Concurring Statement of Commissioner Christine S. Wilson

In the Matter of Bionatrol Health, LLC
   In the Matter of Epichouse, LLC
   In the Matter of CBD Meds, Inc.
   In the Matter of HempmeCBD
   In the Matter of Reef Industries
   In the Matter of Steves Distributing, LLC

December 17, 2020

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission’s complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer’s, diabetes, and Parkinson’s disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission’s complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication.

The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters and a law enforcement action. Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific

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evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission’s proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo-controlled human clinical trials to support disease and other serious health claims for these types of products in the future. Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain conditions – specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy. And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market. And I agree with the observation of my colleague Commissioner Chopra in his statement that “[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine ‘a competitor’s ability to compete’ on honest attributes.” Although I support these cases, I hope that the Commission’s actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.
