Vermont Public Health Sub-Committee Meeting Minutes—October 14, 2021

Mark Gorman called the meeting to order at 11:03 AM.

Attendees
Advisory Committee Members:
- Ingrid Jonas
- Dr. Mark Levine (11:30AM)

VT Cannabis Board:
- Julie Hulburd

NACB:
- Gina Kranwinkel
- Mark Gorman
- Deneka Scott

Expert Guest:
- Omar Oyarzabal, PhD
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2 members of the public

Minutes recorded by Deneka Scott. No quorum was established due to 2 sub-committee members absent in the beginning of the meeting.

No written public comments were made for the Public Health Sub-Committee for 10/14/21. Members of the Vermont public were notified how to submit comments via the CCB website.

Advisor Deneka Scott introduced expert guest, Omar Oyarzabal, PhD. (Microbiology/Food Safety) of Safe Food Team, a consulting firm. Dr. Oyarzabal shared a presentation on Manufacturing of Hemp Products. Dr. Oyarzabal began by presenting his outline, to review terms, and discuss the 2018 Farm Bill, the current position of the FDA, that oversees most manufacturing regulation and safety at the federal level, and the difference in food manufacturers and the manufacturers of dietary supplement products -and mentions of claims. Dr. Oyarzabal noted that he works in regulations/regulatory compliance but, *does not provide legal advice.*

Dr. Oyarzabal began his discussions by moving to the 2018 Farm Bill which better defined Hemp as the plant Cannabis Sativa (as referenced on slide 9) of not more than 0.3% THC. He also noted slide 11 and what each word is defined as in the bill:

- Cannabinoids = Many related compounds (100+) in the plant (e.g., CBD, THC), primarily in the flowering tops and absent in seeds
  - THC = A cannabinoid responsible for psychotropic effects
- Cannabis = Any part of the plant Cannabis sativa L. It includes both hemp and marijuana
  - Hemp = Cannabis with THC content less than 0.3%
  - Marijuana = Cannabis with THC content above 0.3%

He noted that the 2018 Farm Bill brought a removal of restrictions from the DEA on industrial hemp. The 2018 Farm Bill empowered the Secretary of Agriculture in each state to monitor for the growing and cultivation of hemp plants and provides for opportunity to create a farming business for trade. The Farm Bill does not change at all the way the FDA enforces its regulation and they are regulating food manufacturers. He noted that once it moves into manufacturing we are still in limbo with oversight. He noted the compound from the plant that does not have a psychotropic effect, CBD, is still considered a drug by the FDA. The FDA's position is that Hemp and CBD are not the same and that CBD is a drug and therefore cannot be used as a food, dietary ingredient or cosmetic – but they are using "discretionary enforcement". From there he noted that the Food Drug and Cosmetics Act prohibits the "interstate" commerce of any food to which a drug (section 505 of the Act) has been added. Based on available evidence, the FDA has concluded that THC and CBD products are excluded from the dietary supplement definition (FD&C Act) 21 (slide 21). Then Dr. Oyarzabal explained elements of the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, Or Holding Operations For Dietary Supplements - 21 CFR part 111 and elements of it which are important to this topic (slide 37) –which are similar to requirements for foods.

The next segment of Dr. Oyarzabal's discussion was on where the industry is going. He gave his opinion that from what he sees, companies are trying to go into dietary supplement manufacturing because they can make a structural function claim. From there, he moved into discussions on other states with specific discussions of California AB 45 (slide 46). It was noted (slide 47) that with CA AB 45 required testing by an independent laboratory, requires the label "THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY"; a statement that cannabinoids should be kept out of reach of children and that The CA Department of Health may impose maximum serving sizes for hemp-derived cannabinoids, hemp extract and products derived therefrom, active cannabinoid concentration per serving size, the number of servings per container, and any other requirements it deems necessary. (The remaining items of AB 45 are available on slide 48) Dr. Oyarzabal noted he is bringing his perspective on what he is seeing in these areas which concluded his presentation.

Advisor Deneka Scott noted that the question trying to be answered/defined is who (which agency) is responsible for the oversight of edibles for the state of Vermont and welcomed Dr. Oyarzabal to provide his perspective on this question. Dr. Oyarzabal noted the 2018 Farm Bill gives the opportunity for the Secretary of State/Food and Markets to oversee the industrial hemp programs. He noted that once the biomass (of the plant) is created it must be processed (the food) and production of the food would/should go under the Department of Health. He noted that growing and cultivating would fall under one agency and that processing would be under another – like California and Colorado – the Department of Health (for processing). From there he discussed that New Hampshire has all under one agency – the Department of Health. He also noted that all state agencies in charge of manufacturing follow regulations from federal mandates.

From there Advisor Deneka Scott opened the floor to questions. In response to a question regarding regulations from Advisor Mark Gorman, Dr. Oyarzabal noted that he didn't think there is a need for more regulations as it appears the industry is holding out for the FDA to make decisions on this subject. Dr. Oyarzabal provided that while he had not seen allergens (when asked regarding labeling) but he has seen areas where products were shelved due to preparation issues – particularly temperature and cited examples of potential hazards. Dr. Levine asked if any of the discussion centered around potency issue – Dr. Oyarzabal noted that quantification is still an issue in this area of testing and noted he is not an expert in this area. In response to a question by Advisor Mark Gorman, Dr. Oyarzabal also noted that a "standard serving size" has not been calculated yet

either for the industry. Advisor Deneka Scott asked if Dr O had any perspective on warning language – Dr. O noted that this is more of legal advice and discussed more in violations of good manufacturing practices.

From there Advisor Deneka Scott opened the floor and asked if there were any public comments. There were none and it was noted how to submit public comments.

Advisor Mark Gorman adjourned the meeting at 11:52 – Ingrid Jonas motioned with Dr. Levine as second.