IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Medical Marijuana Access & Patient Safety, Inc., Petitioner	:	
v.	:	No. 58 M.D. 2022
Denise A. Johnson, M.D., FACOG, FACHE, Acting Secretary, Pennsylvania Department of Health, John J. Collins, Director of the Pennsylvania Department of Health, Office of Medical Marijuana, and Gregory Elder, Assistant Director and Chief Compliance Officer of the Pennsylvania Department of Health, Office of Medical Marijuana, Respondents	:	Argued: March 8, 2023

BEFORE: HONORABLE RENÉE COHN JUBELIRER, President Judge
HONORABLE ANNE E. COVEY, Judge
HONORABLE MICHAEL H. WOJCIK, Judge
HONORABLE CHRISTINE FIZZANO CANNON, Judge
HONORABLE ELLEN CEISLER, Judge
HONORABLE LORI A. DUMAS, Judge
HONORABLE STACY WALLACE, Judge

OPINION
BY JUDGE CEISLER FILED: May 30, 2024

Before the Court are the cross-applications for summary relief filed by Medical Marijuana Access & Patient Safety, Inc. (Petitioner) and Denise A. Johnson, M.D., FACOG, FACHE, Acting Secretary, Pennsylvania Department of Health (DOH), John J. Collins, Director of DOH's Office of Medical Marijuana (OMM), and Gregory Elder, Assistant Director and Chief Compliance Officer of OMM (collectively, Respondents). Petitioner and Respondents seek counter

declarations as to whether DOH lacks or possesses the statutory authority to adopt the United States Food and Drug Administration's (FDA) "approved for inhalation" standard. After thorough review, we grant in part and deny in part the parties' cross-applications.

I. Background

The Medical Marijuana Act (Act),[1] which took effect on May 17, 2016, establishes a framework for the legalization of medical marijuana in the Commonwealth with regard to certain medical conditions. DOH is the Commonwealth agency responsible for administering and enforcing the Act, including regulating the medical marijuana program in a way that "balances the need of patients to have access to the latest treatments with the need to promote patient safety." Section 102 of the Act, 35 P.S. § 10231.102. The Act also outlines the application process through which medical marijuana grower/processors and dispensaries, also known as medical marijuana organizations (MMOs), can obtain permits from DOH to grow, process, or dispense medical marijuana. *See* Sections 601-616 of the Act, 35 P.S. §§ 10231.601-10231.616.

Section 303(b)(2)(iv) of the Act specifically authorizes the dispensation and patient use of certain forms of medical marijuana, including "a form medically appropriate for administration by vaporization . . . ." 35 P.S. § 10231.303(b)(2)(iv). The cannabis in vaporization products contains substances known as terpenes, which are naturally occurring chemical compounds found in cannabis and other plants that give the plant its flavor, aroma, and color. Petition for Review (PFR), ¶28; Stipulation, 2/25/22, ¶1. MMOs add terpenes extracted from either cannabis itself or other, external sources—such as lemons, hemp, or botanicals—to add flavor to the

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

vapor and to improve the aromatic component of the medicine. PFR, ¶29; Stipulation, ¶2. MMOs have added terpenes to their medical marijuana vaporization products since 2018, when medical marijuana first became legally available in Pennsylvania; DOH has reviewed and approved each such product before it became available for use by our Commonwealth's medical marijuana patients. *Id.*, ¶¶ 27, 30, 38-39.

In 2021, the General Assembly enacted Act 44 of 2021 (Act 44), thereby amending the Act.[2] As a result, Section 702(a)(5) of the Act now provides, in pertinent part:

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

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

35 P.S. § 10231.702(a)(5) (emphasis added). Section 103 of the Act defines "excipients" as "[s]olvents, chemicals or materials reported by a [MMO] and approved by [DOH] for use in the processing of medical marijuana." 35 P.S. § 10231.103. When added to medical marijuana, terpenes qualify as a type of "excipient."

On November 16, 2021, Respondents sent an email to a group of MMOs advising them that DOH was "conducting a review of all vaporized medical marijuana products containing additional ingredients," *i.e.*, excipients, including terpenes, and was requiring every grower/processor to submit for approval each additional ingredient, even if the product was previously approved. PFR, ¶41 and Ex. 2; Stipulation, ¶¶15, 16 and Ex. 3. Then, on December 2, 2021, OMM emailed all patients in the medical marijuana program advising them that DOH had instituted a statewide review of vaporized products containing additional ingredients, including terpenes, for safety. PFR, ¶44 and Ex. 3; Stipulation, ¶19 and Ex. 7. The letter advised: "[Y]ou should be aware that products with added ingredients may not be safe for inhalation and you should make your own decision about whether to use these products." PFR, ¶44 and Ex. 3; Stipulation, ¶17 and Ex. 4. On December 13, 2021, OMM sent another email to MMOs requesting additional information regarding additives, including terpenes. PFR, ¶47 and Ex. 5; Stipulation, ¶18 and Ex. 6.

In response, MMO members submitted approval requests and provided DOH with voluminous submissions, including declarations from medical and scientific professionals affirming there are no known safety concerns associated with the inhalation of fruit or botanically-derived terpenes. PFR, ¶¶43, 49, and Ex. 6. Following review of the submissions, on February 4, 2022, OMM denied the

approval requests, rescinded prior approval of vaporized products containing excipients that had not been approved for inhalation by the FDA, and instituted a recall of those products (Terpene Recall Mandate). PFR, ¶51 and Ex. 7; Stipulation, ¶19 and Ex. 7.

On February 10, 2022, Petitioner[3] initiated this action, on behalf of itself and its members, by filing a nine-count Petition for Review (PFR), seeking declaratory and injunctive relief from DOH's Terpene Recall Mandate. In Count I, Petitioner requests a declaratory judgment for lack of statutory authority. In Count II, Petitioner seeks declaratory relief on the basis that the Terpene Recall Mandate is an unlawful *de facto* regulation. In Count III, Petitioner avers that DOH's regulation set forth in 28 Pa. Code § 1151.42(c) does not grant DOH authority to initiate a mandatory recall because that section applies when grower/processors discover a condition that poses a risk to public health and safety, which did not occur here. In Count IV, Petitioner seeks a declaratory judgment based on vested rights, detrimental reliance, and promissory estoppel. In Count V, Petitioner asserts that the Terpene Recall Mandate violates the Fifth Amendment of the United States Constitution, U.S. CONST. amend. V, and article I, section 10 of the Pennsylvania Constitution, PA. CONST. art. I, § 10, in that it effects an unconstitutional taking of private property without compensation. In Count VI, Petitioner claims that the Terpene Recall Mandate violates the due process rights of Petitioner's members under the Fourteenth Amendment of the U.S. Constitution, U.S. CONST. amend. XIV, and article I, sections 1 and 11 of the Pennsylvania Constitution, PA. CONST. art. I, §§ 1, 11. In Count VII, Petitioner

[3] Petitioner is an association consisting of various stakeholders in the medical marijuana industry, including MMOs and medical marijuana patients. Respondents previously challenged Petitioner's standing, but this Court determined that Petitioner has associational standing to bring this action. *See Med. Marijuana Access & Patient Safety, Inc. v. Klinepeter* (Pa. Cmwlth., No. 58 M.D. 2022, filed June 2, 2022) (Wojcik, J.) (single-judge op.) (*MMAPS I*).

requests a declaratory judgment for damage to reputation under article I, section 11 of the Pennsylvania Constitution, Pa. Const. art. I, § 11. In Counts VIII and IX, Petitioner seeks preliminary and permanent injunctive relief.

Respondents countered by filing an answer and new matter, after which this Court granted a preliminary injunction on June 2, 2022, thereby enjoining Respondents from enforcing the Terpene Recall Mandate until the merits of Petitioner's claims could be fully adjudicated. *See MMAPS I*, slip op. at 25-26.[4]

Thereafter, Respondents and Petitioner filed the cross-applications for summary relief that are now before us. The relevant facts of this case are not in dispute. *See* Stipulation. Respondents' application seeks summary relief in their favor as to Counts I and II; dismissal of Counts III through VII on the basis these counts are moot by operation of this Court's preliminary injunction decision in *MMAPS I*; and dissolution of the preliminary injunction previously granted in this matter. Petitioner's application for partial summary relief seeks summary relief in its favor as to Counts I and II, and a permanent injunction under Count IX.[5]

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[4] Respondents appealed *MMAPS I* to the Supreme Court, which triggered an automatic stay of the preliminary injunction. This Court granted Petitioner's request to vacate the automatic stay, and, after the Supreme Court denied Respondents' application to reinstate the stay, Respondents elected to discontinue their appeal of the preliminary injunction on August 17, 2022.

[5] Pa. R.A.P. 1532(b) provides that "[a]t any time after the filing of a petition for review in an appellate or original jurisdiction matter, the court may on application enter judgment if the right of the applicant thereto is clear."; *see also Summit School, Inc. v. Dep't of Educ.*, 108 A.3d 192, 195 (Pa. Cmwlth. 2015). In deciding a request for summary relief, "this [C]ourt must determine whether it is clear from the undisputed facts that either party has a clear right to the relief requested." *Bell Atl.-Pa., Inc. v. Tpk. Comm'n*, 703 A.2d 589, 590 (Pa. Cmwlth. 1997), *aff'd*, 713 A.2d 96 (Pa. 1998). Determinations as to whether an agency lacks statutory authority or whether an agency's particular statement of policy is an unpromulgated regulation are questions of law. *Markham v. Wolf*, 136 A.3d 134, 138 (Pa. 2016).

II. Discussion

A. De facto Regulation

1. Contentions

We address Count II first, for reasons that will become apparent *infra*. Regarding Count II, Respondents contend that DOH's criteria for approving terpenes added to vaporized medical marijuana products are not an unlawful *de facto* regulation. Respondents further argue that even if Petitioner's argument has any merit, its claim has been mooted by the adoption of a final regulation encompassing the criteria. But even if no such regulation had been adopted, the criteria are simply an interpretative rule regarding patient safety and the approval of medical marijuana products in the Commonwealth. Therefore, summary relief should be granted in Respondents' favor.

Petitioner responds that it is entitled to summary relief as to Count II, because the Terpene Recall Mandate constitutes a *de facto* regulation, and its promulgation outside of the formal rulemaking process renders it void *ab initio*. Consideration of the three binding norm factors makes clear that the Terpene Recall Mandate is an unlawful regulation. First, the language employed in DOH's state-wide communications to all industry stakeholders made it clear that DOH's "approved for inhalation" standard was being implemented with the force of law because it notified stakeholders these products could no longer be produced under the threat of regulatory sanctions resulting from any noncompliance with DOH's newly announced standard. Second, DOH's pronouncement was also quite clear that DOH intended to implement the new standard immediately. DOH immediately put the new standard into effect by denying approvals of these products, revoking all prior approvals, and mandating the recall of all products that did not meet the standard.

Third, the imposition of its new standard stripped DOH of all discretionary powers when approving a terpene by implementing a policy from which no deviation is permitted – the very hallmark of a regulation. Respondents' claim that the Terpene Recall Mandate is merely a policy statement flies in the face of its plain language that established that it was effective immediately and retroactively and that proclaimed a bright-line rule applicable to all products containing botanically-derived terpenes. Contrary to Respondents' mootness argument, Count II is not moot because DOH's final regulations are not yet effective and they do not authorize the "approved for inhalation" standard. *See* Stipulation, ¶13.

2. Analysis

It is well established that, while regulations are subject to the formal rulemaking process, interpretative rules or statements of policy "need not be subject to notice and comment procedures because, presumably, they only provide guidance by which administrative agency personnel carry out their power delegated to them by the General Assembly." *Dep't of Env't Res. v. Rushton Mining Co.*, 591 A.2d 1168, 1171 (Pa. Cmwlth. 1991). "[A]n interpretative rule must genuinely track the meaning of the underlying statute, rather than establish an extrinsic substantive standard." *Borough of Pottstown v. Pa. Mun. Ret. Bd.*, 712 A.2d 741, 743 (Pa. 1998); *accord Eastwood Nursing & Rehab. Ctr. v. Dep't of Pub. Welfare*, 910 A.2d 134, 142 (Pa. Cmwlth. 2006) (holding a statement of policy must track the statute and not expand upon its plain meaning). Moreover, interpretative rules, "which 'do not in themselves establish binding standards of conduct . . . need not be promulgated . . . to the extent they merely construe a statute and do not improperly expand upon its terms.'" *Victory Bank v. Com.*, 219 A.3d 1236, 1243 (Pa. Cmwlth. 2019) (quoting *Borough of Pottstown*, 712 A.2d at 743). Such "'substantive rulemaking is a widely

used administrative practice, and its use should be upheld whenever the statutory delegation can reasonably be construed to authorize it.'" *Eagle Env't II, L.P. v. Dep't of Env't Prot.*, 884 A.2d 867, 877 (Pa. 2005) (quoting *Process Gas Consumers Grp. v. Pa. Pub. Util. Comm'n*, 511 A.2d 1315, 1320 (Pa. 1986)).

On the other hand, a regulation creates a mandatory standard of conduct. *Eastwood*, 910 A.2d at 144. "Where an agency, acting pursuant to delegated legislative authority, seeks to establish a substantive rule creating a controlling standard of conduct," it must comply with proper notice-and-comment procedures. *Borough of Pottstown*, 712 A.2d at 743. "[D]uly authorized and promulgated regulations of an administrative agency have the force of law and are binding on the agency." *State Coll. Manor, Ltd. v. Dep't of Pub. Welfare*, 498 A.2d 996, 998 (Pa. Cmwlth. 1985).

If an interpretative rule or statement of policy "functions as a regulation, then it will be nullified due to the agency's failure to obey the processes applicable to the promulgation of a regulation." *Transp. Servs., Inc. v. Underground Storage Tank Indemnification Bd.*, 67 A.3d 142, 154 (Pa. Cmwlth. 2013) (citing *Rushton Mining Co.*, 591 A.2d at 1171). In assessing whether an agency's pronouncement is a regulation or a statement of policy, we follow the "binding norm test," which provides:

> "Binding norm" means that the agency is bound by the statement until the agency repeals it, and if the statement is binding on the agency, it is a regulation. . . . [I]n determining whether an agency action is a regulation or a statement of policy, one must look to the extent to which the challenged pronouncement leaves the agency free to exercise discretion to follow or not follow the announced policy in an individual case.

Rushton Mining Co., 591 A.2d at 1173.

Here, DOH's February 4, 2022 emails to both medical marijuana grower/processors and patients stated that DOH has determined that certain vaporization products containing terpenes may no longer be produced and are subject to recall because they have not been "approved for inhalation" by the FDA. Stipulation, Exs. 1 and 7. The email to grower/processors rescinded DOH's prior approval of the products and mandated that grower/processors "**MUST follow the mandatory recall procedures outlined in 28 Pa. Code § 1151.42(c)**." Stipulation, Ex. 1 (emphasis in original). Moreover, Respondents do not dispute that failure to follow the Terpene Recall Mandate may result in sanctions, or that the majority of the recalled products were previously approved for production and distribution by DOH. *See* Stipulation, Ex. 1. Upon review, the Terpene Recall Mandate goes beyond a mere statement of policy and instead creates a binding norm. Because Respondents failed to obey the processes applicable to the promulgation of a regulation, Petitioner is entitled to summary relief on Count II.[6]

B. Permanent Injunction

1. Contentions

Petitioner asserts that, having demonstrated a clear right to summary relief, DOH should be permanently enjoined from enforcing the "approved for inhalation" standard. Absent a permanent injunction that enjoins DOH's unlawful standard, Petitioner's members will not be able to produce, sell, or consume these critically important vaporized medicines. Legal damages are not available to Petitioner's members because of sovereign immunity protections and because there is no remedy that can adequately fulfill a patient's inability to access medications that have been recommended by a physician or pharmacist. Accordingly, a permanent injunction is

[6] Contrary to Respondents' mootness argument, the issue is not moot because the proposed regulation has not yet been adopted. *See* Stipulation, ¶13.

required both to avoid an injury that cannot be compensated by legal damages and to prevent a greater injury by prohibiting access to medications.

By contrast, Respondents argue that a permanent injunction is not warranted here, because it is entitled to judgment in its favor regarding Counts I and II, as well as the dismissal of Counts III through VII on the basis of mootness. Respondents do concede, however, that the preliminary injunction previously entered by this Court continues to act as a permanent injunction unless the Supreme Court reverses such a determination.

2. Analysis

"In order to obtain permanent injunctive relief, a party must establish the following elements relative to [its] claims: (1) the right to relief is clear, (2) the injunction is necessary to avoid an injury that cannot be compensated by damages, and (3) . . . greater injury will result if the court does not grant the injunction than if it does." *Mazin v. Bureau of Pro. & Occupational Affs.*, 950 A.2d 382, 389 (Pa. Cmwlth. 2008).

Having entered judgment in favor of Petitioner as to Count II, we conclude that Petitioner is entitled to permanent injunctive relief, but only as to DOH's *current* Terpene Recall Mandate, which, again, we have concluded is unlawful because it is an unpromulgated *de facto* regulation.

III. Conclusion

For these reasons, we grant Petitioner's application for partial summary relief in full regarding Count II of the PFR and in part as to Count IX of the PFR. In addition, we deny Respondents' application for summary relief as to Count II.[7]

/s/ *Ellen Ceisler*
ELLEN CEISLER, Judge

[7] Since Petitioner sought relief via Counts I and III through VII that is identical to the relief we have granted regarding Count II, we need not address the merits of the parties' respective cross-applications for summary relief with regard to those remaining counts (*i.e.*, Counts I, III-VII). As for Count VIII, Petitioner already obtained the relief sought therein, *i.e.*, a preliminary injunction, through *MMAPS I*. That preliminary injunction has now dissolved and has been replaced by the aforementioned permanent injunction. *Den-Tal-Ez, Inc. v. Siemens Cap. Corp.*, 566 A.2d 1214, 1217 n.1 (Pa. Super. 1989) ("[A] preliminary injunction is super[s]eded by a decision on the merits, and terminates upon the issuance of a permanent injunction."); *see Lerch v. Unemployment Comp. Bd. of Rev.*, 180 A.3d 545, 550 (Pa. Cmwlth. 2018) ("In general, Superior Court decisions are not binding on this Court, but they offer persuasive precedent where they address analogous issues.").

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O R D E R

AND NOW, this 30th day of May, 2024, it is HEREBY ORDERED:

1. Petitioner Medical Marijuana Access & Patient Safety, Inc.'s application for partial summary relief is GRANTED IN FULL regarding Count II of the Petition for Review (PFR); and GRANTED IN PART and DENIED IN PART regarding Count IX of the PFR;

2. The Pennsylvania Department of Health is permanently enjoined from enforcing the Terpene Recall Mandate in its **current** form;

3. Respondents Denise A. Johnson, M.D., FACOG, FACHE, Acting Secretary, Pennsylvania Department of Health, John J. Collins, Director of the Pennsylvania Department of Health, Office of Medical Marijuana, and Gregory Elder, Assistant Director and Chief Compliance Officer of the Pennsylvania Department of Health, Office of Medical Marijuana's application for summary relief is DENIED as to Count II;

4. Counts I and III through VII of the PFR are DISMISSED.

/s/ *Ellen Ceisler*
ELLEN CEISLER, Judge

Order Exit
05/30/2024