Institute For Behavior and Health
Creating Tomorrow's Drug Policy

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Docket No. FDA-2019-N-1482, Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments

As a Harvard Medical School graduate, a board-certified and practicing psychiatrist, a veteran of NIH training and a clinical professor at Georgetown Medical School since 1980, I've witnessed many dramatic changes over my career. Yet the hoopla and hysteria surrounding the medical use of marijuana and cannabinoid-containing products is unlike anything I have ever seen. It is frightening to me and should be to all who are trusted to protect the public's health and safety.

With that perspective as context, I commend the FDA for tackling the enormous challenge of creating a regulatory pathway for cannabis-derived products. I believe that Congress had products like these in mind when it passed the Food, Drug and Cosmetic Act in 1906. Yet even with an eye toward protecting the public's health and safety as the motivation for the act, a century ago people couldn't have imagined the amount of deceptive advertising we're seeing today for cannabidiol (CBD). To hear the marketers tell it, CBD cures everything.

We are watching the explosive creation of a multi-billion-dollar industry poised to make tremendous profits off desperate patients and their loved ones. Anecdotes and testimonials, not science, drive the marketing of unregulated, non-prescription forms of CBD. It is reminiscent of 19th century patent medicines, with its peddlers commonly known as "snake oil" salesmen.

Regulation to Protect the Nation

Commercial interests are putting CBD into more products than anyone could have imagined. Most consumers touting the benefits of CBD based on anecdotal claims are experiencing a placebo response in the midst of a financially driven mass delusion. This is not the random placebo effect; people are taking these products with magical expectations. This delusion is contagious.

Today's CBD industry is sidestepping the great advances made over the past 113 years to subject health claims to careful investigation, providing accurate information to the public and ensuring the safety, efficacy and purity of health-related products. It is well known that CBD is going into myriad products because of the widespread and growing – the unprecedented – mystique associated with the substance. In the absence of meaningful regulation, CBD will pose a major threat to public health and safety. We appear to be at that dangerous point already.

The FDA must act. It's time to require CBD-product manufacturers making health claims to subject their products to robust pre-clinical and clinical trials, and ultimately submit their data to FDA for review and, if appropriate, clearance for marketing.

I recognize that opponents of regulation argue that if CBD-based products are made available only through a prescription, they will be expensive and more difficult to access. I agree. CBD products for medicinal use should not be cheap in terms of price and especially not manufacture. Patients and their clinicians have fought for and deserve the ability to rely upon the FDA's regulatory process and enforcement mechanisms when making decisions about what they ingest to improve their health and treat disease. We have a century of experience that shows the societal benefits of having an independent FDA safeguard the health of our society.

I enthusiastically support the development of cannabinoid-based medicines, but today, scientific support for using these unique chemicals for medical purposes is scant, outside of three FDA-approved drugs. At present, there are no robust clinical studies that demonstrate safety and efficacy, dosing guidelines don't exist and there are no standardized products to assess for concentration and purity. That's because every dose is different due to wide variations in the amounts of CBD, THC, other potentially active ingredients, additives, and toxins that are present in these products.

CBD + THC Creates Serious Problems for Individuals and Society

I've been working to combat drug abuse for 51 years, including positions as the first director of the National Institute on Drug Abuse (NIDA) and as the nation's second White House "Drug Czar." As an expert in the drug abuse field, I am deeply concerned that the tetrahydrocannabinol (THC) levels in most CBD products, even those derived from the hemp plant, could upend all drug testing currently in place in treatment centers, the workplace, in the transportation sector and elsewhere. Why? Because today's drug assays can detect metabolites of THC at very low levels. Introduction of health products containing THC provides a defense against workplace and roadside drug tests that confounds or even eliminates the significant safety requirements.

We may increasingly find ourselves in situations where people using marijuana in violation of legal statutes or employer regulations will claim that their CBD product must have contained THC and that's why they tested positive for cannabis. Conversely, people using CBD products with no knowledge or expectation that they contained THC could be fired from their jobs due to positive drug tests. Those unjust terminations could follow them for the rest of their lives.

An unregulated CBD industry creates a wide-open path for that bogus defense, and for the wrongful terminations of employees, and society will suffer because of it.

As a nation, we are sitting back while a tidal wave of CBD seems to be going into everything to cure anything. Doesn't this set off alarms? I can hear them; I believe FDA does as well. I urge FDA to respond to this need to protect all Americans through the FD&C Act mandate. Use the tools the FDA has to regulate CBD just the way it treats other products making health claims. The public health demands this. The country deserves it.

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