

July 16, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Public Comments Submission (Docket FDA-2019-N-1482) Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds

To Whom It May Concern:

On behalf of the 54 million adults and 300,000 children in the US living with doctor-diagnosed arthritis, the Arthritis Foundation is pleased to submit comments to the FDA on its request for comments on Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds.

Based on the Arthritis Foundation's mission and its research into patient insights, we recommend that the FDA focus on efforts to gather more data on CBD-based products and their effects; implement standardized quality control and labeling requirements; and prioritize consumer education about these products. Please find our detailed patient insights and recommendations below.

The Arthritis Foundation conducted a survey in July 2019 to gain patient insights on their use and perception of CBD-based products. Key data points include:

- 79% of those surveyed are currently using CBD-based products, have used them in the past, or are considering using them; only 17% said they are not using it and would never consider it.
- Of those currently using CBD:
 - 87% use it to manage their arthritis symptoms
 - 94% use it to relieve their pain
 - Over 70% reported it to be "very effective" or "effective" in relieving each of the following symptoms: anxiety, nausea, inability to sleep, and pain
 - 66% talked to their doctor about using it; of those, 46% report receiving information about it from their health care provider
 - 63% use it daily, and 26% use it several times per week
 - 62% take it via oral application of a liquid solution; 55% use topical application on affected joints
 - 33% purchase CBD products online; 29% purchase through a dispensary; 25% purchase through a retail store; in some areas, patients report getting it directly from their doctor.

- Of those who haven't tried CBD-based products or are considering using them, 47% say the reason is because they are not sure if it will work; 40% said it is because they don't trust it; 17% said it is because it's not legal
- Of those who are not considering using CBD, 45% say it's because their symptoms are managed via other treatments; the primary treatment they report using to manage their symptoms is NSAIDs.

The quantitative and qualitative data we have collected from patients on this topic indicate a clear need for more research and data on CBD-based products and their effects, in addition to more consumer education about these products.

People with arthritis primarily use CBD products for symptom management, particularly pain management, which correlates with the many surveys we have conducted over the past three years showing pain as the number one arthritis-related challenge patients face. The prevalence and impact of pain among people with arthritis is startling. Our surveys show that 91% said pain interfered with their day-to-day activities.

Scientific literature and our patient insights show that people with arthritis are disproportionately affected by emotional and mental health challenges, such as anxiety and depression, as well as sleep problems. This increases the likelihood that they currently use or are considering the use of cannabis-based products as remedies, as initial research suggests they may be useful in mitigating the impact of these conditions.

Several survey respondents have indicated they use CBD products because it seems less addictive and risky than other pain management options like opioids. They've also taken it to transition off opioids following joint replacement surgery.

We received several responses that indicate a need for more patient education. Some common themes include:

- Lack of knowledge of any risks of CBD, including responses indicating there is no downside to taking CBD.
- Lack of knowledge of whether CBD products are legal.
- Lack of understanding regarding quality standards among products.

Other responses indicate a need for broader FDA regulation, including:

- Differences in effectiveness of products with purportedly similar concentrations of CBD, indicating misleading labeling, marketing, or quality control.
- Lack of data on dosage, which makes it difficult to know how much to use.

- Lack of data and industry standards to compare efficacy across products.

With the above patient insights in mind, the Arthritis Foundation recommends that the FDA:

- Use its regulatory authority to establish a set of minimum standards that all companies that manufacture and market CBD-based products must meet.
- Implement labeling requirements to at a minimum differentiate the uses, dosage recommendations, and risks of each product.
- Work closely with the National Institutes of Health, other agencies, and companies engaged in CBD research to strengthen the level of research and data collection on CBD products and their efficacy, and to expedite the work given the percentage of patients already using the product.
- Develop an education initiative to provide trusted, easy-to-use educational tools to consumers.

We are continuing to collect patient insights and urge the FDA to use the Arthritis Foundation as a resource and work with us to implement the above recommendations. Please contact Vincent Pacileo, Director of Federal Affairs, at vpacileo@arthritis.org for more information or if we can be of assistance in any way.

Sincerely,



Anna Hyde
Vice President, Advocacy and Access
Arthritis Foundation

