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Dear Dr. Gottlieb;

I hope this finds you well. We write today to ask for FDA's enforcement strategy on unapproved new drug products containing CBD as dietary supplements. We are aware and supportive of the FDA page titled "FDA and Marijuana" which clearly states that *"FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, respectively. Under those provisions, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the FD&C Act), or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act."* Moreover, the page goes on to add further clarity that *"There is an exception to sections 201(ff)(3)(B)(i) and (ii) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD. For more information on this provision, including an explanation of the phrase "marketed as"*. Additionally, we are aware of the twenty (20) plus warning letters FDA has sent to companies marketing CBD as dietary supplements.

Despite the agency's actions and message, the market for CBD products in the US is surging. According to a recent report issued by New Frontier Data, the U.S. CBD industry grew by nearly 40% in 2017, reaching \$367 Million in sales across hemp-derived and marijuana-derived markets. At present the only federally approved CBD product, Epidiolex. A drug made by GW Pharma, and approved by FDA just this year, currently has no sales in the US. It would appear that the Agency's tactics to deter the use of illegal marijuana/hemp products are being ignored at best and are being flouted by criminals. Look no further than a recent Washington Post story on the subject and they state that *"Although CBD is technically a federally "scheduled" substance, several states allow access to CBD oil and/or high-CBD strains of marijuana. To date, marijuana is legal in nine states and the District of Columbia for recreational use; CBD is legal*

*with varying restrictions in 46 states.*¹ This message is at odds with the agency's clearly iterated position.

While we are respectful and intimately knowledgeable of the agency's limited resources and vast priorities when it comes to keeping our foods and drugs safe, we are concerned over what appears to be an absence of establishing a deterrent in this instance. The magnitude of a deterrent effect depends, on a potential perpetrator's assessment of three factors: (a) the likelihood of getting caught (i.e. the probability of being detected or reported); (b) the probability of being punished once detected; and (c) the severity of the punishment. Firms may weigh the regulatory risk of receiving a warning letter vs. the potential profitability and gains realized in sales of an unlawful CBD product. Warning letters do not appear to be severe punishment in this regard. Furthermore, the companies that have received them do not appear to believe that there is a likelihood of being caught while engaged in criminal activity to the broader market place.

If the Agency sees the matter as a harm, or potential for harm we are happy to assist the agency in any way we can. We certainly support effective punishment for white collar crimes, particularly those that so clearly involve an abuse of the public trust. But I would urge the agency to consider also the following proposals, which would help to clarify the true nature and scope of the problem, and dramatically increase the likelihood that criminal activity will be detected in the first place and then pursued in an appropriately aggressive manner: (1) As a matter of urgency, require that the OIG provide an independent audit of all firms marketing or manufacturing illegal hemp/marijuana products on annual basis, and the disposition of FDA actions against said firms; (2) FDA should annually conduct blitz type enforcement actions against the most visible or sizeable firms marketing or manufacturing illegal hemp/marijuana products, independent of distribution channel (e.g. retail, internet, etc.); and (3) FDA should coordinate outreach with the States where Cannabis products are legal and educate the states on interstate commerce and the likelihood that the overwhelming majority of CBD products that are being sold in those states are illegal per Federal laws.

If the agency is disinterested in pursuing this issue based on the agency's belief that a public health concern regarding the sale of illegal marijuana/hemp products (i.e. CBD dietary supplements) lacks merit, given the magnitude of the CBD marketplace, such information should be made public. The agency as a matter of course has frequently made clear, on issues that may not rise to the level of said priority, are subject to enforcement discretion. This is important for established manufacturers and retailers who are facing the question every day as to why such products continue to be available for sale but not by those who have taken the FDA's word to heart. If CBD enforcement is not a priority for the Agency, then such a formal signal from the FDA would allow for the reputable firms to begin establishing standards for qualification and conduct. These activities would help keep irresponsible or incompetent

¹ Washington Post – Step right up for this cannabis cure, October 19, 2018
https://www.washingtonpost.com/opinions/step-right-up-for-this-cannabis-cure/2018/10/19/1eff6f66-d3da-11e8-8c22-fa2ef74bd6d6_story.html?utm_term=.b2263f3a8b72

players out of the market, thereby enhancing the credibility and reputation of the established firms, limiting the potential for consumer harm.

The Agency was established to provide protection from harms in the marketplace. FDA has ample and adequate authority to regulate the marketplace, especially one, in this instance, that by its own word are products not eligible to be lawfully marketed. Yet this market of unlawful CBD products is surging, creating a problem that does indeed involve conscious opponents, and which even in considering resource constraints seems to be an approach of willful ignorance or learned helplessness. Understanding that no situation is one size fits all at the agency, it is unclear as to what the principles are here from the agency's tradition of upholding the Federal Food Drug and Cosmetic Act. Taking final agency action on some of the largest CBD players and developing an enforcement strategy would go a long way to closing this perceived loophole and belief that CBD is permitted to be sold in interstate commerce as a dietary supplement.

Our Association and our member companies would welcome the opportunity to meet with you to discuss this above and any other ways we could address this very serious issue.

Thanks for your consideration of this matter,

Daniel Fabricant, Ph.D.