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Pa. Health Dept. Sued Over Cannabis Vape Product Recall

By **Katryna Perera**

Law360 (March 30, 2022, 8:59 PM EDT) -- The Pennsylvania Department of Health is facing a lawsuit over a recent recall of hundreds of medical cannabis vape products as a group of cultivators, manufacturers and dispensaries claims the decision has cost the industry tens of millions of dollars and deprived "patients of one of the most important forms of medical marijuana."

Medical Marijuana Access and Patient Safety Inc., a nonprofit made up of dispensaries, growers, processors, certified patients that use medical marijuana vaporization products, and other industry stakeholders, filed suit against three high-ranking members of the state DOH in February in Pennsylvania state court.

The defendants are DOH acting Secretary Keara Klinepeter, DOH Assistant Director and Chief Compliance Officer Sunny Podolak and DOH Office of Medical Marijuana Director John Collins.

The DOH did not immediately respond to requests for comment on Wednesday. The lawsuit was earlier reported on by the website Grown In.

A lawyer who represents MMAPS said in an interview that the group is awaiting next steps.

In a phone call with Law360, Judith D. Cassel of Hawke McKeon & Sniscak LLP said the parties have filed briefs and responses since the suit was launched on Feb. 10. Now, the issue is pending until a judge makes a decision on the group's request for a preliminary injunction.

Cassel added that the court authorized the recalled products to be held in quarantine instead of being destroyed until a decision is reached. She said the damages at this point are estimated to be $18 million.

"[Medical marijuana] patients and safety is at the heart of this litigation, and we feel removing these products without any motivation or from an adverse effect does a disservice to patients who rely on this medicine," Cassel said.

According to MMAPS' complaint, the DOH issued the recall on Feb. 4, stating 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."

The products included in the recall had previously been approved by the DOH for more than three years, according to the complaint, and the recall specifically focused on medical marijuana vaporization products that contained terpene additives. At least 670 products were covered by the recall, the lawsuit states.

MMAPS says the recall cost the industry tens of millions of dollars and continues to deprive patients of an important and highly used form of medical marijuana.

In its complaint, MMAPS said the recall was issued "under the rationale" that the products were not listed on the FDA's website as safe for inhalation. MMAPS says this reasoning is both "nonsensical" and outside the authority of the DOH, as stated in the state's Medical Marijuana Act.

According to the complaint, terpene manufacturers do not submit research and testing to the FDA since terpenes are almost exclusively used in marijuana products, and marijuana is still an illegal substance at the federal level.

Therefore, there is no reason for terpenes to be listed on the FDA's website "as safe for inhalation," MMAPS says.

"DOH's rationale for the Terpene Recall Mandate – 'not listed on FDA website as safe for inhalation' – is not only an impossible standard, but one not provided for in the [Medical Marijuana Act]," the complaint states.

MMAPS argues that the standard by which the state legislature has directed the DOH to approve additives such as terpenes is whether products containing such additives would be considered "safe for use in food" or "generally recognized as safe" by the FDA — and according to the complaint, all the terpenes listed in the recall are also listed on the FDA's website as "safe for use in food" or "generally recognized as safe."

The DOH has also stepped outside the purview of its authority as provided by the state's Medical Marijuana Act, the complaint states. MMAPS says the DOH may only recall products if a patient, caregiver or practitioner makes a complaint.

"[MMAPS is] not aware of a single complaint made by a patient, caregiver, or practitioner, and DOH has not cited to any," the complaint states. "Pennsylvania patients have been using the inhalation products enhanced with these terpenes for over three years without a single adverse incident, let alone an adverse incident requiring a mandatory recall."

The complaint states that the recall will not only cost the state's medical marijuana industry millions of dollars it has expended in equipment, supplies and labor as well as the transportation and marketing of these products, but it will also deprive approximately 150,000 Pennsylvania medical marijuana patients of their preferred, and sometimes needed, products.

"Terpene infused vaporization products are essential medicine for many … cancer patients undergoing chemotherapy treatment and patients suffering from severe chronic or intractable pain," the complaint states. "If unable to secure them through the program's dispensaries, [patients] likely will turn to the dangerous black market to obtain these types of products."

MMAPS seeks declaratory and injunctive relief to preliminarily and permanently enjoin the DOH from enforcing the recall.

MMAPS is represented by Judith D. Cassel, Kevin J. McKeon, Dennis A. Whitaker and Micah R. Bucy of Hawke McKeon & Sniscak LLP.

Counsel information for the defendants was not immediately available.

The case is Medical Marijuana Access & Patient Safety Inc. v. Keara Klinepeter, Acting Secretary Pennsylvania Department of Health et al., case number 58MD2022, in the Commonwealth Court of Pennsylvania.

--Editing by Ellen Johnson.
