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 Respondents.	:	No. __ MD 2022

ORDER GRANTING
APPLCATION FOR RELIEF
IN THE NATURE OF A PRELIMINARY INJUNCTION

NOW, this ___ day of _____, 2022, Petitioner's application for special relief in the nature of a preliminary injunction is hereby granted.

1. Respondent Keara Klinepeter, Acting Secretary, Pennsylvania Department of Health, Respondent John J. Collins, Director of the Pennsylvania Department of Health, Office of Medical Marijuana ("DOH"), and Respondent Sunny D. Podolak, Assistant Director and Chief Compliance Officer of the

Pennsylvania Department of Health, Office of Medical Marijuana are hereby preliminarily enjoined from enforcing the Terpene Recall Mandate issued on February 4, 2022, pursuant to 28 Pa. Code §1141.45, to medical marijuana grower/processors and dispensaries permitted to operate under the Medical Marijuana Act, 35 P.S. §10231.101, *et seq*., and from making further comments concerning the safety of the medical marijuana vaporization products that are subject to the Terpene Recall Mandate pending the outcome of this litigation or further order of court.

2. Petitioner's members shall be permitted to return the medical marijuana vaporization products that are subject to the Terpene Recall Mandate and previously approved by DOH to the medical marijuana dispensary shelves for sale to certified medical marijuana patients.

3. Petitioner shall post bond in the amount of $100.00

4. Should any Respondent appeal this order, such appeal shall not act as a 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 Petitioner would be entitled to have any Rule 1736(b0 supersedeas vacated.

Under the circumstances of this case, and in the interests of judicial economy, the Court makes that ruling at this time.

BY THE COURT:

_____

J.

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 Respondents.	:	No. __ MD 2022

APPLICATION FOR SPECIAL RELIEF
IN THE NATURE OF A PRELIMINARY INJUNCTION

Petitioner respectfully applies, pursuant to Pa. R.A.P. 1532, for a Preliminary Injunction to prevent enforcement of the Department of Health's Office of Medical Marijuana's (DOH) February 4, 2022, determination "that certain vaporization products containing added ingredients, such as externally sourced flavorings or terpenes," must be recalled and destroyed because they "have not been approved for

inhalation by the United States Food and Drug Administration" (Terpene Recall Mandate).[1] In support, Petitioner states as follows:

INTRODUCTION

1. Petitioner seeks a preliminary injunction to halt ongoing enforcement of DOH's Terpene Recall Mandate pending resolution of Petitioner's contemporaneously filed petition for review, which requests a declaration that the Terpene Recall Mandate is unlawful and a permanent injunction preventing its continued enforcement.

2. "Terpenes" are naturally occurring chemical compounds found in cannabis and other plants that give the plant its flavor, aroma, and color. In addition to the terpenes that naturally occur in cannabis, medical marijuana producers nationwide, including in Pennsylvania, add terpenes extracted from other natural sources (such as lemons, hemp, or botanicals) to add flavor to the vapor and to improve the aromatic component of the medicine. All the recalled products containing terpenes were expressly approved for production and dispensing by DOH at some time between 2018 and 2021.

3. The Terpene Recall Mandate, issued and immediately effective as of February 4, 2022, abruptly orders the recall and destruction of tens of millions of

[1] DOH's Terpene Recall Mandate was issued as an email to Pennsylvania's Medical Marijuana Organizations (MMOs). A copy is attached as **Appendix 1**.

dollars' worth of medical marijuana vaporization products that contain added terpenes, despite DOH's prior approval of the recalled products and their composition, despite patient need for the recalled medical marijuana vaporization products, despite DOH's failure to identify a single adverse event experienced by a Pennsylvania medical marijuana patient that is attributable to the added terpenes in a medical marijuana vaporization product during the three years Petitioner's members have been producing and dispensing such products, and despite DOH's failure to cite any basis in science or medicine for the recall.

4. A preliminary injunction is appropriate where:

> (1) it is needed to prevent irreparable harm that cannot be adequately compensated by damages; (2) greater injury would result from refusing the injunction than from granting it, and, concomitantly, an injunction will not substantially harm other interested parties in the proceedings; (3) the injunction will restore the parties to their status as it existed prior to the alleged wrongful conduct; (4) the party seeking injunctive relief has a clear right to relief and is likely to prevail on the merits; (5) the injunction is reasonably suited to abate the offending activity; and, (6) the injunction will not adversely affect the public interest.

Marcellus Shale Coalition v. Department of Environmental Protection, 185 A. 3d 985, 986 n. 4 (Pa. 2018), *citing SEIU Healthcare Pennsylvania v. Com.*, 104 A.3d 495, 501-02 (Pa. 2014) (reciting multi-factor preliminary injunction standard).

5. Each of these factors is present here; the court should therefore enjoin DOH's Terpene Recall Mandate pending resolution of Petitioner's underlying petition for review.

6. The court should require only a nominal bond to secure the preliminary injunction as no entity will sustain reasonably foreseeable damages because of the issuance of a preliminary injunction.

7. In addition, Petitioner requests that the court specify in its order granting a preliminary injunction that no appeal from the order will act as an automatic supersedeas under Pa. R.A.P. 1736(b).

FACTS

8. Petitioner, a 501(c)(6) non-profit association consisting of a cross-section of medical marijuana industry stakeholders of permitted grower/processors and dispensaries, certified patients that use the medical marijuana vaporization products that are subject to DOH's Terpene Recall Mandate, and terpene suppliers. Petitioner's members account for 75% of the medical marijuana operations in Pennsylvania and produce more than 90% of the vaporization products that are subject to DOH's Terpene Recall Mandate.

9. Respondent Klinepeter is the Acting DOH Secretary, the executive agency that issued the February 4, 2022 Terpene Recall Mandate and that has the

duty and authority to administer and enforce the Medical Marijuana Act, 35 P.S § 10231.702(a)(5) (Act or Medical Marijuana Act), *as amended.*

10. Respondent John J. Collins is the Director of the Pennsylvania Department of Health, Office of Medical Marijuana, the DOH office that is tasked with implementing and enforcing the Act and its regulations on a day-to-day basis. Respondent Collins is the DOH official who instituted the vaporization re-approval process that resulted in the Terpene Recall Mandate.

11. Respondent Sunny D. Podolak is the Assistant Director and Chief Compliance Officer of the Pennsylvania Department of Health, Office of Medical Marijuana, the DOH office that is tasked with implementing and enforcing the Act and its regulations on a day-to-day basis. Respondent Podolak is the DOH employee who sent the emails initiating the vaporization re-approval process and imposing the Terpene Recall Mandate.

12. Petitioner's grower/processor and dispensary members produce and sell medical marijuana vaporization products, a form of administering medical marijuana requiring inhalation that is expressly authorized by the Act, 35 P.S. §10231.303(b)(2)(iv), and which now represents 35% of medical marijuana usage among Pennsylvania patients.

13. Petitioner's grower/processor and dispensary members' vaporization products that are the subject of the Terpenes Recall Mandate, like all cannabis,

contain naturally occurring terpenes, but also contain terpenes extracted from other natural sources (such as lemons or botanicals) to add flavor to the vapor and to improve the aromatic component of the medicine, which the grower/processors add during the production of the products to supplement the loss of terpenes through the extraction and refinement processes; at varying times beginning in 2018, DOH expressly approved for production and sale in Pennsylvania each of the vaporization products it has now ordered to be recalled. *See*, Declaration of Dr. Shawna Vreeke attached hereto as **Appendix 2**.

14. Without citing any scientific or medical evidence in support of its decision, without citing a single complaint about a vaporization product containing added terpenes, without notice or an opportunity to be heard about what is in essence a *de facto* rulemaking in the absence of a demonstrated health or safety risk, and without citing a single adverse event experienced by a Pennsylvania medical marijuana patient attributable to the added terpenes in a medical marijuana vaporization product, DOH on February 4, 2022 abruptly issued the Terpenes Recall Mandate to Petitioner's grower/processor and dispensary members, advised medical marijuana patients of the recall, and posted a list on DOH's website of all products subject to the Terpene Recall Mandate and the grower/processors that produce those products.

15. Pursuant to the Terpene Recall Mandate dispensaries are shipping the medical marijuana vaporization products containing the added terpenes back to the grower/processors who produced them where they are currently in quarantine.

16. DOH stated its reasoning for the Terpene Recall Mandate as "certain vaporization products containing added ingredients, such as externally sourced flavorings or terpenes, have not been approved for inhalation by the United States Food and Drug Administration," and relied on the 2021 amendment to Section 702)(a)(5) of the Act for support.

17. However, Section 702)(a)(5) of the Act, 35 P.S. § 10231.702(a)(5) provides only that such added terpenes need to be pharmaceutical grade, or otherwise approved by the Department, expressly limiting the Department's discretion to whether such added terpenes are permitted by the FDA "for use in food," are "Generally Recognized as Safe (GRAS) under Federal guidelines," or "constitutes a known hazard such as diacetyl… and pentanedione"; nothing in the 2021 amendments or otherwise in the Act permits DOH to withhold or revoke approval of a product based on whether terpenes are considered "safe for inhalation" by the FDA.

18. On information and belief, all added terpenes used by Petitioner's grower/processor members are pharmaceutical grade and FDA-approved for use in food or are GRAS.

19. That the legislature did not authorize DOH to utilize the FDA's approval of terpenes as "safe for inhalation" as a consideration in approving (or, as in this case, revoking the long-standing DOH approval of) a medical marijuana product for production and dispensing is not surprising:

A. The FDA does not develop or test products; rather, the FDA reviews results of testing done by manufacturers who wish to obtain FDA approval for their products;

B. Terpenes extracted from cannabis and other plants are predominantly or exclusively used as additives to marijuana vaporization products that are inhaled by the user;

C. As marijuana is illegal under federal law, producers of terpenes used in marijuana vaporization products that are inhaled do not seek FDA approval or submit test results to the FDA;

D. The FDA has not reviewed terpenes used in medical marijuana products made for inhalation and therefore does not list any of these on its website;

E. Medical marijuana, itself, is not listed on the FDA website as "safe for inhalation."

20. The Terpene Recall Mandate that recalls over 670 individual product types ("Terpene Infused Vaporization Products") represents 30% of the total

available medical marijuana products at a cost of more than $ 17,000,000 to Petitioner's grower/processor and dispensary members.

21. Because many of the products subject to the Terpene Recall Mandate were already approved by the DOH months or even years ago, in addition to the specific lost-product costs, the Petitioner's members will suffer more than $9,000,000 in costs associated with the development, creation, marketing, and distribution of these products including but not limited to the equipment, supplies, and labor necessary to create these products.

22. In addition to the economic loss from the Terpene Recall Mandate, Petitioner's grower/processor members are suffering damage to their reputations caused by the emails DOH sent to patients that imply without evidence that Petitioner's members are producing and dispensing unsafe products, and by including Petitioner's members on a list posted on DOH's website that identifies them as producers of products that must be recalled.

23. The Terpene Recall Mandate will deprive approximately 150,000 Pennsylvania medical marijuana patients of their preferred products each month.

PETITIONER'S CLEAR RIGHT TO RELIEF

24. Petitioner and its members have a clear right to relief. DOHs' Terpene Recall Mandate is unlawful for multiple reasons.

25. First, it exceeds and is inconsistent with DOH's statutory authority. The Medical Marijuana Act as amended in June 2021 does not authorize DOH to base approval or disapproval of the addition of an excipient such as a terpene based on whether the FDA has approved or disapproved it "for inhalation." Rather, it expressly addresses the issue of excipients, permits a grower/processor to add an excipient to a medical marijuana product if it is pharmaceutical grade, and provides DOH limited discretion to disapprove a proposed added substance *which is not pharmaceutical grade* if the FDA has not approved it "for use in food or is Generally Recognized as Safe (GRAS) under Federal guidelines" or otherwise constitutes a "known hazard." 35 P.S. § 10231.702(a)(5). All added terpenes used by Petitioner's grower/processor members *are* pharmaceutical grade or otherwise FDA-approved for use in food or GRAS. Because the Medical Marijuana Act expressly addresses the use of excipients and authorizes DOH to non-approve a medical marijuana product if it contains an excipient not approved by the FDA for use in food, but is silent on the issue of FDA approval of an excipient for inhalation, DOH's Terpene Recall Mandate based on the absence of FDA approval for inhalation exceeds DOH's authority under the Medical Marijuana Act, and is in fact contrary to the Medical Marijuana Act.

26. Second, the Terpene Recall Mandate is an unlawful *de facto* regulation that is therefore void and of no effect. The Terpene Recall Mandate announces for

the first time an immediately effective industry-wide rule that purports to have the force and effect of law: that if a terpene is not approved by the FDA for inhalation, it may not be used in a vaporized medical marijuana product. The Terpene Recall Mandate is a binding norm; even assuming the requisite statutory authority that DOH lacks, it may only be imposed through a properly promulgated regulation: "[i]f an interpretative rule or statement of policy functions as a regulation, then it will be nullified due to the agency's failure to obey the processes applicable to the promulgation of a regulation." *Department of Environmental Resources v. Rushton Mining Company*, 139 Pa.Cmwlth. 648, 591 A.2d 1168, 1171 (1991).

27. Third, the Terpene Recall Mandate improperly invokes an existing DOH regulation, 28 Pa. Code § 1151.42(c), as the procedural basis for implementing the recall. The cited regulation applies only where a grower/processor "discovers that a condition relating to … medical marijuana products …processed at its facility poses a risk to public health and safety." Petitioner's grower/processor members have made no such "discovery." Petitioner's members that are grower/processors and dispensers most certainly do not believe that the vaporized products that are subject to the Terpene Recall Mandate pose "a risk to public health and safety" and they have not so discovered. Nor does the regulation confer on DOH the authority to initiate a recall, but even if it did, even DOH has stopped well short of stating that the recalled products pose a "risk to public health and safety." Accordingly, 28 Pa.

Code § 1151.42(c) does not provide the requisite regulatory authority for DOH to initiate the Terpene Recall Mandate, and no other DOH regulation confers that authority on DOH.

28. Fourth, the Terpene Recall Mandate violates Petitioner's members' vested rights: each of Petitioner's members adversely affected by the recall secured prior approval to produce and sell the now-recalled products; complied with DOH's regulations in good faith; expended very substantial sums in reliance; had no reason to believe DOH would revoke its approval; and there is no basis to conclude that public health, safety or welfare would be adversely affected by continued production and dispensing of the vaporized medical marijuana products that are the subject of the Terpene Recall Mandate. Thus, under Pennsylvania's doctrine of vested rights based on detrimental reliance and promissory estoppel, Petitioner's grower/processor and dispensary members are entitled to retain the approvals DOH previously gave. *Dept. of Environmental Resources v. Flynn,* 344 A.2d 720 (Pa. Cmwlth. 1975).

29. Fifth, the Terpene Recall Mandate violates the Fifth Amendment of the United States Constitution and Article I, Section 10 of the Pennsylvania Constitution, in that it effects an unconstitutional taking of private property without compensation. DOH's Terpene Recall Mandate requiring the recall and destruction of products previously approved for sale, absent an adverse event and without a

credible public health or safety concern, resulting in the total loss of the value of the products and forfeiture of funds expended to develop, market, create, and distribute these products, plainly interferes with "distinct investment-backed expectations" of Petitioner's members. *Smith v. Cortes*, 879 A.2d 382, 386 n. 3 (Pa. Cmwlth. 2005).

30. Sixth, the Terpene Recall Mandate violates Petitioner's members' constitutionally protected right to due process. "When an individual is deprived of property by governmental action, he must be afforded at some point in the proceeding an opportunity to be heard." *Cedarbrook Realty, Inc. v. Nahill,* 399 A.2d 374, 377 (Pa. 1979). Further, "[i]f the right to notice and a hearing is to serve its full purpose, then, it is clear that it must be granted at a time when the deprivation can still be prevented." *Fuentes v. Shevin*, 407 U.S. 67, 81-82 (1972). Because the Terpene Recall Mandate is effective immediately and prior to Petitioner's grower/processor and dispensary members having had an opportunity to be heard and defend against the imposition of the mandate, Petitioner's member's due process rights have been violated.

31. Seventh, the Terpene Recall Mandate impugns Petitioner's members' constitutionally protected right to reputation. Article I, Section 1 of the Pennsylvania Constitution designates the right to reputation as an inherent and indefeasible right, and Article I, Section 11 provides for a remedy through the courts for injury to reputation. Despite a lack of evidence and DOH's own prior approval of the products

subject to recall, DOH has issued the Terpene Recall Mandate, which impugns Petitioner's members' well-deserved and valuable reputation for producing and dispensing high quality medical marijuana products that are safe for use by medical marijuana patients.

PETITIONER'S IRREPARABLE HARM

32. Petitioner and its grower/processor and dispensary members will be irreparably harmed if the Terpene Recall Mandate remains in effect pending resolution of the underlying petition for review, because the Terpene Recall Mandate requires the immediate recall and destruction of more than 670 individual medical marijuana vaporization products resulting in a collective economic loss of more than $17,000,000; in addition, Petitioner's members, in reliance on previous DOH approvals of the recalled products, have invested more than $9,000,000 in development, creation, marketing, and future distribution of these products including but not limited to the equipment, supplies, and labor necessary to create the products, all of which will be stranded; further, Petitioner's grower/processor members will continue to suffer damage to their reputations caused by the emails DOH sent to patients that imply without evidence that Petitioner's members are producing and dispensing unsafe products, and by the inclusion of Petitioner's members on a list posted on DOH's website that identifies them as producers of products that must be recalled.

THE BALANCE OF HARMS

33. The balancing of the significant immediate and irreparable economic and reputational harms to Petitioner's members if a preliminary injunction is not granted, against DOH's apparent unsupported speculation that patients could possibly be harmed by continued use of vaporization products if a preliminary injunction pausing the recall is granted, weighs heavily in favor of granting the preliminary injunction. There is no evidence that the recalled products could harm patients. DOH has cited no evidence that the recalled products containing added terpenes have any adverse effect on patients, has failed to identify a single adverse event experienced by a Pennsylvania medical marijuana patient that is attributable to a medical marijuana vaporization product containing added terpenes during the three years Petitioner's members have been producing and dispensing such products, has failed to point to any basis in science or medicine for the recall, and without notice or an opportunity to be heard about what is in essence a *de facto* rulemaking in the absence of a demonstrated health or safety risk. Patients will actually be harmed by the recall, in that 35% of the medical marijuana presently administered in Pennsylvania is delivered through the vaporization products subject to recall; at a minimum, patients will be significantly inconvenienced by the recall, and some may resort to the black market to acquire vaporization products that are neither legal nor produced under the safety standards employed by Petitioner's members.

RESTORATION OF STATUS QUO

34. A preliminary injunction is suitable relief that will restore the status quo. For three years, Petitioner's members have been producing and dispensing medical marijuana vaporization products that contain added terpenes, and Pennsylvania patients have been using the products, with DOH's approval, and without a single patient or physician complaint or a single adverse event. DOH's sudden about-face on its prior approval of the products is unexplained, unsupported, and without legal basis. Restoring the parties to the status quo as it existed before the Terpene Recall Mandate will best serve the interests of Petitioner's grower/processor and dispensary members, medical marijuana patients, and the Pennsylvania medical marijuana program.

SUITABILITY OF INJUNCTIVE RELIEF

35. A preliminary injunction will abate the harm caused by the Terpene Recall Mandate.

THE PUBLIC INTEREST

36. A preliminary injunction enjoining the Terpene Recall Mandate is in the public interest. The public interest is advanced by adherence to the General Assembly's statutory guidelines and by transparent agency decision making; DOH has failed on both counts. Worse, it has done so without providing any basis in science or medicine to reverse its longstanding decisions to approve for production

and dispensing more than 670 medical marijuana vaporization products on which a sizable segment of Pennsylvania patients now rely.

NOMINAL BOND REQUESTED

37. Petitioner requests that the bond required by Pa. R.C.P. 1531(b) be set at the nominal level of $100. No entity will sustain reasonably foreseeable damages in the event it is later determined that the requested preliminary injunction was wrongfully issued.

RELIEF FROM AUTOMATIC SUPERSEDEAS

38. Petitioner requests that the court specify in its order granting a preliminary injunction that that no appeal from the order 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 Petitioner would be entitled to have any Rule 1736(b) supersedeas vacated. Under the circumstances of this case and in the interests of judicial economy Petitioner respectfully requests that the Court make that ruling coincident with its order granting preliminary injunctive relief.

WHEREFORE, Petitioner and its members respectfully request that the Court preliminarily enjoin enforcement of the Department of Health's Office of Medical Marijuana's February 4, 2022 Terpene Recall Mandate.

Respectfully submitted,

/ s / Kevin J. McKeon
Kevin J. McKeon, I.D. No. 30428
Judith D. Cassel I.D. No. 209393
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
kjmckeon@hmslegal.com
jdcassel@hmslegal.com
dawhitaker@hmslegal.com
mrbucy@hmslegal.com

Counsel for Petitioners

DATED: February 10, 2022

APPENDIX 1

From:	Podolak, Sunny
To:	Podolak, Sunny
Cc:	Bosack, Tabbitha; Azar, Michael; Dougherty, Danielle; Elliott, Jaime
Subject:	Important information regarding statewide review of all vaporization products containing added ingredients
Date:	Friday, February 4, 2022 11:14:37 AM

Hello,

The Department conducted a statewide review of all vaporization products containing added ingredients and has determined that certain vaporization products containing added ingredients, such as externally sourced flavorings or terpenes, have not been approved for inhalation by the United States Food and Drug Administration. 35 P.S. § 10231.702(a)(5), 28 Pa. Code § 1151.27(f).

The affected grower/processors have just been notified that these products meet the conditions for recall under 28 Pa. Code § 1151.42(c)(1); accordingly, mandatory recall procedures must be implemented. 28 Pa. Code § 1151.42(c). Certain vaporization products will no longer be available for dispensing to patients or caregivers. The list of affected products is posted on our website at www.medicalmarijuana.pa.gov.
You must return all recalled products to the grower/processor for proper disposal of these products in accordance with 28 Pa. Code § 1161.38(c). **You must provide proof of the return of all recalled products.** A manifest is acceptable as proof of return and should be emailed to RA-DHMMRCompliance@pa.gov. Failure to comply will result in the Department acting to impose sanctions against you under 28 Pa. Code § 1141.47.
You may appeal this action to the Secretary of Health in writing **within 30 days of the date of emailing** in accordance with 28 Pa. Code Chapter 1230 (relating to practice and procedure – temporary regulations).

If you have questions about specific products, please contact the grower/processor.

Thank you for your commitment to keeping patients safe.

Sunny

Sunny D Podolak, MS
Assistant Director and Chief Compliance Officer
PA Department of Health | Office of Medical Marijuana
Room 628, Health and Welfare Building
625 Forster Street | Harrisburg, PA 17120 - 0701
Phone: 717.547.3047 | Fax: 717.265.8280
www.medicalmarijuana.pa.gov

APPENDIX 2

IN THE COMMONWEALTH COURT OF PENNSYLVANNIA

Medical Marijuana Access & Patient Safety, Inc.,	:	
Petitioner,	:	
v.	:	No. __ MD 2022
Keara Klinepeter, Acting Secretary, Pennsylvania Department of Health, John Collins Director of the Office of Medical Marijuana, Sunny Podolak, Assistant Director and Chief Compliance Officer of Office of Medical Marijuana	:	
Respondent.		

DECLARATION OF DR. VREEKE

I, Dr. Shawna Vreeke, declare and state as follows:

1. My name is Dr. Shawna Vreeke. I am over 18 years of age, am of sound mind, and am fully competent to give this Declaration. The facts stated within this Declaration are within my personal knowledge and are true and correct. I make this Declaration based on my education, training, experience, and my analysis of documents and information in this matter.

2. My CV is attached to this affidavit, but in summary, I am the Head of Research and lead Safety Chemist at True Terpenes. I study the toxicology of all materials used in our products and define guideline use levels to inform our formulations based on scientific research. I also collaborate with other toxicologists and scientists in the cannabis and consumer products

fields. Previous to my employment at True Terpenes, I received my doctorate degree in chemistry under Professor Robert Strongin for the investigation of toxin formation in electronic cigarettes. I have investigated characteristics of vaping for potential health hazards to the user; such as flavor additives, thermal degradation, user topography, and device design. I have performed toxicological risk assessments on over 150 substances used in True Terpenes products to provide guidance on ingredient safety. Previous to my employment at True Terpenes, I received my doctorate degree in chemistry under Professor Robert Strongin for the investigation of toxin formation in electronic cigarettes. I have investigated characteristics of vaping for potential health hazards to the user, such as flavor additives, thermal degradation, user topography, and device design. I have performed toxicological risk assessments on over 150 substances used in True Terpenes products to provide guidance on ingredient safety.

How Terpene Additive Levels are Determined to Be Safe

3. Toxicological risk is a function of the inherent toxicity of a substance and the amount someone consumes. If exposure is below this scientifically derived safety limit, the risk to the vast majority of consumers will be minimal; especially when compared to combustion (i.e., smoking a joint / flower). In cases where insufficient inhalation toxicity data is available, natural concentrations in the cannabis plant, route to route extrapolation, structure-activity relationships, safety factors, and other state-of-the-art toxicological methods were used to derive a conservative safety limit. Toxicological risk is a function of the inherent toxicity of a substance and the amount someone consumes. If exposure is below this scientifically derived safety limit, the risk to the vast majority of consumers will be minimal; especially when compared to combustion (i.e., smoking a joint / flower). In cases where insufficient inhalation toxicity data is available, natural concentrations in the cannabis plant, route to route extrapolation, structure-

activity relationships, safety factors, and other state-of-the-art toxicological methods were used to derive a conservative safety limit.

Testing and Research Conducted on Medical Marijuana Inhalation Products for Safety and Efficacy

4. During the process of deriving the safety limits of our products, I have collected and reviewed over 1,000 scientific literature papers and toxicological databases thus far. Attached hereto as Exhibit A, is a small list of references. This list is not exhaustive of all materials that have been reviewed. The references are only provided as an example of the work which has been undertaken to minimize the risk to cannabis consumers.

States that have Approved Natural Terpene Additives

5. In addition to Pennsylvania, True Terpenes provides its naturally sourced terpenes and blends in all 50 states. The requirements for oversight vary for each regulated market, but our current packet of compliance materials have been satisfactory for even the most advanced regulatory review.

I declare under penalty of 18 Pa. C.S. 4904 relating to unsworn falsification to authorities.

that the foregoing is true and correct

Executed this 09 day of February, 2022, at 5:16 pm

Shawna Vreeke, PhD

Exhibit A

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Sowndhararajan, K., et al.. Effect of olfactory stimulation of isomeric aroma compounds, (+)-limonene and terpinolene on human electroencephalographic activity. European Journal of Integrative Medicine 7, 561-566, doi:https://doi.org/10.1016/j.eujim.2015.08.006 (2015).

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VERIFICATION

I, Darin Chapman, certify that I am a member of Medical Marijuana Access & Patient Safety, Inc., and that in this capacity I am authorized to, and do make this Verification on its behalf, that the facts set forth in the foregoing Application for Special Relief in the Nature of a Preliminary Injunction and its attachments are true and correct to the best of my knowledge, information and belief. I understand that false statements made therein are made subject to the penalties of 18 Pa. C.S. §4904, relating to unsworn falsifications to authorities.

Darin Chapman 2/10/2022

Darin Chapman

Dated: February 10, 2022

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 / Kevin J. McKeon
Kevin J. McKeon, I.D. No. 30428
Judith D. Cassel I.D. No. 209393
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
kjmckeon@hmslegal.com
jdcassel@hmslegal.com
dawhitaker@hmslegal.com
mrbucy@hmslegal.com

Counsel for Petitioner

DATED: February 10, 2022