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Independent Regulatory Review Commission

Comments on the Department of Health's Final Rulemaking, Medical Marijuana Regulations;
IRRC #3290/"Regulation #10—219: Medical Marijuana"
September 29, 2022

## Introduction

Cannabis Law PA (CLP) represents grower/processors, dispensaries, physician groups, and laboratories approved to grow, process, sell, and test medical marijuana in Pennsylvania. CLP submits these comments to the Department of Health (DOH) and the Independent Regulatory Review Commission (IRRC) to request that certain regulations proposed by DOH not be included in the final approved medical marijuana regulations currently being considered by IRRC under the Pennsylvania Medical Marijuana Act (the Act).

Specifically, the proposed permanent regulation at §1151a.27(f)(iii) that requires an added substance be permitted by the U.S. Food and Drug Administration (FDA) for the applicable route of administration and dosage is a non-sensical requirement that effectively violates a court order and exceeds the authority granted under the enabling statute.

## Promulgation of § 1151a.27(f) Effectively Violates A Court Order

DOH's promulgation of §1151a.27(f)(iii) is nothing more than an attempt to circumnavigate a court order that preliminarily enjoins DOH from enforcing the standard embodied in its proposed regulation. Pursuant to the Act, Section 702(a)(5) permits grower/processors to add excipients or "added substances" so long as they are pharmaceutical grade *or* if DOH has otherwise approved their use.[1] The Act provides that the standard that DOH "shall consider" when "determining whether to approve an added substance" is: (i) whether it has been approved by the FDA for use in food or is generally recognized as safe (GRAS) and (ii) whether the proposed added substance constitutes a known hazard. These are the only two standards DOH is authorized to use under Section 702(a)(5) when evaluating whether to approve an added substance.

On February 4, 2022, the DOH initiated a mandatory recall of 330,000 vaporized medical marijuana products because the FDA had not approved the non-cannabis derived terpenes in these products as being "safe for inhalation". On February 10, 2022, a lawsuit was filed in the Commonwealth Court seeking to preliminarily and permanently enjoin DOH from enforcing its newly created "safe for inhalation" standard and DOH's accompanying product recall based on that standard.[2] On June 2, 2022, after two scheduled hearing dates at which DOH provided zero evidence to support its authority or reasoning to adopt this new "safe for inhalation" standard, the

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1 35 P.S. §10231.702(a)(5).

2 *Medical Marijuana Access & Patient Safety, Inc. v. Denise A. Johnson, M.D., FACOG, FACHE, Acting Secretary, Pennsylvania Department of Health, et al.*, Commonwealth Court Docket No. 58 MD 2022 ("MMAPS Litigation").

Commonwealth Court granted the petitioners a preliminary injunction and prevented DOH from implementing and enforcing its newly created "safe for inhalation" standard.[3]

One of the primary arguments being litigated in this pending litigation is whether DOH's "safe for inhalation" standard violates Section 702(a)(5) of the Act. In fact, in its post-hearing brief, DOH characterizes the claims in the lawsuit as follows: "[t]he heart of petitioner's argument is that the Medical Marijuana Act does not permit the Department to use the criteria it has relied on to determine that the vaporized medical marijuana products at issue here should not be approved for sale to patients."[4] In this sentence DOH concedes the primary legal question is whether the Act authorizes DOH to implement the "safe for inhalation" standard to vaporized products, the precise standard DOH seeks to reimpose with §1151a.27(f)(iii). The court specifically found that petitioners met the preliminary injunction standard of establishing a clear right to relief and a likelihood of success on the merits on this claim.[5] But with DOH's proposed §1151a.27(f)(iii) regulation, DOH is attempting to do what it previously attempted to do with its February 4th recall: impose the "safe for inhalation" standard, which was subsequently enjoined pending the outcome of the lawsuit. DOH's proposed regulation is a transparent attempt to ignore the court's order and re-impose a standard that the court has specifically denied. In reaching its conclusion to grant a preliminary injunction of DOH's newly established standard, the court stated:

> ... Act 44 recently amended Section 702(a)(5) of the Act to expressly permit grower/processors to add excipients to their medical marijuana products. This section now provides that in determining whether to approve an added substance, such as terpenes, DOH shall consider "[w]hether the added substance is permitted by the [FDA] for use in food or is [GRAS] under Federal guidelines." Section 702(a)(5)(i) of the Act, 35 P.S. § 10231.702(a)(5)(i). Notably absent from this newly amended statutory provision is whether the added substance is approved as safe for inhalation by the FDA, the standard DOH used in issuing the Terpene Recall Mandate here. Petitioner observes that in "[a]pplying the rules of statutory construction, the inclusion of a specific matter in a statute implies the exclusion of other matters." *Independent Oil and Gas Association of Pennsylvania v. Board of Assessment Appeals of Fayette County*, 814 A.2d 180, 184 (Pa. 2002). Petitioner has raised a substantial argument that, given the express language of the Act and the specificity of the criteria the General Assembly stated could be considered, DOH may have exceeded its statutory authority by issuing the Recall.[6]

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3 *Id.*, Opinion Granting Preliminary Injunction (Jun. 16, 2022) (not reported).

4 *Id.*, DOH Post-Hearing Brief, at p. 28 (Mar. 11, 2022).

5 *Id.*, Opinion Granting Preliminary Injunction, at 19 (Jun. 16, 2022) (not reported)

6 *Id.*

By attempting to reinstate this standard, DOH either fundamentally misunderstands or intentionally disregards the court's decision: if the court ultimately adjudicates that Section 702(a)(5) does not confer upon DOH the authority to implement its "safe for inhalation" standard, then DOH is without any power to promulgate a regulation, like §1151a.27(f)(iii), that seeks to do just that.

The promulgation of §1151a.27(f)(iii) effectively violates the Commonwealth Court's preliminary injunction order and is premature given that the very statutory authority from which DOH seeks to issue §1151a.27(f)(iii) is in doubt.

**Section 1151a.27(f)(iii) Violates the Act**

As discussed above by the Commonwealth Court, DOH's proposed regulation at §1151a.27(f)(iii) mirrors it's February 4th attempt to enforce a new standard for added substances into vaporized marijuana medicines, except that §1151.27(f)(iii) proposes to create new standards for each different medical marijuana route of administration. Accordingly, the claim that DOH lacked the authority under the Act to implement its "safe for inhalation" standard applies equally to §1151a.27(f)(iii)'s proposal to add separate and new standards for pills, oils, creams or ointments, inhalation products, tinctures, or liquids.

The standard DOH is seeking to implement is not the standard prescribed by the Act; accordingly, the standard DOH has used in its Terpene Recall Mandate exceeds the statutory authority conferred on DOH by the General Assembly.[7] The counter-argument to this point: that Section 702(a)(5) generally permits DOH to consider whether added substances are approved by the FDA for the specific route of administration into which they will be introduced and the 2021 amendments to Section 702 of the Act do not expressly exclude that authority, runs headlong into the doctrine of *exclusio unius est exclusio alterius*: "[a]pplying the rules of statutory construction, the inclusion of a specific matter in a statute implies the exclusion of other matters."[8] In Section 702(a)(5), the General Assembly was specific and precise in enumerating the factors DOH is entitled to consider when approving an "added substance" and such entitlement is only given to DOH when a product fails to meet the initial standard of "pharmaceutical grade". While DOH may consider FDA findings if an ingredient is not of pharmaceutical grade, those FDA findings are expressly limited to whether the substance is permitted "for use in food or is [GRAS]" or whether it is a known hazard. Section 702(a)(5) is silent on the issue of DOH considering whether the proposed added substance has been approved by the FDA for specific routes of administration.

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7 *Aetna Cas. And Sur. Co. v. Com., Ins. Dep't.*, 628 A.2d 194 (Pa. 1994) ("An administrative agency can only exercise those powers which have been conferred upon it by the Legislature in clear and unmistakable language.") (internal citation omitted); *see also*, *Hanaway v. Parkesburg Group, LP*, 168 A.3d 146, 154 (Pa. 2017) ("when interpreting a statute we must listen attentively to what the statute says, but also to what it does not say.") (internal citation omitted).

8 *Independent Oil and Gas Ass'n of PA v. Board of Assessment Appeals*, 814 A. 2d 180, 184 (Pa. 2002), quoting *Ken R. on behalf of C.R. v. Arthur Z.*, 682 A.2d 1267, 1270 (Pa. 1996).

This silence does not confer tacit approval, but rather the opposite because "the 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."[9]

The Commonwealth Court found that petitioners' lawsuit on this claim was likely to succeed on the merits of this argument. If the lawsuit does succeed with respect to DOH's attempt to impose additional criteria on vaporization products (i.e. the "safe for inhalation" standard), then the same statutory construction argument and logic would apply to any attempt by DOH to impose additional criteria on products in the form of pills, oils, creams or ointments, tinctures, or liquids. Accordingly, §1151a.27(f)(iii) is violation of the Act. The legislature has provided DOH with specific standards on which to approve medical marijuana, the DOH may not invent new standards beyond those specifically provided.

**Section 1151a.27(f)(iii) is a Non-Sensical Standard**

The General Assembly had good reason not to include the "safe for inhalation" standard, the DOH now seeks to infer from the Act. The legislature likely knew that such a standard would be inconsistent with the FDA's limits of review and approval of ingredients. DOH's decision to promulgate § 1151a.27(f)(iii) represents a fundamental misunderstanding of the FDA's role in approving ingredients that are contained in pharmaceutical drugs; many of the substances that get added to medical marijuana product have not and cannot be evaluated by the FDA because medical marijuana remains illegal at the federal level and the FDA can only approve federally legalized pharmaceuticals and their corresponding components. At the preliminary injunction hearing related to DOH's "safe for inhalation" standard, two of the petitioners' witnesses, Dr. Vreeke (a PhD chemist that works for a terpene company that provides terpenes to Pennsylvania grower/processors) and Dr. Sisley (a medical doctor and an approved FDA researcher of medical marijuana) testified to this dilemma.[10] The court found both of these witnesses and their testimony credible when they explained that the FDA is responsible for regulating pharmaceutical drugs that are legal under federal law, and this entails approving the component ingredients of a given FDA-approved drug. However, the FDA cannot approve marijuana-derived pharmaceutical drugs because marijuana remains a Schedule I drug at the federal level. The added substances introduced to Pennsylvania medical marijuana products are not common component ingredients for drugs that the FDA can approve. In turn this means the excipients added into medical marijuana never have an opportunity to be considered by the FDA for approval. This, of course, establishes a nearly impossible standard for grower/processors to meet in order to add ingredients, which as Dr. Sisley

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9 *Apartment Ass'n v. Pittsburgh*, 261 A. 3d 1036, 1050 n. 62 (Pa. 2021).

10 MMAPS Litigation, Feb. 24, 2022 Preliminary Injunction Hearing Transcript, at 135:5—137:9 (Dr. Vreeke); 229:20—231:5 (Dr. Sisley) (Feb. 24, 2022).

testified are common to the nationwide medical marijuana industry and which have been used for more than a decade without incident.[11]

The standard DOH seeks through §1151a.27(f)(iii) is non-sensical in that until marijuana is legalized under federal law the FDA is essentially prohibited from reviewing, let alone approving, the standard DOH seeks to impose on Pennsylvania medical marijuana organizations.

DOH's proposed regulation is even more non-sensical once one realizes that many of the added substances subject to DOH's recall and prohibition under § 1151a.27(f)(iii) are terpenes that are found naturally in the marijuana plant. This means that under DOH's proposed § 1151a.27(f)(iii), identical ingredients would be subject to very different standards and approval outcomes. For example, terpenes are essentially botanically-derived oils (e.g. d-limonene is the naturally occurring oil in citrus fruits that gives the fruit their taste); these terpenes are introduced to certain vaporized medicines to provide flavoring and make the medication more palatable for, in many cases, very sick patients. While it is possible to obtain a terpene like d-limonene from a citrus fruit, it may also be possible to extract that from a marijuana plant. Under the DOH's proposed regulation, a terpene like d-limonene obtained from a citrus fruit would need to be FDA-approved for whichever type of medication it was going to be used, whereas d-limonene extracted from a marijuana plant would not be subject to the same FDA-approval requirement because it is not an "added substance" since it was obtained from the marijuana plant. As Dr. Vreeke testified in the MMAPS Litigation, at the molecular level "a terpene is a terpene is a terpene" regardless of its source.[12] So, the DOH's decision to treat a terpene based solely on its source and which ignores the underlying science is an arbitrary and non-sensical standard.

**Conclusion**

DOH should be prohibited from promulgating § 1151a.27(f)(iii) and doing an end run around the Commonwealth Court's decision for all the reasons listed in that decision and described herein. DOH's proposed regulation goes beyond the specific authority given to it by the legislature and sets up an unattainable standard with inconsistent outcomes - the very definition of an arbitrary and capricious action by an agency.

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11 *Id.* at Tr. 235:23—236:15.

12 *Id.* at Tr. 108:10-14.