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

[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

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

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

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.

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

Ongoing

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.

Cost to research & develop a new medicine:

$2.3 - 2.8 billion

Completed Clinical Trials

2018

2019

$512 mi

$813 mi
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.  

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<tr>
<th>RESEARCH FOR CBD MEDICINES</th>
<th>RESEARCH FOR CBD MARKETING</th>
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<tr>
<td><strong>Intensive Oversight Protects Consumers</strong></td>
<td>FDA continues to take enforcement action against companies making dubious claims, issuing <strong>50% more warning letters</strong> since May of 2019.</td>
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<td>There is currently only <strong>1 prescription CBD medicine legally available today</strong>, meaning it has met the rigorous FDA evaluation standards for safety and efficacy.</td>
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<td><strong>Research Publications Provide Further Proof</strong></td>
<td>Cannabis companies increasingly ink <strong>partnership deals with prestigious U.S. universities</strong>, publishing early-phase or proof-of-concept results - often misleading the public to believe therapeutic claims are legitimate.</td>
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<td>Peer-reviewed publication of translational research, including publication of early (pre-clinical) to late phase (phase III) <strong>clinical research is required</strong> to demonstrate safety and efficacy of new medicines.</td>
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--- **FDA, March, 2020**

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.  

When it comes to the research and study behind FDA-approved CBD products and research involved in marketing unregulated CBD products, more work must be done to ensure that CBD products are safe, effective, and ethically marketed. We must do more to protect consumers.

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3. Ibid., at 41-42.