CONSUMERS FOR
Safe CBD
4safecbd.org

CBD: IMPLICIT, UNSUBSTANTIATED THERAPEUTIC CLAIMS

Unregulated, untested CBD products are being irresponsibly marketed to consumers across the United States – we need scientific research to ensure Americans have access to safe CBD.

Retail CBD products are not confirmed to be safe

> FDA U.S. FOOD & DRUG ADMINISTRATION
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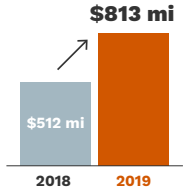
> [S]ome people wrongly think that the myriad of CBD products on the market, many of which are illegal, have been evaluated by the FDA and determined to be safe, or that trying CBD 'can't hurt.' We want to be clear that **a number of questions remain regarding CBD's safety** – including reports of products containing contaminants, such as pesticides and heavy metals – **and there are real risks that need to be considered.**
>
> **- FDA,** November 25, 2019[1]

The difference between FDA-approved products and the countless others on the retail market, is significant:

	RESEARCH FOR CBD MEDICINES	RESEARCH FOR CBD MARKETING
1 Cost of Thorough Research	A manufacturer spends on average **$2.6 billion** to develop a new FDA-approved medicine and demonstrate safety and effectiveness. **Cost to research & develop a new medicine:** **$2.3 - 2.8 billion**	All CBD consumer products forego the FDA review process, ultimately avoiding that investment, yet sales have jumped from **$512 MILLION** in 2018 to **$813 MILLION** in 2019
2 Quality and Safety Take Time	Developing a new FDA approved drug takes **at least 12 years** from initial discovery to the marketplace—with clinical trials alone taking six to seven years on average. **12-15** years	Of the nearly **500 CBD clinical trials registered**, less than 10% are in Phase 3 – nearing approval – and few will lead to FDA-approved medicines. **10%** Completed Clinical Trials



	RESEARCH FOR CBD MEDICINES	RESEARCH FOR CBD MARKETING
3	**Intensive Oversight Protects Consumers**	There is currently only **1 prescription CBD medicine legally available today**, meaning it has met the rigorous FDA evaluation standards for safety and efficacy. 	FDA continues to take enforcement action against companies making dubious claims, issuing **50% more warning letters** since May of 2019. 
4	**Research Publications Provide Further Proof**	Peer-reviewed publication of translational research, including publication of early (pre-clinical) to late phase (phase III) **clinical research is required** to demonstrate safety and efficacy of new medicines. 	Cannabis companies increasingly ink **partnership deals with prestigious U.S. universities**, publishing early-phase or proof-of-concept results - often misleading the public to believe therapeutic claims are legitimate. 

> FDA U.S. FOOD & DRUG ADMINISTRATION
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> If the widespread availability of consumer CBD products were to significantly discourage clinical research, our knowledge of CBD's potential medical uses could be stunted.
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> **- FDA,** March, 2020[2]

Clinical research studies have barely scratched the surface when considering the vast array of cannabis products available to consumers. The risk of retail cannabis products harming public health must be mitigated by swift and evidence-based regulatory action.[3]

When it comes to the research and study behind FDA-approved CBD products and research involved in marketing unregulated CBD products,

there is no comparison.

More work must be done to ensure that CBD products are safe, effective, and ethically marketed. We must do more to protect consumers.

[1] Abernethy A, FDA Principal Deputy Commissioner, FDA News Release, "FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns," (November 25, 2019); available at https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details.

[2] FDA, Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations, Cannabidiol (CBD), Report in Response to Further Consolidated Appropriations Act, 2020, at 7 (March 5, 2020); available at https://cannalawblog.lexblogplatform.com/wp-content/uploads/sites/109/2020/03/Report-to-the-US-House-Committee-on-Approrpriations-and-the-US-Senate-Committee-on-Appropriations-Cannabidiol-FDA.pdf

[3] Ibid., at 41-42.

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