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58 MD 2022

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

MEDICAL MARIJUANA ACCESS & PATIENT SAFETY, INC.,	:	
Petitioner,	:	
v.	:	No. 58 MD 2022
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.	:	

NOTICE TO PLEAD

To: Petitioner

You are hereby notified to file a written response to the enclosed New Matter within thirty (30) days from service hereof or a judgment may be entered against you.

/s/ Bruce P. Merenstein
Bruce P. Merenstein, Pa. ID No. 82609
SCHNADER HARRISON SEGAL & LEWIS LLP
1600 Market Street, Suite 3600
Philadelphia, Pennsylvania 19103
(215) 751-2249
Counsel for Respondents

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

MEDICAL MARIJUANA ACCESS & PATIENT SAFETY, INC.,	:	
Petitioner,	:	
v.	:	No. 58 MD 2022
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.	:	

ANSWER WITH NEW MATTER

Respondents, 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"), by and through their undersigned counsel, answer petitioner's Petition for Review in the Nature of a Complaint in Equity Seeking Declaratory Relief and Injunctive Relief (the "Complaint") as follows:

1. Admitted in part, denied in part. Respondents admit that DOH sent an email on February 4, 2022 to some grower/processors, but deny that an email was sent to all grower/processors in the medical marijuana program. Respondents deny that Exhibit 1 to the Complaint was an email to grower/processors. Respondents further deny any mischaracterizations of the February 4, 2022 email to grower/processors, as it is a document that speaks for itself. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and they are therefore denied.

2. Denied. By way of further response, Respondents are not aware of any application submitted by named Petitioner to sell inhalation medical marijuana products.

3. Denied. The February 4, 2022 email to grower/processors is a document that speaks for itself and Respondents deny any inaccurate characterization thereof. By way of further response, Respondents specifically deny that the February 4, 2022 email to grower/processors was "without explanation" or "nonsensical." The remaining allegations of this paragraph constitute legal conclusions to which no response is required.

4. Denied. By way of further response, the FDA conducts research of products.

5. Denied. It is denied that terpenes are almost exclusively used in marijuana products. Terpenes are used in many different products. It is further denied that terpene manufacturers never submit their testing and research to the FDA. It is further denied that terpenes added to inhalation medical marijuana products could not be listed on the FDA website "as safe for inhalation."

6. Denied as stated. To the extent this paragraph alleges that terpenes added to inhalation medical marijuana products have been extensively tested for safety and efficacy, this averment is denied. Many terpene manufacturers do not extensively test their terpenes for safety or efficacy. And even those that do some safety testing do not necessarily test their terpenes for safe use in inhalation products.

7. Respondents deny that the DOH's policy is an "impossible standard." The remaining allegations of this paragraph constitute legal conclusions to which no response is required.

8. The allegations in this paragraph constitute legal conclusions to which no response is required. By way of further response, the fact that a product is deemed by the FDA as safe for ingestion as food does not mean that it is deemed by the FDA as safe for inhalation. Similarly, the "generally recognized as safe" ("GRAS") designation means only that a product is safe to ingest as food, not that it is safe to inhale.

9. Denied. Some of the products referred to in this paragraph of the Complaint are not listed as GRAS on the FDA website. By way of further response,

the GRAS designation means only that a product is generally recognized as safe for consumption, not that it is safe to inhale.

10. Denied as stated. Respondents specifically deny that there is anything "absurd" about the DOH's requirement that an externally sourced additive be deemed safe for inhalation by the FDA before it can be used in a product intended for inhalation.

11. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph and they are therefore denied.

12. The allegations in this paragraph constitute legal conclusions to which no response is required.

13. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

14. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

15. Denied. All of the inhalation products at issue have not been available for use in Pennsylvania "for over three years." By way of further answer, the

Department is aware of at least one reported adverse event involving the use of a recalled product.

16. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

17. This paragraph sets forth the relief that Petitioner is seeking and requires no response from Respondents. To the extent that the allegations in this paragraph constitute legal conclusions, no response is required as well.

18. This paragraph sets forth the relief that Petitioner is seeking and requires no response from Respondents. To the extent that the allegations in this paragraph constitute legal conclusions, no response is required as well.

STATEMENT OF JURISDICTION

19. The allegations in this paragraph constitute legal conclusions to which no response is required.

PETITIONER

20. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

RESPONDENTS

21. Admitted in part and denied in part. It is admitted that Keara Klinepeter is the Acting Secretary of Health and that the Medical Marijuana Act, 35 P.S. § 10231.101 – 10231.2110 (the "Act"), tasks the DOH with the implementation and administration of the Act. It is denied that the DOH issued the recall as described by Petitioner.

22. Admitted in part and denied in part. It is admitted that John Collins is the Director of the Office of Medical Marijuana, that he instituted the review of vaporization products, and that the Act tasks the DOH with the implementation and administration of the Act. It is denied that the DOH issued the recall as described by Petitioner.

23. Admitted in part and denied in part. It is admitted that Sunny Podolak is the Chief Compliance Officer for the Office of Medical Marijuana, that she sent the emails attached as Exhibits 1, 2, and 5 to the Complaint, and that the Act tasks the DOH with the implementation and administration of the Act. It is denied that Podolak sent the remaining emails described in this paragraph. By way of further answer, the remaining emails originated from the Office of Medical Marijuana compliance resource account. It is further denied that the DOH issued the recall as described by Petitioner.

FACTUAL BACKGROUND

24. Admitted.

25. The allegations in this paragraph constitute legal conclusions to which no response is required.

26. Denied as stated. Respondents state that, as of October 2021, vaporization cartridges, only a portion of which may contain unapproved terpenes, represent about 35% of total sales of medical marijuana products in Pennsylvania.

27. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, Petitioner refers to its "member grower/processors and dispensaries," but does not identify any of these members.

28. Admitted in part and denied in part. It is admitted that marijuana plants contain terpenes. It is further admitted that some other plants also contain terpenes. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of this paragraph, and they are therefore denied.

29. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

30. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, Petitioner

refers to its "grower/processor members," but the Complaint does not identify any such members.

31. Respondents admit that the Medical Marijuana Act was amended in June 2021 by Act 44 of 2021. Whether this is "[r]elevant to the present Petition" is a legal conclusion to which no response is required.

32. The allegations in this paragraph constitute legal conclusions to which no response is required.

33. The allegations in this paragraph constitute legal conclusions to which no response is required.

34. The allegations in this paragraph constitute legal conclusions to which no response is required.

35. Admitted.

36. Admitted. By way of further answer, Act 44 codified substantial portions of the temporary regulations into statute. Further, additional regulatory amendments under the authority of Act 44 are incorporated in the final-form regulations currently in the regulatory review process.

37. The allegations in this paragraph constitute legal conclusions to which no response is required.

38. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

39. Respondents deny the allegations in this paragraph as unintelligible.

40. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, Respondents are unaware of who Petitioner's members are or the information about which Petitioner and its members are aware.

41. Respondents admit that Sunny Podolak sent the email attached as Exhibit 2 to the Complaint on behalf of the DOH on November 16, 2021. The November 16, 2021 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

42. Respondents admit that Sunny Podolak sent the email attached as Exhibit 2 to the Complaint on behalf of the DOH on November 16, 2021. The November 16, 2021 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

43. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

44. Respondents admit that the DOH Office of Medical Marijuana sent the email to medical marijuana patients attached as Exhibit 3 to the Complaint on

December 2, 2021. The December 2, 2021 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

45. Respondents admit that Respondent John Collins was sent the email attached as Exhibit 4 to the Complaint on December 2, 2021. The December 2, 2021 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

46. Denied as stated. Respondents deny that they have not addressed any of the issues raised in Exhibit 4 to the Complaint.

47. Respondents admit that Sunny Podolak sent the email attached as Exhibit 5 to the Complaint on behalf of the DOH on December 13, 2021. The December 13, 2021 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

48. Respondents admit that Sunny Podolak sent the email attached as Exhibit 5 to the Complaint on behalf of the DOH on December 13, 2021. The December 13, 2021 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

49. Admitted in part and denied in part. Respondents admit that they received responses from grower/processors to the information requested in the November 16, 2021 and December 13, 2021 emails. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of this paragraph, and they are therefore denied.

By way of further response, Respondents do not know when each submission was received, or whether Exhibit 6 reflects a "representative sample of Petitioner's members' submissions" in light of the fact that none of "Petitioner's members" are identified in the Complaint.

50. Denied as stated. The email correspondence from the DOH to grower/processors, dispensaries, patient and physicians concerning the vaporization re-approval process, including those attached to the Complaint, are documents that speak for themselves, and Respondents deny any inaccurate characterization thereof.

51. Admitted in part and denied in part. Respondents admit that the DOH sent the email attached as Exhibit 7 to the Complaint to medical marijuana patients and caregivers on February 4, 2022. The February 4, 2022 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof. It is denied that DOH was recalling medical marijuana products from dispensaries.

52. Respondents admit that the DOH sent the email attached as Exhibit 7 to the Complaint to medical marijuana patients and caregivers on February 4, 2022. The February 4, 2022 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

53. Respondents admit that the DOH sent the email attached as Exhibit 7 to the Complaint to medical marijuana patients and caregivers on February 4, 2022. The February 4, 2022 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

54. Respondents admit that the DOH sent the email attached as Exhibit 7 to the Complaint to medical marijuana patients and caregivers on February 4, 2022. The February 4, 2022 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

55. Admitted in part and denied in part. Respondents admit that Sunny Podolak sent the email attached as Exhibit 1 to the Complaint on behalf of the DOH on February 4, 2022. The February 4, 2022 email attached as Exhibit 1 to the Complaint is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof. Respondents deny that the DOH "institut[ed] a mandatory recall."

56. Admitted in part and denied in part. Respondents admit that the DOH posted on its website a list titled "Withdraw of Products Containing Additives Not Approved for Inhalation by the FDA." This list is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

57. Denied. Respondents are not aware of any application submitted by Petitioner to sell inhalation medical marijuana products nor are Respondents aware of any reason why marijuana products would be sent to Petitioner. By way of further response, Respondents deny that they have required any grower/processor to destroy product.

58. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

59. Denied as stated. The February 4, 2022 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

60. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

61. Denied as stated. The February 4, 2022 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof. Additionally, the allegations in this paragraph constitute legal conclusions to which no response is required.

62. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, none of "Petitioner's grower/processor members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

63. The allegations in this paragraph constitute legal conclusions to which no response is required.

64. The allegations in this paragraph constitute legal conclusions to which no response is required.

65. Admitted in part and denied in part. It is admitted that the primary role of the FDA is to protect the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices. The FDA may order additional testing and clinical trials in order to determine whether a product is safe. By way of further response, the FDA also regulates tobacco products, including e-cigarettes, vapes, and other electronic nicotine delivery system products. Respondents are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of this paragraph, and they are therefore denied.

66. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

67. Admitted in part and denied in part. It is admitted that marijuana is illegal under federal law. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of this paragraph, and they are therefore denied.

68. Denied. Some terpenes used in medical marijuana products made for inhalation are listed on the FDA's website.

69. Admitted.

70. Denied. It is denied that no terpene could be approved by the FDA as safe for inhalation. The remaining allegations in this paragraph constitute legal conclusions to which no response is required.

71. Denied as stated. The February 4, 2022 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

72. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

73. Respondents deny that the DOH initiated a recall in this matter. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of this paragraph, and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

74. Denied as stated. Respondents state that, as of October 2021, vaporization cartridges, only a portion of which may contain unapproved terpenes, represent about 35% of total sales of medical marijuana products in Pennsylvania.

75. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

76. Denied. Petitioner fails to define "preferred products" and therefore, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

77. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied.

78. Admitted in part and denied as stated in part. It is denied that the majority of vaporized Medical Marijuana products are "Terpene Infused Products," which is not defined in the Complaint. It is denied as stated that there are 670,000 certified patients, rather there are 670,000 patients registered in the Pennsylvania medical marijuana program. By way of further answer, there are currently over 400,000 active certified patients. The remaining averments in this paragraph are admitted.

79. Denied. Petitioner's averments regarding what marijuana medical patients will do are speculative and unsupported generalizations, and therefore are denied. Averments regarding what the Legislature sought to do or considered when enacting the Act constitute legal conclusions to which no response is required. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of any remaining averments of this paragraph, and they are therefore denied.

80. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

81. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

82. Admitted in part and denied in part as stated. The implication of this paragraph that the DOH has determined that all terpenes are unsafe is denied. By way of further response, Respondents admit that the DOH does not conduct its own tests on terpenes.

83. Respondents admit that on September 12, 2019, Rachel Levine, Pennsylvania's Secretary of Health at the time, issued a statement concerning vaping illegally obtained products. The statement is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

84. Respondents admit that John Collins participated in a Medical Marijuana Advisory Board meeting on August 17, 2021. The transcript of that

proceeding is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

85. Admitted in part and denied as stated in part. It is denied that the terpenes in the products at issue are subject to stringent testing. It is admitted that the inhalation medical marijuana products at issue have specific expiration dates of one year after undergoing final testing and labeling.

86. Denied. By way of further response, Petitioner has not received any approval from the DOH to produce medical marijuana products.

87. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent that a response is required, Respondents deny that Petitioner will suffer any harm, as it is not a grower/processor or dispensary of medical marijuana products in Pennsylvania. By way of further response, it is denied that patients will suffer irreparable harm as the Department's actions serve to protect patient health and safety, and other alternative products remain continuously available.

COUNT I: DECLARATORY JUDGMENT
LACK OF STATUTORY AUTHORITY

88. The responses to paragraphs 1-87 are incorporated by reference as if set forth fully herein.

89. The allegations in this paragraph constitute legal conclusions to which no response is required.

90. The allegations in this paragraph constitute legal conclusions to which no response is required.

91. The allegations in this paragraph constitute legal conclusions to which no response is required.

92. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, none of Petitioner's "members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph. Additionally, some terpenes used in medical marijuana products made for inhalation are listed on the FDA's website.

93. The allegations in this paragraph constitute legal conclusions to which no response is required.

COUNT II: DECLARATORY JUDGMENT
UNLAWFUL DE FACTO REGULATION

94. The responses to paragraphs 1-93 are incorporated by reference as if set forth fully herein.

95. The allegations in this paragraph constitute legal conclusions to which no response is required.

96. The allegations in this paragraph constitute legal conclusions to which no response is required.

97. The allegations in this paragraph constitute legal conclusions to which no response is required.

COUNT III: DECLARATORY JUDGMENT
IMPROPER RELIANCE ON RECALL REGULATION

98. The responses to paragraphs 1-97 are incorporated by reference as if set forth fully herein.

99. The allegations in this paragraph constitute legal conclusions to which no response is required.

100. The allegations in this paragraph constitute legal conclusions to which no response is required.

101. The allegations in this paragraph constitute legal conclusions to which no response is required.

102. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph or what "Petitioner's members" believe poses a risk to public health and safety.

103. Denied as stated. The February 4, 2022 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

104. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent that a response is required, after reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

105. Admitted in part and denied in part as stated. It is admitted that the DOH emails attached as Exhibits 1 and 2 to the Complaint do not identify an "adverse event." By way of further answer, the Department is aware of at least one reported adverse event involving the use of a recalled product.

106. The allegations in this paragraph constitute legal conclusions to which no response is required.

COUNT IV: DECLARATORY JUDGMENT VESTED RIGHT, DETRIMENTAL RELIANCE, AND PROMISSORY ESTOPPEL

107. The responses to paragraphs 1-106 are incorporated by reference as if set forth fully herein.

108. The allegations in this paragraph constitute legal conclusions to which no response is required.

109. The allegations in this paragraph constitute legal conclusions to which no response is required.

110. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent that a response is required, after reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

111. The allegations in this paragraph constitute legal conclusions to which no response is required.

COUNT V: DECLARATORY JUDGMENT – TAKING

112. The responses to paragraphs 1-111 are incorporated by reference as if set forth fully herein.

113. The allegations in this paragraph constitute legal conclusions to which no response is required.

114. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

115. The allegations in this paragraph constitute legal conclusions to which no response is required.

116. The allegations in this paragraph constitute legal conclusions to which no response is required.

117. The allegations in this paragraph constitute legal conclusions to which no response is required.

118. The allegations in this paragraph constitute legal conclusions to which no response is required.

COUNT VI: DECLARATORY JUDGMENT
PROCEDURAL DUE PROCESS

119. The responses to paragraphs 1-118 are incorporated by reference as if set forth fully herein.

120. The allegations in this paragraph constitute legal conclusions to which no response is required.

121. The allegations in this paragraph constitute legal conclusions to which no response is required.

122. The allegations in this paragraph constitute legal conclusions to which no response is required.

123. The allegations in this paragraph constitute legal conclusions to which no response is required.

124. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent that a response is required, the February 4, 2022 email is a document that speaks for itself, and Respondents deny any inaccurate

characterization thereof. Respondents deny that the DOH initiated a recall in this matter. By way of further response, none of "Petitioner's grower/processor and dispensary members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

124. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent that a response is required, pursuant to the March 1, 2022 Order, destruction of quarantined product will not occur until the conclusion of this matter.[1]

125. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent that a response is required, the February 4, 2021 email is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

126. The allegations in this paragraph constitute legal conclusions to which no response is required.

127. The allegations in this paragraph constitute legal conclusions to which no response is required.

COUNT VII: DECLARATORY JUDGMENT
DAMAGE TO REPUTATION

128. The responses to paragraphs 1-127 are incorporated by reference as if set forth fully herein.

[1] The Complaint includes two consecutive paragraphs numbered 124.

129. The allegations in this paragraph constitute legal conclusions to which no response is required.

130. The allegations in this paragraph constitute legal conclusions to which no response is required.

131. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

132. Respondents admit that the DOH posted on its website a list titled "Withdraw of Products Containing Additives Not Approved for Inhalation by the FDA." This list is a document that speaks for itself, and Respondents deny any inaccurate characterization thereof.

133. After reasonable investigation, Respondents are without knowledge or information sufficient to form a belief as to the truth of the averments of this paragraph, and they are therefore denied. By way of further response, none of "Petitioner's members" are identified in the Complaint, so it is impossible to determine the truth of the averments of this paragraph.

134. Admitted in part and denied in part as stated. It is admitted that the DOH emails attached as Exhibits 1 and 2 to the Complaint do not identify an "adverse

event." By way of further answer, the Department is aware of at least one reported adverse event involving the use of a recalled product.

135. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent that a response is required, the factual averments in this paragraph are denied.

COUNT VIII: PRELIMINARY INJUNCTION

136. The responses to paragraphs 1-135 are incorporated by reference as if set forth fully herein.

137. The allegations in this paragraph constitute legal conclusions to which no response is required.

138. This paragraph does not require a response.

COUNT IX: PERMANENT INJUNCTION

139. The responses to paragraphs 1-138 are incorporated by reference as if set forth fully herein.

140. The allegations in this paragraph constitute legal conclusions to which no response is required.

141. The allegations in this paragraph constitute legal conclusions to which no response is required.

142. The allegations in this paragraph constitute legal conclusions to which no response is required.

WHEREFORE, Respondents respectfully request that the Complaint be dismissed, judgment be entered in favor of Respondents and against Petitioner, Respondents be awarded their costs of suit and reasonable attorneys' fees, and that the Court grant such other relief as the Court deems just and proper.

NEW MATTER ADDRESSED TO PETITIONER

1. Respondents incorporate by reference their responses to paragraphs 1 through 142 of the Complaint as if set forth fully herein.

2. Petitioner fails to state a claim or cause of action against Respondents upon which relief can be granted.

3. Petitioner lacks standing to assert the claims in the Complaint.

4. Petitioner lacks the capacity to bring this action.

5. Petitioner has failed to exhaust available administrative remedies, and therefore, this Court lacks jurisdiction over this action.

6. Petitioner's claims are barred by sovereign immunity.

7. Petitioner fails to allege that it has suffered any harm as a result of the actions alleged in the Complaint.

8. Petitioner has failed to identify any member who has suffered any harm as a result of the actions alleged in the Complaint.

9. Petitioner has not met its burden to demonstrate that at least one of its members would have standing to bring this action.

10. All of the actions by Respondents alleged in the Complaint were pursuant to the authority provided to the Department of Health by the Medical Marijuana Act, 35 P.S. § 10231.101 – 10231.2110.

11. All of the actions by Respondents alleged in the Complaint were consistent with regulations promulgated pursuant to the authority provided to the

Department of Health by the Medical Marijuana Act, 35 P.S. § 10231.101 – 10231.2110.

WHEREFORE, Respondents respectfully request that the Complaint be dismissed, judgment be entered in favor of Respondents and against Petitioner, Respondents be awarded their costs of suit and reasonable attorneys' fees, and that the Court grant such other relief as the Court deems just and proper.

/s/ Bruce P. Merenstein
Bruce P. Merenstein, Pa. ID No. 82609
John R. Timmer, Pa. ID No. 89814
SCHNADER HARRISON SEGAL & LEWIS LLP
1600 Market Street, Suite 3600
Philadelphia, PA 19103
(215) 751-2000

Counsel for Respondents

March 14, 2022

VERIFICATION

I, Sunny D. Podolak, Assistant Director and Chief Compliance Officer of the Pennsylvania Department of Health, Office of Medical Marijuana, affirm that the allegations of fact contained in the foregoing Answer with New Matter are true and correct to the best of my knowledge, information and belief. This Verification is made subject to the penalties of 18 Pa. C.S.A. § 4904, relating to unsworn falsification to authorities.

/s/ Sunny D. Podolak
Sunny D. Podolak
Assistant Director and Chief Compliance Officer
Office of Medical Marijuana
Pennsylvania Department of Health

Dated: March 14, 2022

CERTIFICATE OF COMPLIANCE

Rule 127 Compliance. I certify that this filing complies with the provisions of the *Case Records Public Access Policy of the Unified Judicial System of Pennsylvania* that require filing confidential information and documents differently than non-confidential information and documents.

Service. I certify that, on March 14, 2022, this Answer with New Matter was filed with the Court and served on the following through the Court's PACFile System:

Kevin J. McKeon
Judith D. Cassel
Dennis A. Whitaker
Micah R. Bucy
HAWKE MCKEON & SNISCAK LLP
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