



Dr. Debra L. Bogen
Acting Secretary of Health
Chair, Medical Marijuana Advisory Board
Pennsylvania Department of Health
Delivered via electronic mail to: dbogen@pa.go

June 12, 2023

Dr. Bogen,

On behalf of the members of the Pennsylvania Cannabis Coalition (PCC),¹ I am writing to request that the Medical Research Subcommittee (“Subcommittee”) of the Medical Marijuana Advisory Board (“Advisory Board”) be required to reevaluate the information presented by Organic Remedies and the Philadelphia College of Osteopathic Medicine (“PCOM”) at the April 12, 2023 Advisory Board meeting, regarding the efficacy of solvent-based remediation, in the manner required and supported by the legislature in Act 44 of 2021 (“Act 44”).²

Since 2019, the PCC has been actively advocating for its members to be allowed to use a solvent-based process to remove microbial contamination from medical marijuana that has failed during microbial testing. An extremely common practice, at least 35 other medical marijuana programs allow this practice, commonly referred to as “remediation.” In those jurisdictions, once solvent-based extraction is complete, the now remediated products are tested by state licensed labs to ensure safety and that the microbial contaminants are no longer present in the final product. Hydrocarbon solvents contain bacteriostatic properties, meaning they can effectively suppress the growth of and kill microbes via cell membrane disruption.³ As seen in the study conducted by Organic Remedies and PCOM in December 2022, cannabis material containing failing levels of microbes in its raw plant form were completely free of microbes in its extract form post solvent-based extractions.⁴ These products are chemically indistinguishable from those produced from plant material that passes initial testing.⁵

During the 2020-2021 legislative session, remediation was a much-discussed topic for inclusion in HB 1024, which later became Act 44. While stakeholders were unable to reach immediate consensus, an agreement was facilitated by Governor Wolf, Acting Secretary of Health Alison Beam, and the Pennsylvania Cannabis Coalition to use the Academic Clinical Research Centers and their Clinical Registrant partners to study the efficacy and safety of solvent-based remediation. This compromise was included in Act 44 as follows:

¹ PCC is a 501(c)(6) trade organization comprised of Pennsylvania medical marijuana operators (MMOs) representing the current medical marijuana industry in Pennsylvania and advocating for a robust yet scientifically valid regulatory framework.

² Act of Jun. 30, 2021, P.L. 210, No. 44 Cl. 35.

³ Aono, R. et al. (1994). Effects of Organic Solvents on Growth of E. coli. *Bioscience, Biotechnology, and Biochemistry*, 58(11), 2009-2014.

⁴ June-Wells, M.R., et al. (2022). Contaminated Cannabis Material to Microbe-Free Extracts: A Real-World Test. *Cannabis Science and Technology*, 5(9), 20-31.

⁵ Solvent-Based Extraction Remediation of Microbial Contamination in Cannabis Flower. Cresco Labs, June 2021.

Section 2003.1. Research initiative.

(b)(3) An academic clinical research center and its contracted clinical registrant shall present research initiative findings to the advisory board and the board's research subcommittee for the board's review and consideration under sections 1201 and 1202. The board shall issue a written report, with recommendations and findings regarding the use of solvent-based extraction methods and processes on microbial contamination by a clinical registrant or grower/processor. The secretary may approve the board's recommendation in accordance with section 1202.⁶

The research was conducted by Organic Remedies and the PCOM and presented to the Medical Marijuana Advisory Board in July of 2022, and showed without a doubt that the process of extraction safely and completely removed contamination from medical marijuana. On April 12, 2023, the Subcommittee presented their recommendation to the Medical Marijuana Advisory Board. The presentation correctly offered the question intended by Act 44:

"Amend the Act to Allow Cannabis Product Remediation when products exceed microbial contamination thresholds."⁷

However, the Subcommittee ultimately recommended the following:

"In the interest of patient safety, at this time, do not recommend to change the PA DOH regulations on allowable qualities of colony forming units of: bacteria; total yeast and fungus."⁸

The slides presented by the Subcommittee ultimately show that the Subcommittee was looking at the wrong research and information. We are not requesting changes to the allowable levels of microbials. We are asking that the Department of Health allow us to remediate our products.

Solvent based extraction methods optimize quality assurance, keeping patients safe while mitigating against unnecessary product loss. The ability to use solvent-based extraction methods results in the least amount of wasted biomass and the most medicine delivered to patients. The unnecessary product loss, which is currently estimated as millions of pounds of biomass since the inception of Pennsylvania's medical marijuana program, has had the unintended consequence of increasing the cost medical marijuana for program participants. For these reasons, the PCC requests that you, in your role as Chair of the Advisory Board, charge the Medical Research Subcommittee with evaluating the Organic Remedies / PCOM study as intended by Act 44, and in line with the research and scientific knowledge available related to decontamination of consumable products.

Respectfully,



Meredith Buettner
Executive Director, Pennsylvania Cannabis Coalition

⁶ 35 P.S. § 10231.2003.1(b)(3).

⁷ Slide 21 of the Medical Research Advisory Committee Presentation, Medical Marijuana Advisory Board meeting, April 12, 2023.

⁸ *Id.* at Slide 22.