

United States Senate

WASHINGTON, DC 20510

September 23, 2019

The Honorable Norman E. “Ned” Sharpless
Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Acting Commissioner Sharpless:

We write today to ask that the U.S. Food and Drug Administration (FDA) urgently clarify and implement regulations for cannabidiol (CBD) derived from hemp. Since the passage of the 2018 Farm Bill (P.L. 115-334), which paved the way for industrial hemp cultivation and marketing, farmers, processors, and retailers across the country are eager to enter this new market and leverage its potential. With new products containing CBD becoming available nearly every day, your agency’s lack of an official stance on this ingredient remains confusing to manufacturers and potentially dangerous to consumers. It is now imperative that the FDA finalize and implement a comprehensive regulatory framework for CBD, including guidance on the classification, labeling, quality, marketing, and sale of CBD-containing products, to ensure each manufacturer is producing safe and effective products for consumers. In accordance with your agency’s July statement regarding CBD oversight, we expect an update on your activities no later than 90 days from today’s date.¹

The CBD industry has exploded in recent years. Estimated annual sales of CBD-containing products were over \$200 million in 2018, and CBD oils, gummies, balms, lotions, capsules, and other products are broadly available and widely advertised in stores and online.² However, as the CBD industry expands, the lack of clarity and regulation around CBD use has created significant confusion and uncertainty among stakeholders in every segment of the supply chain. It is crucial that the FDA remain proactive in its duty to safeguard public health, protect

¹ U.S. Food and Drug Administration, July 23, 2019, *FDA warns company marketing unapproved cannabidiol products with unsubstantiated claims to treat cancer, Alzheimer’s disease, opioid withdrawal, pain and pet anxiety*, <https://www.fda.gov/news-events/press-announcements/fda-warns-company-marketing-unapproved-cannabidiol-products-unsubstantiated-claims-treat-cancer>.

² Pieter A. Cohen and Joshua Sharfstein, “The Opportunity of CBD – Reforming the Law,” *New England Journal of Medicine* 381, (2019): 297, <https://www.nejm.org/doi/full/10.1056/NEJMp1906409>

consumers from potentially unsafe products, and provide a predictable pathway to market for producers and manufacturers.

Purveyors of CBD-containing products attribute a wide range of health benefits to this ingredient, including relieving pain and anxiety, preventing seizures, treating post-traumatic stress disorder, and easing inflammation. But consumers still lack answers to questions about the potential risks, including adverse side effects and drug interactions, associated with CBD.

Consumers rely on the FDA to conduct timely and appropriate oversight of new and emerging ingredients, and guidance from the FDA would also help manufacturers to develop safer, more effective, and more credible products for consumer use. The market for CBD products is rapidly outpacing the FDA's current regulatory efforts, and your agency clearly must expedite its efforts to promote accuracy and transparency within the CBD industry. It is imperative that any comprehensive regulatory framework for products containing CBD provide straightforward guidance to manufacturers and retailers who wish to incorporate CBD into new products.

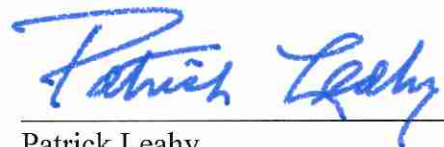
Consumers and manufacturers of this fledgling industry are counting on regulatory oversight and certainty that only the FDA can provide. Your efforts to date have been woefully inadequate. Within 90 days please provide our offices with an outline of your agency's current plans for a specific regulatory framework related to CBD along with a timeline for when comprehensive enforcement policies for CBD products will be finalized and implemented.

Thank you for your attention to this matter and we look forward to your response.

Sincerely,



Richard Blumenthal
United States Senator



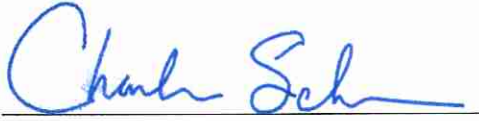
Patrick Leahy
United States Senator



Jon Tester
United States Senator



Tammy Duckworth
United States Senator



Charles E. Schumer
United States Senator



Kirsten Gillibrand
United States Senator