IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Medical Marijuana Access & Patient Safety, Inc., Plaintiff, 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, Defendants.	:	NO. 58 MD 2022

BRIEF OF AMICUS CURIAE PENNSYLVANIA CANNABIS COALITION

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I. INTRODUCTION

The Pennsylvania Cannabis Coalition ("PCC") submits the following brief in support of Petitioner Medical Marijuana Access & Patient Safety, Inc.'s ("Petitioner") Application for Special Relief in the Nature of a Preliminary Injunction, incident to Petitioner's Petition for Review in the Nature of a Complaint in Equity Seeking Declaratory Relief and Injunctive Relief (the "Application") requesting the Department of Health's ("DOH") recent "Terpene Recall Mandate," as that term is defined in the Application, issued and enforced against medical marijuana growers/processors and dispensaries under the Pennsylvania Medical Marijuana Act, 35 P.S. § 10231.101, *et seq*. (the "Act"), be preliminary enjoined.

As set forth below, the Terpene Recall Mandate is inconsistent with the medical marijuana and adult-use legislation in a number of other states that either explicitly or impliedly permits the inclusion of added ingredients, including botanically sourced terpenes, in medical marijuana and adult-use marijuana products sold in those states. Moreover, prior to issuing the Terpene Recall Mandate, DOH ignored PCC's requests in November 2021 for any information DOH had demonstrating that any of the vapor products or added ingredients now at issue, including botanically sourced terpenes, were posing a public health and safety risk. Were there such a risk, DOH certainly would have provided that information to PCC and the consuming public then, as opposed to waiting three months to implement the Terpene Recall Mandate in February 2022, without providing such information. To this date, DOH has never made such a showing.

As of November 2021, there are approximately 680,000 approved medical marijuana patients and caregivers in Pennsylvania, and approximately 1,700 physicians approved to recommend medical marijuana products to them. Vapor products, like those at issue here, are the second largest category of medical marijuana product sold, comprising approximately 35%-

45% of the medical marijuana products sold by dispensaries to patients and caregivers from January 2020 to November 2021. In addition to severely restricting the sales of grower/processors and dispensaries, the Terpene Recall Mandate, which requires the recall of a large portion of the vapor products on the market, will impede patients' access to the medical treatment they need and prefer.

II. STATEMENT OF INTEREST

PCC is a 501(c)(6) trade organization comprised of Pennsylvania medical marijuana permit holders under the Act, including grower/processors and dispensaries. PCC takes an active role in advocating on behalf of its members and seeks sound application of the Act. Many of PCC's members have been selling medical marijuana products containing added ingredients, including botanically sourced terpenes, that are now subject to the Terpene Recall Mandate despite being previously approved for sale by DOH. The recall of such products subjects these members to irreparable harm. PCC's members, and therefore PCC, have a direct and substantial interest in the outcome of this matter. Continued enforcement of the Terpene Recall Mandate will continue to cause harm to many of these members, notwithstanding their adherence to all pertinent permitting requirements under the Act. Enforcement of the recall will hamper the growth of these members, many of which are small businesses. An injunction, however, will allow these businesses to resume providing the improperly recalled medications to patients so that they may continue unimpeded in their treatment with those medical marijuana products.

III. SUMMARY OF ARGUMENT

Medical marijuana patients in Pennsylvania expect the medical marijuana products they treat with to have certain flavors and scents. Botanically sourced terpenes are chemical compounds derived from cannabis and other plants, such as lemon, lime, and orange, that may be added to medical marijuana products to provide patients with the flavors and scents they expect.

Many states permit botanically sourced terpenes to be added to the medical marijuana and adult-use marijuana products sold in those states. Prior to the Terpene Recall Mandate being issued, in November 2021, PCC requested that DOH provide information demonstrating that the use of added ingredients such as botanically sourced terpenes posed a public health and safety risk. DOH ignored that request and has never provided such information. Were there such an immediate health risk, DOH surely would have informed PCC and the consuming public then, as opposed to instituting the Terpene Recall Mandate without providing such information three months later. To PCC's knowledge there have been no adverse health events specifically attributed to botanically sourced terpenes added to medical marijuana products in Pennsylvania. Accordingly, PCC submits that the Terpene Recall Mandate should be preliminarily enjoined and the status quo of permitting the sale of medical marijuana products containing the added ingredients, including botanically sourced terpenes, at issue should be reinstated.

IV. ARGUMENT

A. The Terpene Recall Mandate is Inconsistent with Regulations in Other States Permitting Their Use in Medical Marijuana and Adult-Use Marijuana Products Sold in Those States.

"Botanically-sourced terpenes" are naturally-occurring aromatic chemical compounds found in a variety of plants, including cannabis grown for use under the Act. As noted in the Application, such terpenes can also be extracted from other natural sources, including lemons, hemp, or botanicals. *See* Application at ¶ 29; *see also* Kluger, Ronald H. and Eastman, Richard H., *Encyclopedia Britannica*, "isoprenoid" (April 11, 2018), *available at* https://www.britannica.com/science/isoprenoid.

As noted in the Application, medical marijuana patients generally expect color, flavor, and odor to be present in the marijuana products they use. *See* Application at ¶ 29. To provide medical marijuana patients with a vapor product that has these distinct sensory characteristics,

grower/processor permittees under the Act, such as PCC's grower/processor members, in formulating their vapor products, add certain botanically sourced terpenes that are intended to provide the vapor product with a signature flavor, scent, and/or color. Inhaled products, including those now at issue under the Terpene Recall Mandate, are the second most popular form of medical marijuana product in Pennsylvania, comprising approximately 35%-45% of the products sold to patients between January 2020 and November 2021. *See* Medical Marijuana Advisory Board Meeting Presentation, November 16, 2021 ("MMAB Presentation"), attached hereto as **Exhibit 1**, at 13.

The Terpene Recall Mandate, which now prohibits the use of botanically sourced terpenes in medical marijuana vapor products in Pennsylvania, is inconsistent with regulations in a number of other states that explicitly or implicitly permit the use of such terpenes in medical marijuana and adult-use marijuana products sold in those states.

In ***New Jersey***, "Cannabis products intended for inhalation and vaporized formulations may include oil, cannabis-derived ingredients including terpenes, *and botanically-derived terpenes.* (1) Except that the total amount of terpenes in a cannabis product intended for inhalation or vaporized formulation may not exceed 10 percent of the product." NJ Admin. Code 17:30-11.6(d)(2) (emphasis added). In ***Maryland***, non-medical marijuana ingredients are permitted with a listing of any cannabinoid and terpene ingredients. Md. Code Regs. 10.62.24.01(B)(11)-(12) (emphasis added). In ***Ohio***, a "Processor may use non-marijuana ingredients in the manufacture of medical marijuana products" provided the ingredients "are nontoxic and safe for human consumption." Ohio Admin Code Rule 3796:3-2-01.

In ***Illinois***, "*botanically-derived terpenes* are permitted in cannabis products, provided "all [non-cannabis] ingredients of the item, including any colors, artificial flavors, and

preservatives, listed in descending order by predominance of weight shown with common or usual names." 410 ILCS 705/55-21(e)(8)(A)(v) (emphasis added). In ***Colorado***, "Other Permitted Ingredients" include "marijuana-derived ingredients *or Botanically Derived Compounds and/or terpenoids*." 1 CCR 212-3:3-335(I) (emphasis added). In ***Washington***, "marijuana processors may incorporate in marijuana vapor products a characterizing flavor if the characterizing flavor is *derived from botanical terpenes naturally occurring in the cannabis plant, regardless of source*, and if the characterizing flavor mimics the terpene profile found in a cannabis plant." Wash. Rev. Code Ann. § 69.50.327 (emphasis added).

That botanically sourced terpenes are permitted to be used in the above states suggests those states have determined that such terpenes do not pose a health and safety risk. PCC urges the Court to consider the legislation in other states permitting the use of botanically sourced terpenes in those states.

B. DOH Ignored PCC's Requests for Information Demonstrating that Ingredients in Vapor Products Being Sold in Pennsylvania Were Presenting a Health and Safety Risk.

As set forth in the Application, prior to the Terpene Recall Mandate, DOH approved vapor products containing botanically sourced terpenes. *See* Application at ¶¶ 27-30. On November 16, 2021, DOH sent Pennsylvania operators an email announcing a "Vapor Product Review" intended to identify the ingredients, including any botanically sourced terpenes, contained in the vapor products DOH had previously approved. *See* Application at Ex. 2. In response to that email and announcement, PCC requested that DOH inform PCC and operators in the state about any health and safety risk being posed by any of the vapor products at issue, and that DOH engage with PCC and operators in the state to address any such public health and safety concerns. DOH ignored those requests.

Specifically, in a letter to John Collins, Director, DOH Office of Medical Marijuana, and Carol Mowery, Counsel for DOH, dated November 19, 2021, just three days after DOH announced its Vapor Product Review, PCC, on behalf of its members, requested a meeting with DOH to determine the basis for the Vapor Product Review; whether any actual health and safety concerns were animating it; and whether DOH would consider working with PCC and its members to address any such concerns. As that letter states, in pertinent part:

> Due to the harm the [Vapor Product Review] could potentially cause to operators, the patients whose health and well-being depends on these products, and the Pennsylvania Medical Marijuana Program as a whole, should the [Vapor Product Review] be enforced as written, PCC, on behalf of its members, requests the Department issue an amendment to the [Vapor Product Review] by close of business on Monday, November 22, 2021, extending by forty-five (45) days the time-period for compliance with the [Vapor Product Review]. PCC further requests that the Department meet with PCC and other program stakeholders regarding the [Vapor Product Review] so that the Department can provide clarification of its authority to take this measure and so the Department can provide written clarification of the terms and appropriate guidance for this measure to operators and patients…
>
> [T]he Department has previously required that permittees resubmit products it has already approved for re-approval, and then denied approval for those products, requiring those permittees to cease and desist the distribution of those products. In the Department's view, those products were not "medically appropriate," a definition that does not appear in the Act or the current temporary regulations. Given the significance of this issue to permittees, PCC believes the Department's meeting with PCC and stakeholders to clarify the Department's implementation of the statutes and regulations pertinent to this issue would be extremely beneficial to the program.
>
> Based on the foregoing, PCC requests the Department recall or amend the [Vapor Product Review], and agree to meet with PCC and stakeholders to work in a transparent and collaborative manner towards resolution, as set forth above.

See November 19, 2021 Letter from S. Goldberg to J. Collins and C. Mowery, attached as **Exhibit 2**, at 1, 3.

DOH did not respond to PCC's letter, nor did DOH return calls from PCC, made on November 18, 23, and 24, 2021, to discuss the Vapor Product Review. Consequently, PCC

wrote to Director Collins and Ms. Mowery to discuss the Vapor Product Review in a letter dated November 24, 2021, wherein PCC again requested that DOH provide any health and safety information supporting the need for the Vapor Product Review, and inviting DOH to meet with and work with Pennsylvania grower/processors and dispensaries to address any health and safety concerns resulting from the vapor products at issue. As that letter states, in part:

> PCC and its members wish to work with the Department to ensure that vaporization products in the Pennsylvania medical marijuana market are safe and effective. To that end, if the Department has identified any such products or their ingredients that has raised a public health concern for the Department warranting immediate action by permittees or the Department, we would have expected the Department to issue a notice to permittees and patients accordingly…
>
> If the Department is aware of a public health concern that warrants the shorter timeframe imposed under the Notice, please let us know what that is so that it can be addressed. Likewise, if the Department believes that PCC and its members can be helpful to the Department in addressing any health concern relating to vaporization products, we would greatly appreciate hearing from the Department. As the Department may recall, during the vaping crisis in 2019, PCC and permittees worked collaboratively with the Department to address those public safety concerns, and the industry remains ready to address any such concerns identified by the Department now.
>
> We truly hope the Department will enlarge the 14-day time period required under the Notice, especially in light of the Thanksgiving holiday, to the forty-five days requested herein and in my earlier letter. Likewise, if there is any public health concern of which we should be aware, we would appreciate being informed of that at once.

See November 24, 2021 Letter from S. Goldberg to J. Collins and C. Mowery, attached as **Exhibit 3**, at 1, 3.

DOH never responded to PCC's letter dated November 24, 2021. In fact, to date, DOH has never published any information reflecting that the added ingredients now at issue, including botanically sourced terpenes, pose a health and safety risk. Nevertheless, without any information demonstrating a specific health and safety concern, which was required of DOH to

issue a recall under the temporary regulations promulgated under the Act, *see* 28 Pa. Code § 1151.42(c), DOH has purported to implement the expansive Terpene Recall Mandate.

As set forth above, as of November 2021, there were approximately 680,000 approved medical marijuana patients and caregivers in Pennsylvania and approximately 1,700 physicians approved to recommend medical marijuana products. *See* MMAB Presentation, at 13. Vapor products, including those at issue under the Terpene Recall Mandate because they contain certain added ingredients, comprised between 35%-45% of the medical marijuana products sold to consumers between January 2020 and November 2021 when DOH announced the Vapor Product Review. *Id.* at 4. Were the vapor products and added ingredients now at issue, including botanically sourced terpenes, truly causing a risk to public health, DOH would have provided such information to PCC and informed the public in November 2021 when DOH commenced the Vapor Product Review instead of waiting three months to implement the Terpene Recall Mandate without providing such information. DOH has never made such a showing.

C. The Terpene Recall Mandate Contravenes the Temporary Regulations.

The Act, as amended through 2021 Act 44, Medical Marijuana Act Omnibus Amendments ("Act 44"), expressly states that terpenes – cannabis derived and otherwise – are permitted in medical marijuana products, including in vaporized formulations, provided they are pharmaceutical grade or otherwise permitted by the DOH. 35 P.S. § 10231.702(a); *see also* Application at ¶ 33. However, in contrast to those states whose regulations provide for the use of added ingredients, including botanically sourced terpenes, as set forth above, DOH has not promulgated regulations pursuant to the Act identifying the added ingredients that would not be permitted for use in medical marijuana products under the Act. Instead, DOH has attempted to regulate the use of added ingredients through the series of email and website postings announcing the Vapor Product Review on November 16, 2021 and the Terpene Recall Mandate

on February 4, 2022, and has done so without demonstrating any public health and safety concern regarding the at-issue products, as it was required to do. *See* 28 Pa. Code § 1151.42(c).

V. CONCLUSION

For the foregoing reasons, PCC respectfully requests Petitioner's request for a preliminary injunction be granted, and for the status quo of permitting "added ingredients," including botanically sourced terpenes, to be included in medical marijuana products under the Act to be reinstated.

Respectfully submitted,

Dated: February 22, 2022

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CERTIFICATE OF COMPLIANCE

It is hereby certified that this brief is in compliance with the word count limitations of Pennsylvania Rule of Appellate Procedure 2135 because this brief does not exceed 7,000 words as calculated by the Word Count feature of Microsoft Word 2010, excluding the materials specified in Pa. R.A.P. 2135(b).

Dated: February 22, 2022

/s/ Seth A. Goldberg
Seth A. Goldberg

CERTIFICATE OF COMPLIANCE

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.

Dated: February 22, 2022

Submitted by: Seth A. Goldberg

Signature: */s/ Seth A. Goldberg*

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