any scientific fact suggesting non-cannabis derived terpenes such as those contained in the Recalled Medicines pose a risk to public health or safety that would justify the Terpene Recall Mandate under 28 Pa. Code § 1151.42.

Dr. Sisley, a practicing physician, researcher, manufacturer of medical marijuana with an emphasis on inhalation medications, and a volunteer medical director of more than 30 medical marijuana operators nationwide, was offered as an expert witness in medical marijuana research, the FDA approval process, and patient impacts. Tr. 199-204, 205:21-206:2, 219:24-220:22. Dr. Sisley testified that no patient of hers nor any of the 30 medical marijuana producers for which she has served as a medical director over the last 10-plus years has reported an adverse event attributable to non-cannabis derived terpenes found in vaporization medicines. Tr. 219:5-222:11. Dr. Sisley testified that there are real benefits to inhalation medicines such as the rapid onset of symptom alleviation in the case of seizure disorders or chronic pain, and that dosage amounts can be readily adjusted on an as needed basis. Tr. 223:7-224:7. She also offered unrebutted testimony that there are medical

benefits to non-cannabis derived terpenes that include promoting the entourage effect, which significantly improves the efficacy of the marijuana medicine, and delivering consistent and reproducible medicinal effects at a lower cost than can be delivered through cannabis-derived terpenes that depend on the vagaries of the terpene levels contained in marijuana crop that is harvested. Tr. 210:9-225:15. Further, Dr. Sisley presented testimony that patients who no longer have access to the Recalled Medicine are likely to either turn to the illicit market or return to pharmaceutical prescriptions, which in the case of a condition like chronic pain means returning to addictive opioids. Tr. 245:4-246:11. DOH presented no evidence refuting Dr. Sisley's medical and patient-based testimony that (a) there have been no adverse events attributable to non-cannabis derived terpenes, (b) there are benefits to using non-cannabis derived terpenes in vaporization medicines, and (c) restricting access to the Recalled Medicine is likely to force patients to revert to addictive prescriptions or the illicit market.

The unchallenged evidence presented by MMAPS through the testimony of Dr. Sisley, Dr. Vreeke, and Mr. Woloveck provide a factual record that is clear: greater harm will result to patients if an injunction is not granted than if one is because patients rely on the Recalled Medicine and no evidence demonstrates that the Recalled Medicines are unsafe.

c. The Recall Is Based On A New Standard That Has No Basis In Law, Is Procedurally Void, And That Otherwise Violates MMAPS' Members' Rights: MMAPS Is Likely To Prevail On The Merits

To satisfy the clear right to relief prong of the preliminary injunction standard MMAPS is not required to prove its case absolutely but instead need only demonstrate that substantial legal questions must be resolved to determine the rights of the litigants. *Fischer v. Dep't of Publ. Welfare*, 439 A.2d 1172, 1174 (Pa. 1982). As discussed in greater detail in MMAPS' pre-hearing brief in support of this preliminary injunction request, and now supported by unrefuted record evidence, MMAPS has raised substantial legal questions that DOH's Terpene Recall Mandate is unlawful, such that MMAPS has demonstrated a clear right to relief.

First, the Terpene Recall Mandate effectively created a new "safe for inhalation" standard that DOH now imposes industry-wide when reviewing for approval products containing non-cannabis derived terpenes. This new standard exceeds the plain language of its enabling statute. In 2021, when the General Assembly amended the Act in a specific and precise manner to confer on DOH the power and the duty to consider whether an added terpene is approved by the FDA for use *in food,* it was silent on the issue of FDA approval for *inhalation*. *See* 35 P.S. § 10231.702(a)(5). Contrary to DOH's position, this silence does not confer tacit approval, 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). As the evidence showed here through Dr. Vreeke's and Dr. Sisley's testimony, the General Assembly's decision to omit FDA's "safe for inhalation" standard was purposeful. It is nonsensical to look to the FDA's list of ingredients approved for inhalation in the context of medical marijuana because the list only includes ingredients in FDA approved drugs, most terpenes are not used as ingredients in drugs approved for inhalation by the FDA, and the FDA does not review and approve marijuana inhalation products that do contain terpenes because marijuana is illegal under federal law. Tr. 136:14-137:9, 230:1-231:5.

Second, the Terpene Recall Mandate imposed an immediately effective industry-wide rule through email, outside the prescribed rulemaking process, that terpenes added to medical marijuana vaporization products must be "approved as safe for inhalation by" the FDA. Exh. S-1, P-1, S-7. DOH's February 4 announcements make clear that its new standard imposes substantive obligations on the entire medical marijuana industry that purport to have the force and effect of law, the violation of which could result in revocation of Petitioner's members medical marijuana permits. Exh. S-1. It is a new industry regulation that is improperly promulgated and is therefore invalid *ab initio*. *Dep't of Envtl. Res. v. Rushton*

Mining Co., 591 A.2d 1168 (Pa. Cmwlth. 1991) ("if an interpretive 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."); *Corman v. Acting Secretary, Pa. Dep't of Health*, 266 A.3d 452 (Pa. 2021).

Third, DOH lacks the power under 28 Pa. Code §1151.42 to initiate a recall. Pursuant to DOH's regulations, mandatory recalls emanate from grower/processors "discover[ing] a condition … [that] poses a risk to public health and safety." 28 Pa. Code §1151.42(c)(1). The factual record contains zero evidence that an adverse event, customer complaint, or risk to public health and safety has been identified and attributed to the Recalled Medicine. Exh. S-1, S-3, S-4, S-6, S-7; Tr. 65:1-6, 67:4-10, 69:5-8, 72:23-75:15. In response to this MMAPS' claim, DOH asserted in its answer that it did not initiate a recall but merely indicated that grower/processors must follow the recall procedures. DOH Ans. ¶ 1. DOH has presented no indication that this argument is anything more than disingenuous semantics, and it is belied by the evidence that has been presented: in its February 4th email to patients, DOH informed patients that the Recalled Medicine has not been approved for inhalation and "[t]herefore, *the Department has issued mandatory recalls[s]* for all affected [Recalled Medicine]." Exh. S-7 (emphasis added). Absent a finding that the Recalled Medicine posed a risk to public health and safety—and there is no such finding here-- the mandatory recall is unwarranted. DOH's initiation of the mandatory recall, as

plainly communicated in its February 4 email, without any regulatory authority to do so, renders the Terpene Recall Mandate unlawful.

Fourth, the Terpene Recall Mandate violated MMAPS' members' vested rights to produce and sell the medicines subject to recall because DOH previously approved the production and sale of every product. *Dep't of Envtl. Res. v. Flynn*, 344 A.2d 720, 725 (Pa. Cmwlth. 1975) (reciting elements of vested right claim). As Mr. Woloveck testified, a prerequisite to producing any medicinal marijuana is DOH approval. Tr. 45:17. Each of MMAPS' permit holding members complied in good faith with DOH's regulations concerning producing and dispensing what are now the Recalled Medicines. Tr. 45:17, 48:22-49:24, 65:23, 68:25. MMAPS' members have expended substantial amounts of money as detailed by Mr. Ahern in the production and dispensing of the Recalled Medicine. Tr. 293-319. There are no appeals from prior approvals of MMAPS' members Recalled Medicine that are pending. And DOH has cited no evidence that the public health, safety, or welfare would be adversely affected by MMAPS' members' continued production and dispensing of the Recalled Medicine. Exh. S-1, S-3, S-4, S-6, S-7; Tr. 65:1-6, 67:4-10, 69:5-8, 72:23-73:10. Accordingly, DOH's Terpene Recall Mandate is barred by the doctrine of vested rights – MMAPS' members have reasonably relied to their detriment on DOH's prior approvals of the Recalled Medicine.

Fifth, DOH's Terpene Recall Mandate constitutes a regulatory taking under both the Fifth Amendment of the United States Constitution and under Article 1, Section 10 of the Pennsylvania Constitution because it deprives MMAPS' members of *all* economic value they had in the Recalled Medicine and because it significantly interferes with MMAPS' members legitimate property interests. *Lucas v. South Carolina Coastal Council,* 505 U.S. 1003 (1992) (holding that government action that deprives property owner of all value is a regulatory taking); *Lingle v. Chevron U.S.A., Inc*., 544 U.S. 528, 539 (2005) (holding that the traditional fact-based inquiry of whether government action constitutes a regulatory taking "turns in large part … upon the magnitude of a regulation's economic impact and the degree to which it interferes with legitimate property interests") (internal citations omitted). Even if DOH has walked back its initial hardline destruction mandate until this case is resolved, *all* value in Recalled Medicine will be lost because the12-month shelf-life will undoubtedly be much shorter than the time it will take to reach resolution of this litigation and related appeals. Tr. 98:22-99:15. The Terpene Recall Mandate has resulted in more than $18 million in damages to MMAPS' members by prohibiting the sale of previously DOH-approved vaporized medicines; it has imposed significant monetary harm on legitimate property interests. Tr. 45:17, 293-319. The Terpene Recall Mandate amounts to a taking under either the *Lucas* or *Lingle* line of cases.

Sixth, the Terpene Recall Mandate violates MMAPS' members' constitutionally protected right to due process under the Fourteenth Amendment of the United States Constitution and Article I, Sections 1 and 11 of the Pennsylvania Constitution by failing to provide a pre-deprivation hearing. *Fuentes v. Shevin*, 407 U.S. 67 (1972); *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).

Here, the private interest affected—millions of dollars MMAPS' members invested into previously DOH-approved vaporized medicines of which over 330,000 units of Recalled Medicine produced by MMAPS' members has been recalled and effectively, if not yet actually, destroyed—is significant. Tr. 293-319, 39:12-14, 45:17. The risk that the Terpene Recall Mandate is an erroneous deprivation weighs heavily in favor of finding a pre-deprivation hearing necessary. DOH failed to present any case that justified the Terpene Recall Mandate and consequently MMAPS, its members, this court, and the public are still in the dark about what prompted DOH to recall approximately 15 percent of all medical marijuana products in Pennsylvania. Further, contrary to DOH's pronouncements that the Recalled Medicines are unsafe, the record is clear that the Recalled Medicines have not

resulted in any known adverse event, customer complaint, or risk to public health or safety, Exh. S-1, S-3, S-4, S-6, S-7; Tr. 65:1-6, 67:4-10, 69:5-8, 72:23-75:15; DOH previously-approved the medicines it recalled, Tr. 45:17; and, DOH lacks both the statutory and regulatory authority to impose the Terpene Recall Mandate. A preliminary injunction would return the parties to the status quo as it existed just prior to the unlawful Terpene Recall Mandate when patients had access to their medicine that was tested and approved by DOH and used without incident for years by Pennsylvania patients. Because a pre-deprivation hearing would not have imposed an undue burden on DOH, the third prong also weighs heavily in favor of requiring a pre-deprivation hearing. There was no emergency to get the Recalled Medicines off the shelves and out of patients' hands—in fact, DOH's communications with patients did not even advise that they should stop using the Recalled Medicines. Exh. S-4, S-7. The record reflects that there was no known reason to issue the Terpene Recall Mandate, period. Without an immediate and real public health or safety concern, DOH could and should have provided MMAPS' members an opportunity to be heard before removing this medicine from shelves and requiring the effective destruction of millions of dollars' worth of vaporization products. Accordingly, DOH's actions failed to provide MMAPS' members with any meaningful process in violation of their right to due process.

Seventh, DOH's pronouncement to the public that the Recalled Medicines produced by MMAPS' members were unsafe without any scientific, medical, or even anecdotal evidence to support its claim violates MMAPS' members right to reputation as protected by Pa. Const. Art. I, §§ 1 and 11. As the Pennsylvania Supreme Court has stated, a party's reputation "cannot be abridged without compliance with constitutional standards of due process and equal protection." *R. v. Com., Dep't of Pub. Welfare*, 636 A.2d 142, 149 (Pa. 1994); *see also Summit Academy v. Dep't of Human Services*, 2015 WL 8190829 (Pa. Cmwlth. 2015) (applying the Art. I, §1 and §11 reputational protections to a corporate entity).[5] Although there is a compelling interest in protecting the public health and safety of medical marijuana patients, DOH's announcements that medicines it previously approved and which patients have relied on for years are unsafe without any factual, scientific, or medical evidence to support such a claim is certainly not narrowly tailored to achieve that interest. *Pa. Bar Ass'n v. Com., Pa. Ins. Dep't*., 607 A.2d 850, 858 (Pa. Cmwlth. 1992) (finding that strict scrutiny applies to the constitutional right of reputation). Therefore, DOH's Terpene Recall Mandate and its associated announcements have unconstitutionally impugned MMAPS' members.

[5] 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**.

d. The Public Interest Favors Preliminarily Enjoining The Recall

The General Assembly enacted the Medical Marijuana Act to provide access to safe and effective medicinal marijuana, and DOH's Terpene Recall Mandate greatly restricts access to medicines that have been previously approved by DOH and used and relied upon by Pennsylvania patients for years, and patients nationwide for over a decade, without incident. 35 P.S. §10231.102. Mr. Woloveck provided unrebutted testimony that the Recalled Medicines account for approximately 57 percent of all vaporized medicines. Tr. 47:9. Likewise, Mr. Ahern testified that the Recalled Medicines represent 15 percent of all medicinal marijuana products available in Pennsylvania. Tr. 316:17-18. And Dr. Sisley provided context to what those numbers mean: patients will not have the medicine they need and depend on and may look to the illicit market or revert to their prescription medications, two options that the Act was enacted to curb. Tr. 245:4-246:11. As discussed *supra*, DOH's Terpene Recall Mandate is illegal; it serves only to undermine the intention of the Act.

Moreover, and perhaps most telling of all with respect to the public interest, is that DOH has utterly failed to present any evidence that suggests the Recalled Medicine is unsafe or poses a risk to the public health and safety of patients. DOH's refusal to explain the rationale behind its recall is damning evidence that the recall is an arbitrary exercise of administrative power that lacks any reasoned basis. It is

difficult to conjure circumstances that more clearly demonstrate that the Terpene Recall Mandate is not in the public's interest.

III. MMAPS SHOULD BE REQUIRED TO POST A NOMINAL BOND

DOH has failed to present any evidence that any person would sustain reasonably foreseeable damages if it were later determined that the preliminary injunction was wrongfully granted. Therefore, MMAPS should only be required to post bond, pursuant to Pa.R.C.P. 1531(b), in the nominal amount of $100.00.

IV. NO AUTOMATIC SUPERSEDEAS SHOULD ISSUE ON APPEAL

MMAPS requests that the court specify in its order granting a preliminary injunction that that no appeal from the order by DOH will act as an automatic supersedeas under Pa. R.A.P. 1736(b). The applicable standards for vacating a Rule 1736(b) supersedeas are substantially identical to those for granting a preliminary injunction. *See Department of Environmental Resources v. Jubelirer,* 614 A.2d 199 (Pa. 1989). Accordingly, the Court's grant of a preliminary injunction demonstrates that MMAPS would be entitled to have any Rule 1736(b) supersedeas vacated. Under the circumstances of this case and in the interests of judicial economy MMAPS respectfully requests that the Court make that ruling coincident with its order granting preliminary injunctive relief.

CONCLUSION

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

Respectfully submitted,

/ s / Judith D. Cassel
Judith D. Cassel I.D. No. 209393
Kevin J. McKeon, I.D. No. 30428
Dennis A. Whitaker, I.D. No. 53975
Micah R. Bucy, I.D. No. 320196
Hawke McKeon & Sniscak, LLP
100 North Tenth Street
Harrisburg, PA 17101
(P) 717-236-1300
(F) 717-236-4841
jdcassel@hmslegal.com
kjmckeon@hmslegal.com
dawhitaker@hmslegal.com
mrbucy@hmslegal.com

Counsel for Petitioner

Date: March 11, 2022

APPENDIX 1

2015 WL 8190829
Only the Westlaw citation is currently available.

Commonwealth Court of Pennsylvania.

The SUMMIT ACADEMY, Petitioner
v.
DEPARTMENT OF HUMAN SERVICES, Respondent.

No. 257 C.D.2015.
|
Submitted Sept. 4, 2015.
|
Decided Dec. 7, 2015.

BEFORE: BERNARD L. McGINLEY, Judge, and PATRICIA A. McCULLOUGH, Judge, and JAMES GARDNER COLINS, Senior Judge.

MEMORANDUM OPINION

McCULLOUGH, Judge.

***1** The Summit Academy (Facility), a private residential treatment center for dependent and delinquent youth, petitions for review of the February 2, 2015 final order of the Department of Human Services (Department), Bureau of Hearings and Appeals (Bureau), adopting the recommendation of an Administrative Law Judge (ALJ) that the Facility's appeal from a license inspection summary (LIS) should be dismissed for lack of jurisdiction. On appeal, the Facility contends that the Department's regulations and procedures governing the LIS violate due process.

Background

The facts and procedural history of this case are as follows. On October 17, 2014, a representative of the Department conducted an on-site inspection of the Facility. At the conclusion of the inspection, the representative completed an LIS listing two violations. The first violation concerned diagnosed injuries that a resident sustained while being manually restrained by Facility employees. The second violation involved the Facility's inaccurate records as to the time-frame in which the resident was restrained. (Reproduced Record (R.R.) at 3a–6a.)

More specifically, the LIS named the applicable regulations and described the violations as follows:

1. Regulation 55 Pa.Code § 3800

3800.32(b)—A child may not be abused, mistreated, threatened, harassed or subject to corporal punishment.

2a. Description of Violation

Staff Member A manually restrained resident # 1 on 10/8/14 around 8:30 p.m. on the facility's third floor catwalk resulting in the resident's diagnoses of a closed rib fracture, a left wrist injury, and a facial contusion.

* * *

1. Regulation 55 Pa.Code § 3800

3800.213—A record of each use of a restrictive procedure, including the emergency use of a restrictive procedure, shall be kept and shall include the following:

(2) The date and time the procedure was used ...

(6) The duration of the procedure ...

2a. Description of Violation

Resident # 1 was manually restrained on 10/8/14 in the cafeteria and minutes later was manually restrained on the third floor catwalk. The restrictive procedure record for the manual restraint in the cafeteria indicated that the restraint began at 8:35 p.m. and ended at 8:40 p.m. and the restrictive procedure record for the manual restraint on the third floor catwalk indicated that the restraint began at 8:30 p.m. and ended at 8:35 p.m. The restrictive procedure records do not accurately indicate the time of the manual restraints.

(R.R. at 4a–5a.)

On November 26, 2014, the Department sent the Facility a letter with the LIS enclosed. In pertinent part, the letter stated:

> The Department requires that you submit an acceptable plan to correct noncompliant items pursuant to 55 Pa.Code § 20.52 (relating to plan of correction). You should begin to implement your plan immediately upon submission. The Department will notify you if the plan you submit is not acceptable and must be changed.
>
> ***2** In order to submit an acceptable plan of correction, you must complete Section 3 of the attached [LIS], by stating the actions you will take to correct each of the violations. Your plan of correction must immediately correct the specific issue cited, as well as include an ongoing, step-by-step plan to assure continued compliance with the regulation over a substantial period of time. Your plan of correction for each violation should include: what specific change will be made, who will make the change, when will the change be made, how will the change be made, what system have you implemented to make sure that the same violation will not occur again and what training will be provided to your staff. Send any supporting documentation to verify compliance of any corrected violation. **If you believe any violation is incorrect, you may say that in your comments under Section 3 but you still must include a plan to reach and maintain compliance. Sign and date the bottom of each page of the [LIS].**
>
> Return the attached [LIS] within 10 calendar days of the mailing date of this letter. Your license to operate the above facility may be revoked if the [LIS] is not received within the required time period....
>
> I am available to explain any statements on the attached form and to assist you in the development of an acceptable plan of correction. Thank you for your cooperation.

(R.R. at 1a–2a) (emphasis supplied).

On December 4, 2014, the Facility filed an appeal from the November 26, 2014 letter, asserting that the violations listed in the LIS were "unsubstantiated" and could be used "in future enforcement actions." (R.R. at 11a.) Specifically, the Facility contended that the Department's representative relied upon erroneous information, and it asserted that a proper investigation would have revealed that the resident hurt himself when he slipped and fell on a wet floor and that the length of time the resident was restrained was recorded accurately. To support its contentions, the Facility attached the affidavits of two of its employees. (R.R. at 9a–23a.) The Facility further asserted that the Department's failure to provide it "an avenue to appeal these improper and unsubstantiated violations constitutes a violation of [the Facility's] due process rights." (R.R. at 11a.)

On December 12, 2014, the Department acknowledged the Facility's request for appeal and forwarded it to the Bureau. The ALJ issued a rule to show cause as to why the appeal should not be dismissed for want of jurisdiction, and both the Facility and the Department filed responses. (R.R. at 24a–25a.)

In its response, the Facility contended that the November 26, 2014 letter was an adjudication because the LIS could be used to take adverse action against the Facility's certificate of compliance; the Facility would have no recourse to challenge the findings and violations in the LIS; and the failure to permit an appeal and hearing violates the Facility's right to procedural due process. In its response, the Department argued that the LIS did not impose any sanction against the Facility or immediately jeopardize its certificate of compliance; the Facility would have the right to appeal in the event the Department would take action in the future based upon the LIS; and case law establishes that notice of a regulatory violation (absent a sanction) does not constitute an adjudication. (R.R. at 26a–35a.)

***3** Upon consideration of the parties' submissions, the ALJ recommended that the Facility's appeal be dismissed for failing to state a claim for which the Bureau can grant relief. (R.R. at 37a.) On February 2, 2015, the Bureau issued an adjudication and order upholding the ALJ. In doing so, the Bureau made the following findings of fact:

> 1. [The Facility] is a residential juvenile facility.
>
> 2. On November 26, 2014, the Department mailed a letter to [the Facility] which included a[LIS] that cited violations of regulations relating to child residential and day treatment facilities.
>
> 3. The November 26, 2014 letter required [the Facility] to submit a plan of correction to address the cited violations within ten (10) calendar days of the mailing date of the letter.
>
> 4. The November 26, 2014 letter stated that failure to submit a timely plan of correction may result in the revocation of [the Facility's] license to operate.

5. The November 26, 2014 letter stated, "If you believe any violation is incorrect, you may say that in your comments under Section 3 but you must still include a plan to reach and maintain compliance."

6. The November 26, 2014 letter did not propose to deny, not renew, or revoke [the Facility's] certificate of compliance. It did not issue a provisional license, reduce the maximum capacity of the facility or deny a request to increase the maximum capacity of the facility.

7. On December 12, 2014, the Bureau received a request for hearing from [the Facility] to dispute the [LIS] findings because these findings may be used by the Department in future enforcement actions.

8. On December 19, 2014, the Bureau issued an order to show cause why [the Facility's] appeal should not be dismissed as it appears the Bureau does not have jurisdiction.

9. On January 16, 2015, [the Facility] responded to the Bureau's order but the response failed to set forth a cause of action for which the Bureau can grant relief.

(Findings of Fact (F.F.) at Nos. 1–9.)

From these facts, the Bureau determined that it lacked jurisdiction to entertain the Facility's appeal pursuant to the regulation at 55 Pa.Code § 20.81, which grants the right to appeal only when the Department denies, revokes, or decides not to renew a certificate of compliance and for other reasons that are not pertinent to this appeal.[1] The Bureau stated that the November 26, 2014 letter did not revoke the Facility's certificate of compliance and noted that it advised the Facility of its right to explain why it believes the violations are incorrect. Ultimately, the Board concluded that it did not possess jurisdiction to overturn findings in a LIS, but suggested that the Facility would be able to challenge the findings if the Department would decide, in the future, to take adverse action against the Facility's certificate of compliance. (Bureau's decision at 2–3.)

Discussion

On appeal to this Court,[2] the Facility argues that the violations listed in the LIS are baseless and that it should not have to submit a plan of correction. The Facility concedes that 55 Pa.Code § 20.81 does not grant it the right to appeal, but argues that the regulation, as applied, violates its due process rights because the Facility is not afforded an appeal and hearing to contest the violations in the LIS. For support, the Facility cites *Department of Transportation, Bureau of Driver Licensing v. Clayton,* 684 A.2d 1060 (Pa.1996), and claims that the effect of an LIS is to create an impermissible, irrebutable presumption that it committed the violations.[3] Noting that the LIS is made available to the public on the Department's website,[4] the Facility also argues that a Pennsylvania citizen has a fundamental right to protect the individual's reputation and that this right cannot be deprived without due process of law. In this regard, the Facility relies primarily on our decision in *Pennsylvania Bar Association v.. Commonwealth,* 607 A.2d 850 (Pa.Cmwlth.1992).

The Regulations

***4** The regulations at 55 Pa.Code §§ 3800.1–.312 govern child residential facilities in this Commonwealth, such as the Facility. The purpose of the regulations "is to protect the health, safety and well-being of children receiving care in a child residential facility through the formulation, application and enforcement of minimum licensing requirements." 55 Pa.Code §§ 3800.1. In general, the regulations cover a multitude of subjects; for instance, child rights, staff training, the safety of the facility, child and staff health, transportation, medication, restrictive procedures, and secure detention. *See generally* 55 Pa.Code §§ 3800.1–.312. As a licensing matter, a child residential facility must obtain and maintain a certificate of compliance from the Department. *See* 55 Pa.Code § 3800.11.

The Department's regulations define a "certificate of compliance" as a "document issued to a legal entity permitting it to operate a specific type of facility or agency, at a given location, for a specified period of time, and according to appropriate Departmental program licensure or approval regulations." 55 Pa.Code § 20.4. To ensure compliance with the regulations, an authorized agent of the Department can conduct a pre-announced annual inspection and unannounced on-site inspections, and can investigate complaints made against a facility. 55 Pa.Code §§ 20.31–.33. If the agent observes items of noncompliance, an LIS will be issued to the facility, and, in response, the facility "shall submit an acceptable written plan to correct each noncompliance item and shall establish an acceptable period of time to correct

these items." 55 Pa.Code § 20.52. The Department may deny, refuse to renew, or revoke a certificate of compliance when a facility fails "to submit an acceptable plan to correct noncompliance items." 55 Pa.Code § 20.71(3). If the Department decides to revoke or not renew a certificate of compliance, a facility has the right to an appeal and evidentiary hearing before an ALJ and the Bureau. 55 Pa.Code §§ 20.81(2)-(3); 20.82; 3800.12. *See City of Philadelphia, Board of License and Inspection Review v. 2600 Lewis, Inc.,* 661 A.2d 20, 22 (Pa.Cmwlth.1995).

Due Process

The Fourteenth Amendment to the United States Constitution provides, in relevant part, that no "State [shall] deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. To maintain a due process challenge, a party must initially establish the deprivation of a protected property or liberty interest. *Miller v. Workers' Compensation Appeal Board (Pavex, Inc.),* 918 A.2d 809, 812 (Pa.Cmwlth.2007).

Our Supreme Court "has recognized that the right to reputation, although absent from the federal constitution, is a fundamental right under the Pennsylvania Constitution." *In the Interest of J .B.,* 107 A.3d 1, 16 (Pa.2014).

> [I]n Pennsylvania, reputation is an interest that is recognized and protected by our highest state law: our Constitution. Sections 1 and 11 of Article I[5] make explicit reference to 'reputation,' providing the basis for this Court to regard it as a fundamental interest which cannot be abridged without compliance with constitutional standards of due process....

***5** *R. v. Department of Public Welfare,* 636 A.2d 142, 149 (Pa.1994).

In *Pennsylvania Bar Association,* this Court invalidated, on procedural due process grounds, section 1822(b)(5) of the Vehicle Code, 75 Pa.C.S. § 1822(b)(5), which required insurers to report suspected fraudulent claims to a statutorily created Motor Vehicle Fraud Index Bureau, along with "[i]dentification of attorneys representing claimants" in such claims. 607 A.2d at 852. In that case, the Pennsylvania Bar Association commenced suit in our original jurisdiction, asserting, among other things, that maintaining a list of the attorneys' names would operate to damage their reputations in violation of their constitutional right to protect their reputations.

Citing *Wolfe v. Beal,* 384 A.2d 1187, 1189 (Pa.1978), this Court in *Pennsylvania Bar Association* noted that our Supreme Court had already recognized that the existence of government records, specifically records of an individual's illegal commitment to a state mental hospital, posed a "threat" to that individual's reputation. 607 A.2d at 853–54. We then agreed with the Pennsylvania Bar Association "that the maintenance of a list which includes the names of attorneys representing insurance claimants suspected of fraud ... poses a serious threat to the reputations of [the attorneys], as discussed in *Wolfe.*" 607 A.2d at 856. After determining that the attorneys were entitled to protection under the due process clause, we concluded that the statute's failure to provide notice to the attorneys that they were being placed on the list rendered the statute unconstitutional:

> Yet, disturbingly, the reporting requirements in 75 Pa.C.S. § 1822(b) pertaining to the anti-fraud reports provide for no notification to the attorneys when their names are listed in the Index Bureau's record banks.
>
> The Supreme Court of the United States has recognized that notice is the most basic requirement of due process. Notice is necessary both to inform the interested parties of the pending action and to provide an opportunity to present objections.... An attorney may appear on the list, and be subject to negative stigmatization, because the insurer has a suspicion about the client due to previous actions unknown to the attorney. By the time the listing is brought to the attorney's attention, the damage to the attorney's reputation may have been done, and he or she may have lost the opportunity to be heard at a meaningful time and in a meaningful manner....
>
> We find Section 1822 to be unconstitutional inasmuch as it requires the maintenance of records containing the names of attorneys who represent insurance claimants suspected

> of fraud because such a scheme ignores the basic due process requirement of notice, and permits the compilation of secret records that tend to unfairly stigmatize an attorney who is reported to the Index Bureau without any opportunity for the attorney to raise an objection to such listing, or even become informed that such a listing will occur.

***6** 607 A.2d at 856–57 (citations omitted).

Per *Pennsylvania Bar Association,* if an individual's liberty interest in reputation is sufficiently "threatened," the individual possessing the interest is entitled to some method of due process. *See id.* More specifically, procedural due process calls for protections tailored to the demands of the particular situation, making it necessary to balance competing interests. *R.,* 636 A.2d at 146. The three-part inquiry set forth in *Mathews v. Eldridge,* 424 U.S. 319 (1976), provides guidance in this regard. The *Mathews* analysis requires a court to consider the private interest affected by the official action; the risk of an erroneous deprivation of that interest through the procedures used, as well as the probable value of additional safeguards; and the Government's interest, including the administrative burden that additional procedural requirements would impose. *R.,* 636 A.2d at 146.

The United States Supreme Court has stated: "when prompt postdeprivation review is available for correction of administrative error, we have generally required no more than that the predeprivation procedures used be designed to provide a reasonably reliable basis for concluding that the facts justifying the official action are as a responsible governmental official warrants them to be." *Mackey v. Montrym,* 443 U.S. 1, 13 (1979). The High Court has also "recognized, on many occasions, that where a State must act quickly, or where it would be impractical to provide predeprivation process, postdeprivation process satisfies the requirements of the Due Process Clause." *Gilbert v. Homar,* 520 U.S. 924, 930 (1997). *See Zinermon v. Burch,* 494 U.S. 113, 132 (1990) (stating that "in situations where a predeprivation hearing is unduly burdensome in proportion to the liberty interest at stake ... post-deprivation remedies might satisfy due process."). The United States Court of Appeals for the Third Circuit has further explained that "the availability and validity of any pre-deprivation process must be analyzed with reference to the context of the alleged violation and the adequacy of available post-deprivation procedures." *Reilly v. City of Atlantic City,* 532 F.3d 216, 236 (3d Cir.2008).

For purposes of this appeal, we assume that publication of the LIS and the violations on the internet for the public to view has a sufficient and adverse effect or "threat" on the Facility's reputational interests to implicate due process concerns. *See Pennsylvania Bar Association,* 607 A.2d at 856–57.[6] Nonetheless, the LIS contains sufficient and detailed notice of the violations, and before the LIS is posted on the internet, the Department provides the Facility with the opportunity to protect its reputational interests. Particularly, the Facility can contest the violations by making comments in section 3 of the LIS, which is also posted on the internet and made available to the public. (F.F. at No. 5; R.R. at 1a–2a.) This predeprivational process is much more extensive than that in *Pennsylvania Bar Association,* where the attorneys were not even provided notice.

***7** Because the Facility is afforded adequate notice and an opportunity to respond in writing, *Pennsylvania Bar Association* is distinguishable and is not dispositive authority on the present issue. Moreover, this Court in *Pennsylvania Bar Association* was primarily concerned that the lack of notice deprived the attorneys of the opportunity "to raise an objection to [the] listing." 607 A.2d at 857. For the reasons discussed below, we conclude that at this stage of the regulatory procedure, where the Facility's certificate of compliance is not being revoked (*i.e.,* the predeprivation stage), the opportunity to contest the violations in writing, in and of itself, is sufficient to preserve the Facility's right of reputation and minimize any "threat" to its reputation.

Indeed, in cases concerning the discharge of a public tenured employee, which often involve allegations of improper or criminal conduct, it has been held that pre-termination notice and an opportunity to respond in writing is enough to comport with due process. *See, e.g., Pavonarius v. City of Allentown,* 629 A.2d 204, 207 (Pa.Cmwlth.1993) (discussing *Cleveland Board of Education v. Loudermill,* 470 U.S. 532, 545–46 (1985)); *accord Matter of Richie v. Coughlin,* 148 A.D.2d 178, 183 (N.Y.App. Div., 3d Dept.1989). In *Pavonarius,* this Court stated: "Only a meeting with the employer or a written notice sent by the employer to the employee setting forth the reasons for her termination and requesting the employee to respond in writing to the allegations is necessary to satisfy the [tenured employee's] basic due process rights." 629 A.2d at 207. The reason

for this rule is that the predeprivation phase serves as "an initial check against mistaken decisions—essentially, a determination of whether there are reasonable grounds to believe that the charges ... are true and support the proposed action." *Loudermill,* 470 U.S. at 545–46.

In cases analogous to the present scenario, the federal circuit courts of appeals have also concluded that notice and an opportunity to respond in writing satisfied the predeprivation prong of due process.

In *Agility Defense & Government v. United States Department of Defense,* 739 F.3d 586 (11th Cir.2013), the United States Court of Appeals for the Eleventh Circuit concluded that government contractors had a liberty interest in not having stigmatizing allegations disseminated or publicized; this liberty interest was at stake when the agency suspended the contractors for multiple years due to an indictment for fraud; yet, the contractors were afforded procedural due process by virtue of the fact that the contractors received notice of the suspension and had an opportunity to respond in writing. The court explained:

> [E]ven assuming that the suspension of the [contractors] deprived them of their liberty, the regulation does not violate the Due Process Clause because it contains constitutionally adequate procedures. An agency must immediately notify a suspended affiliate of its suspension by certified mail. 48 C.F.R. § 9.407–3(c). That notification includes the basis of the suspension and advises the affiliate of its opportunity to respond in writing. *Id.* These procedures—notification and an opportunity to respond—are constitutionally adequate procedures for multiyear suspensions.

***8** *Id.* at 591.

In *Northlake Community Hospital v. United States,* 654 F.2d 1234 (7th Cir.1981), the United States Court of Appeals for the Seventh Circuit addressed a hospital's claim that it had been denied due process because its Medicare provider agreement was terminated prior to a hearing. In that case, the Department of Health and Human Services conducted several inspection visits and provided the hospital with notices of deficiencies, outlining the hospital's noncompliance with administrative regulations. In turn, the hospital had the opportunity to respond in writing to the notices and was given a grace period to correct the deficiencies. When the hospital failed to correct the deficiencies, the Department sent notice to the hospital that its Medicare provider agreement was terminated. The hospital then filed suit, alleging that the pre-termination procedures did not conform with procedural due process. The court disagreed, concluding that notice and an opportunity to respond in writing fulfilled the requirements of due process.

Similarly, in *Town Court Nursing Center v. Beal,* 586 F.2d 266 (3d Cir.1978) (*en banc*), the Secretary of the Department of Health and Human Services decided not to renew a nursing home's Medicaid provider agreement based upon regulatory violations found by health care inspectors. The Third Circuit concluded that the nursing home was only entitled to notice and an opportunity to respond prior to the non-renewal. In pertinent part, the court stated:

> [T]he decision not to renew a provider agreement is an easily documented, sharply focused decision in which issues of credibility and veracity play little role. It is based in most cases upon routine, standard, unbiased reports by health care professionals. Those professionals evaluate the provider in light of well-defined criteria that were developed in the administrative rule-making process. Written submissions are adequate to allow the provider to present his case. Given the extensive documentation that the provider is able to submit in response to the findings of the survey teams, the provider is unlikely to need an evidentiary hearing in order to present his position more effectively.

Id. at 277.

The reasoning and conclusions of the above cases apply here with equal force. The Department's agents are presumed to have conducted their inspections in good faith and in accordance with the law, *Office of Governor v. Donahue,* 98 A.3d 1223, 1239 (Pa.2014); the regulations are relatively straightforward and lacking discretionary factors or standards; and the LIS constitutes reasonable grounds to believe that the violations were committed. In terms of the LIS, section 3 is located directly beneath the "Description of Violation" section, and the Facility is permitted to state in this section any and all reasons why it believes a violation is incorrect and also to "attach pages as necessary." (*See* R.R. at 1a, 4a, 15a.) Ultimately, by affording the Facility with the initial opportunity to dispute the violations in writing, the Department has provided the Facility with the ability to adequately protect its reputation by responding to allegations concerning its operations. Therefore, we conclude that this predeprivation procedure comports with due process.

***9** The Facility, nevertheless, takes issue with the fact that it must file a plan of correction after receiving the LIS and the Department may revoke its certificate of compliance if the plan submitted is not acceptable. At the outset, this Court is mindful of its duty to interpret a regulation in a constitutional manner if that is reasonably possible. *See Bricklayers of Western Pennsylvania Combined Funds, Inc. v. Scott's Development Co.,* 90 A .3d 682, 692 (Pa.2014).

Notwithstanding the Facility's arguments, there is nothing in the regulations that prohibit the Facility from maintaining its position and stating on its plan of correction that no plan is needed because no violations have occurred. In such a situation, the Department will be forced to consider the Facility's written response to the LIS to determine whether the proposed plan of correction is "acceptable." 55 Pa.Code § 20.52. If the Department decides that the plan is not, the Department may revoke the Facility's certificate of compliance. 55 Pa.Code §§ 20.71(3). Conversely, upon review of the written response, the Department may decide that the violations are not properly supported, and the regulations do not prohibit the Department from retracting or rescinding the LIS. In the event the Department revokes the certificate of compliance, the Facility will have the opportunity to appeal, and it will receive a full-blown postdeprivation evidentiary hearing before an ALJ and the Bureau, along with the right to seek further appellate review in this Court and the Supreme Court. *See generally Millcreek Manor v. Department of Public Welfare,* 796 A.2d 1020, 1028–30 (Pa.Cmwlth.2002) (discussing the requirements for a full, *de novo* evidentiary hearing before an ALJ); *see also Rogers v. Pennsylvania Board of Probation & Parole,* 724 A.2d 319, 321–22 (Pa .1999). Although the Department's regulations are silent on the latest matter, we must interpret them as allowing the Facility to litigate and contest alleged violations at a revocation hearing based upon an unacceptable plan of correction, or at any hearing where violations, both past and present, form the underlying basis (or part of the basis) for nonrenewal or revocation.

When the regulations are interpreted in this manner, the traditional administrative hearing and subsequent judicial review are more than adequate to satisfy the postdeprivation demands of due process. This procedure provides the Facility with a full and fair opportunity to vindicate its reputation and establish that the LIS is incorrect and/or that it did not violate the Department's regulations.

In *Department of Public Welfare v. Eisenberg,* 454 A.2d 513 (Pa.1982), the Department suspended a doctor from participating in a welfare program based on allegations that the doctor maintained inadequate documentation and billed for unnecessary medical services. In the notice of suspension, the Department advised the doctor of his right to appeal to the Bureau. This Court held that the Department's procedures violated due process by failing to provide the doctor with a predeprivation hearing. On appeal, our Supreme Court reversed, concluding that due process was satisfied because the Department provided the doctor with a postdeprivation hearing. Significantly, our Supreme Court determined that "no pre-termination hearing is required" and that the doctor's "due process right has been met by a full administrative hearing accorded to [the doctor] before the [Bureau.]" *Id.* at 516 (citations omitted). *See also Cohen v. City of Philadelphia,* 736 F.2d 81, 86 (3d Cir.1984); *accord Bello v. Walker,* 840 F.2d 1124, 1127–28 (3d Cir.1988).

***10** In *Segal v. City of New York,* 459 F.3d 207 (2d Cir.2006), the government employer terminated an employee for inflicting corporal punishment upon a student under her care and supervision. The court concluded that this allegation constituted a stigmatizing statement about the employee, calling into question her good name, reputation, and integrity, and that the employee was entitled to procedural due process. After balancing the employee's reputational interests and the employer's interest in making quick personnel decisions,

the court concluded that a predeprivation hearing was not required and that a postdeprivation hearing was sufficient:

> Although a pre-termination hearing would provide [the employee] with the opportunity to refute any stigmatizing statements prior to her entry into the job market, such a hearing comes at too high a cost to the government. The government's important interests—in both explaining its employment decisions and exercising its right to terminate an at-will employee immediately—would be unduly impaired if we were to require a pre-termination hearing in such circumstances....
>
> [T]he government is simply required to provide [the employee] with an opportunity to salvage her name. In our view, there is no reason to believe that this limited right —a meaningful opportunity to clear one's name—cannot be adequately vindicated at a reasonably prompt, post-termination name-clearing hearing.

Id. at 216–17 (citations omitted).

Finally, in *González–Droz v. González–Colón,* 660 F.3d 1 (1st Cir.2011), the Puerto Rico Board of Medicine determined that a doctor was engaged in the illegal practice of medicine that posed a risk of harm to patients and suspended the doctor's medical license pending a hearing. Having no opportunity to respond to the suspension notice prior to the hearing, the doctor filed a complaint, contending that the lack of a predeprivation hearing violated his due process rights. The United States Court of Appeals for the First Circuit disagreed, reasoning as follows:

> [W]e conclude that a prompt post-deprivation hearing was constitutionally adequate.
>
> In working this calculus, we give great weight to the proposition that when the state reasonably determines that a license-holder poses a risk to patient safety, pre-deprivation process typically is not required. In these circumstances, moreover, the need for a pre-deprivation hearing is further diminished by the state's strong interest in upholding the integrity of a state-licensed profession. The Board's concern that [the doctor] "may harm patients" because he lacks the "training required by the [regulation] to carry out such procedures" provided a sufficient basis for a founded conclusion that no pre-deprivation hearing was constitutionally compelled.
>
> Neither the possible risk of an erroneous deprivation nor the possible benefit of additional safeguards shifts the balance. Especially in cases involving public health and safety and the integrity of professional licensure, the force of these factors is significantly diminished by the ready availability of prompt post-deprivation review.

***11** *Id.* at 14 (citations, brackets, and most quotations omitted).

Eisenberg, Segal and González–Droz collectively establish that when an individual is deprived of a reputational interest, a postdeprivation administrative hearing to refute the allegations typically satisfies the demands of procedural due process.

Here, the Department and the Commonwealth have an overwhelming interest in ensuring that prompt action is taken when an agent observes that a licensed child residential treatment center has violated the Department's regulations. See also Northlake Community Hospital, 654 F.2d at 1242. Through legislative delegation, the Department has determined that any violation of the regulations threatens the safety and health of children. See 55 Pa.Code § 3800.1. Given the circumstances of this case, a predeprivation hearing is not necessary and a postdeprivation hearing fulfills the requirements of due process. *See also* *Lossman v. Pekarske,* 707 F.2d 288, 291 (7th Cir.1983) ("[T]here is no denial of due process in refusing to grant a full adversary hearing before taking away property or liberty, so long as such a hearing is provided later ... and there is justification for the delay. When a child's safety is threatened, that is justification enough for action first and hearing afterward."). Our interpretation of the regulations above mandates that such a procedure be available to the Facility.

* * *

On one hand, the Department and the Commonwealth have a paramount interest, when compared to the Facility's asserted interest, in ensuring the health and safety of dependent and delinquent children who reside in a child residential treatment center. It would be unduly burdensome to compel the Department to conduct an evidentiary hearing for every violation in an LIS before requiring a facility to take remedial action. As noted above, a facility has the right to dispute the violations in the LIS and is free to assert its compliance in its plan of correction. True, in doing so, the Facility

may risk the revocation of its certificate of compliance, but it will nonetheless receive the full panoply of due process protection that goes along with a prompt, administrative evidentiary hearing and subsequent judicial review. In the event the Facility opts instead to submit a suitable plan of correction, and the violations in the LIS are used in the future as a basis for revocation or nonrenewal, the Facility will have same opportunity to challenge the validity of the initial violations. Regardless of any delay or length of time that may pass from when the Facility affirmatively decides to challenge the violations at a revocation or nonrenewal hearing, the fact that there is a comprehensive and adequate procedural mechanism available to it suffices for purposes of due process. *See* *United States v. Eight Thousand Eight Hundred & Fifty Dollars ($8,850) in United States Currency,* 461 U.S. 555, 568–69 (1983); *Midnight Sessions, Ltd. v. City of Philadelphia,* 945 F.2d 667, 682 (3d Cir.1991).

***12** On the other hand, we have assumed that the Facility has a liberty interest in its reputation and that this interest may be impaired if an unfounded LIS is publicized. Given the procedural safeguards detailed above, this interest is adequately protected at all stages of the regulatory process because the Facility will eventually have the opportunity to contest a violation at an administrative hearing and seek judicial review. *See* *Nnebe v. Daus,* 644 F.3d 147, 159 (2d Cir.2011). On this note, the Facility's reliance on *Clayton* and the irrebutable presumption doctrine is misplaced. Any presumption concerning an alleged violation is not conclusive, and, under the regulatory scheme, the Facility has the opportunity to disprove the violation. *See In the Interest of J.B.,* 107 A.3d at 37 (stating that a presumption is not irrebuttable when the party has the opportunity to rebut or contest the validity of the presumption); *Commonwealth v. Aziz,* 724 A.2d 371, 374–75 (Pa.Super.1999) (same). In the meantime, the Facility's ability to respond to and contest the violations in writing is enough to protect its reputational interests from being unnecessarily impaired until adverse action is taken against the certificate of compliance and the Facility challenges the violations at an evidentiary hearing before the ALJ and the Bureau. Therefore, we conclude that the Facility's due process rights have not been violated.

Any argument that the LIS is an appealable adjudication is waived

Before concluding, we note that in its principal brief, the Facility does not argue that it has a statutory right to appeal. Therefore, this argument is waived. *Jimoh v. Unemployment Compensation Board of Review,* 902 A.2d 608, 611 (Pa.Cmwlth.2006). For the first time in its reply brief, the Facility suggests that the LIS constituted an "adjudication" under the Administrative Agency Law, 2 Pa.C.S. §§ 501–508, 701–704. However, "Pennsylvania Rule of Appellate Procedure 2113(a) precludes an appellant from raising a new issue in a reply brief." *Borough of Glendon v. Department of Environmental Resources,* 603 A.2d 226, 258 (Pa.Cmwlth.1992).

In any event, an "adjudication" is defined as: "[A]ny final order, decree, decision, determination or ruling by an agency affecting personal or property rights, privileges, immunities, duties, liabilities or obligations of any or all of the parties to the proceedings in which the adjudication is made." 2 Pa.C.S. § 101. Although the Facility maintains that the letter was a "final decision," our analysis above establishes that subsequent procedural avenues are available to the Facility to contest the violations in the LIS. *See Citizens Coal v. Department of Environmental Protection,* 110 A.3d 1051, 1059 n. 15 (Pa.Cmwlth.2014) (collecting cases and stating that a letter informing a coal company that it must compensate the Commonwealth was not an adjudication where the letter was merely "one step in a continuing multi-step process").

***13** Moreover, in *Sunbeam Coal Corp. v. Department of Environmental Resources,* 304 A.2d 169 (Pa.Cmwlth.1973), an administrative inspector issued a coal company notices of violations following an inspection of the premises. The statutory scheme provided the coal company with thirty days to correct the violations; if the coal company failed to make the corrections, the agency, after a hearing, could suspend its license or issue a cease and desist order until the coal company came into full compliance. In *Sunbeam Coal Corp.,* the coal company attempted to file an immediate appeal upon receiving the notices of violations. However, this Court dismissed the appeal, holding that "[c]learly, ... the notices here were not adjudications[.]" *Id.* at 171. *See also NHS Human Services of PA v. Department of Public Welfare,* 985 A.2d 992, 993–96 (Pa.Cmwlth.2009); *Fiore v. Department of Environmental Resources,* 510 A.2d 880, 881–83 (Pa.Cmwlth.1986).

Because the Facility waived any argument that the LIS is an appealable adjudication, we need not determine whether our holding in *Sunbeam Coal Corp.* is applicable in this case.

Conclusion

After considering the private and governmental interests at stake, as required by *Mathews* and *R.,* we conclude that the predeprivation and postdeprivation procedures explained above comport with the due process clauses of the United States and Pennsylvania Constitutions. We further conclude that the Facility waived any argument that the LIS constitutes an appealable adjudication under the Administrative Agency Law. Accordingly, we affirm the Bureau's February 2, 2015 order.

As a final matter, after considering the application to strike brief filed by the Facility, it is denied.

ORDER

AND NOW, this 7th day of December, 2015, the February 2, 2015 order of the Department of Human Services, Bureau of Hearings and Appeals, is affirmed.

The application to strike brief filed by Summit Academy is denied.

All Citations

Not Reported in A.3d, 2015 WL 8190829

Footnotes

1 The regulation provides:

> **§ 20.81. Decisions that may be appealed.**
> The legal entity has the right to appeal any of the following:
> (1) The denial of a certificate of compliance.
> (2) The nonrenewal of a certificate of compliance.
> (3) The revocation of a certificate of compliance.
> (4) The issuance of a provisional certificate of compliance.
> (5) The length of time for which a provisional certificate of compliance is issued.
> (6) The reduction in the maximum capacity of the facility or agency.
> (7) The denial of an increase in the maximum capacity of the facility or agency.

55 Pa.Code § 20.81.

2 Our scope of review is limited to determining whether constitutional rights were violated, whether the adjudication is in accordance with the law, and whether necessary findings of fact are supported by substantial evidence. *Nancy Hadlock's Family Child Care Home v. Department of Public Welfare,* 103 A.3d 851, 857 n. 12 (Pa.Cmwlth.2014).

3 In *Clayton,* a regulation provided for the revocation of an individual's driving privileges for one year upon the occurrence of an epileptic seizure. Our Supreme Court declared that the regulation was unconstitutional as violating due process. Significantly, the aggrieved individual had no method of rebutting the regulation's presumption that the seizure rendered him unfit to drive.

4 *See* http://services .dpw.state.pa.us/dhs/ViolationReport.aspx? reportid=47204 & fac=THE SUMMIT ACADEMY

5 Pa. Const. art. I, § 1 ("All men are born equally free and independent, and have certain inherent and indefeasible rights, among which are those of enjoying and defending life and liberty, of acquiring, possessing and protecting property and reputation, and of pursuing their own happiness."); Pa. Const. art. I, § 11 ("All courts shall be open; and every man for an injury done him in his lands, goods, person or reputation shall have remedy by due course of law, and right and justice administered without sale, denial or delay. Suits may be brought against the Commonwealth in such manner, in such courts and in such cases as the Legislature may by law direct.").

6 We also assume, without deciding, that the Facility, as a business entity, possesses the right to reputation in the same manner that an individual citizen does.

End of Document

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
Judith D. Cassel I.D. No. 209393
Kevin J. McKeon, I.D. No. 30428
Dennis A. Whitaker, I.D. No. 53975
Micah R. Bucy, I.D. No. 320196
Hawke McKeon & Sniscak, LLP
100 North Tenth Street
Harrisburg, PA 17101
Telephone: 717-236-1300
Facsimile: 717-236-4841
jdcassel@hmslegal.com
kjmckeon@hmslegal.com
dawhitaker@hmslegal.com
mrbucy@hmslegal.com

Counsel for Petitioner

DATED: March 11, 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 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.

VIA PACFILE AND EMAIL

Kevin Hoffman, Esq.
Pennsylvania Dept. of Health
Office of Legal Counsel
Health and Welfare Building
625 Forster Street
Harrisburg, PA 17120
kjmhoffman@pa.gov

Bruce Merenstein, Esq.
John Timmer, Esq.
Schnader Harrison Segal & Lewis LLP
1600 Market Street, Suite 3600
Philadelphia, PA 19103
bmerenstein@schnader.com
jtimmer@schnader.com

Counsel for Respondents

/ s / Micah R. Bucy
Micah R. Bucy

Date: March 11, 2022