

CANNABIS INTELLIGENCE BRIEFING

Pharmacies vs. Dispensaries: The Future of Cannabinoids as Medicine



Executive Summary



Pharmacies vs. Dispensaries: The Future of Cannabinoids as Medicine

PUBLISHED BY



IN PARTNERSHIP WITH



3	Letter from the Editor
5	Executive Summary The Total Cannabinoids Market: Dawn of New Era
8	The Big Picture Medical versus Pharmaceutical
21	Cannabis Science The Botany and Chemistry of Cannabis
25	Pharmaceutical Cannabis The Regulatory Challenges
29	The Pipeline Pharmaceutical Cannabinoid Research and Development
32	Conclusion Medical Cannabinoid Options Will Abound
35	Appendix Drugs in Development

**Pharmaceutical companies for the first time ever
will have to convince consumers and regulators that
their protocols, trials, compound isolation and purity
processes are really worth the expense versus a much
cheaper option readily available just down the street**

Letter from the Editor

What a chapter it will make in the history of science: A band of true believers in the benefits of consuming cannabis gets states to authorize its use for medical purposes starting in 1996. Many scoff that it's just a ruse to get a recreational drug legalized, but it turns out cannabinoids derived from the plant do have efficacy in the treatment of intractable childhood epilepsy.

Last year the Food and Drug Administration (FDA) made the anecdotes official by approving the sale of GW Pharmaceutical's CBD-based Epidiolex for just that purpose. Meanwhile, the case studies and clinical outcomes overwhelmingly demonstrate that cannabidiol (CBD), tetrahydrocannabinol (THC) and likely other cannabinoids derived from *Cannabis sativa* plants, have efficacy in the treatment of many other health problems.

By the time Epidiolex went on sale in pharmacies in 4Q 2018, the number of states allowing the sale of CBD- and THC-containing products at dispensaries had grown to 33. In December, Congress legalized the growing of hemp, defined as low-THC (but potentially very high-CBD) *C. sativa* plants. In theory, at least, as long as marketers don't make specific health claims, companies can sell products with amounts of CBD similar to Epidiolex in United States retail outlets.

That puts Epidiolex in a unique position in the history of pharmaceutical drugs. GW hopes to sell this CBD drug at an average of \$32,500 annually. This is a drug with an active ingredient that is available not just in cannabis dispensaries in legal states, but in health food stores, grocery stores and every kind of general retail outlet in

the country, at a lower cost. Even if retailers decide not to defy federal laws by explicitly marketing products claiming to treat seizures, there's nothing to stop consumers from emulating the proven dosages either in stores or through home-grown hemp.

But the first approval of a naturally-derived pharmaceutical cannabinoid cuts both ways: Medical cannabis retailers, after 22 years of flying under the radar, now face pharmaceutical-grade competition. This report is a first effort to map out the likely parameters of a race to bring the medical benefits of cannabis to consumers who have been denied them—at least legally—for eight decades.

The stakes for the practice of medicine could not be much larger. What if it turns out, as Dr. Kevin Spelman suggested at the February 7 Arcview Market Research Investor Summit in Santa Monica that “Cannabis is not a gateway drug, it is a gateway plant that shows health-care providers that medicinal plants may provide efficacy at a fraction of the cost of pharmaceuticals.”



Tom Adams
Editor in Chief
Arcview Market Research
Managing Director
BDS Analytics

Acknowledgements & Disclosure

Publisher

Arcview Market Research in partnership with BDS Analytics

Report Design

Jason Deller
Micah Daigle

Editor In Chief

Tom Adams

Advisors

Troy Dayton
Roy Bingham
David Abernathy

Analysts

Brendan Mitchel-Chesebro
Christine Arrington
Michael Arrington
Maya Jasmin
Laura Lee—Director of Operations

Disclosure

There are many companies mentioned in this report. Some of them are clients of The Arcview Group, BDS Analytics and/or their officers and employees. In some cases, the publishers own minority stakes, warrants, or options in them. Neither Arcview nor BDS has received any compensation for coverage in this report. Since such a high percentage of companies in the sector are Arcview or BDS clients it's part of what makes them most suited to have the deepest understanding of the markets.

Methodology

The foundation of Greenedge™ data is BDS Analytics' panel of participating dispensaries who contribute daily point-of-sales data. Dispensary panels are recruited to be both statistically significant as well as representative of the makeup of dispensaries in the market. Panel recruitment is ongoing, and, whenever possible, new participating dispensaries provide historic sales data that is incorporated into the data of record. As the underlying sample increases over time, historic data also undergoes changes that could impact category mix, brand/product share and average retail prices.

Executive Summary

To date, medical cannabis has primarily been sold at dispensaries in the United States and via mail order in Canada to consumers who have obtained government permission to buy it legally. That is changing as more entities explore and study cannabinoids and the other chemicals found in cannabis for use in pharmaceutical drugs.

While the pharmaceutical industry is one of the largest economic sectors by spending, at an estimated \$1.2 trillion worldwide in 2018, pharmaceutical cannabis drugs are in their infancy. Current revenue from existing drugs is estimated in the tens of millions. As drug trials and approvals happen that number will grow, but in the time frame of our forecast the market will remain small (see “Medical Cannabis Lays the Groundwork”), less than 10% of legal cannabis product sales in 2022.

Cannabinoid receptors are present in the nervous systems of mammals where they interact with neurotransmitters to either amplify or inhibit their actions. The endocannabinoid system is a fairly recent discovery that most physicians do not learn about in medical school. Only a relative handful of medical professionals are comfortable even discussing the subject, much less recommending using cannabis as an adjunct to medical treatment.

However, medical cannabis is helping patients, and that has prompted development efforts at dozens of pharmaceutical companies, as detailed in this report. How far

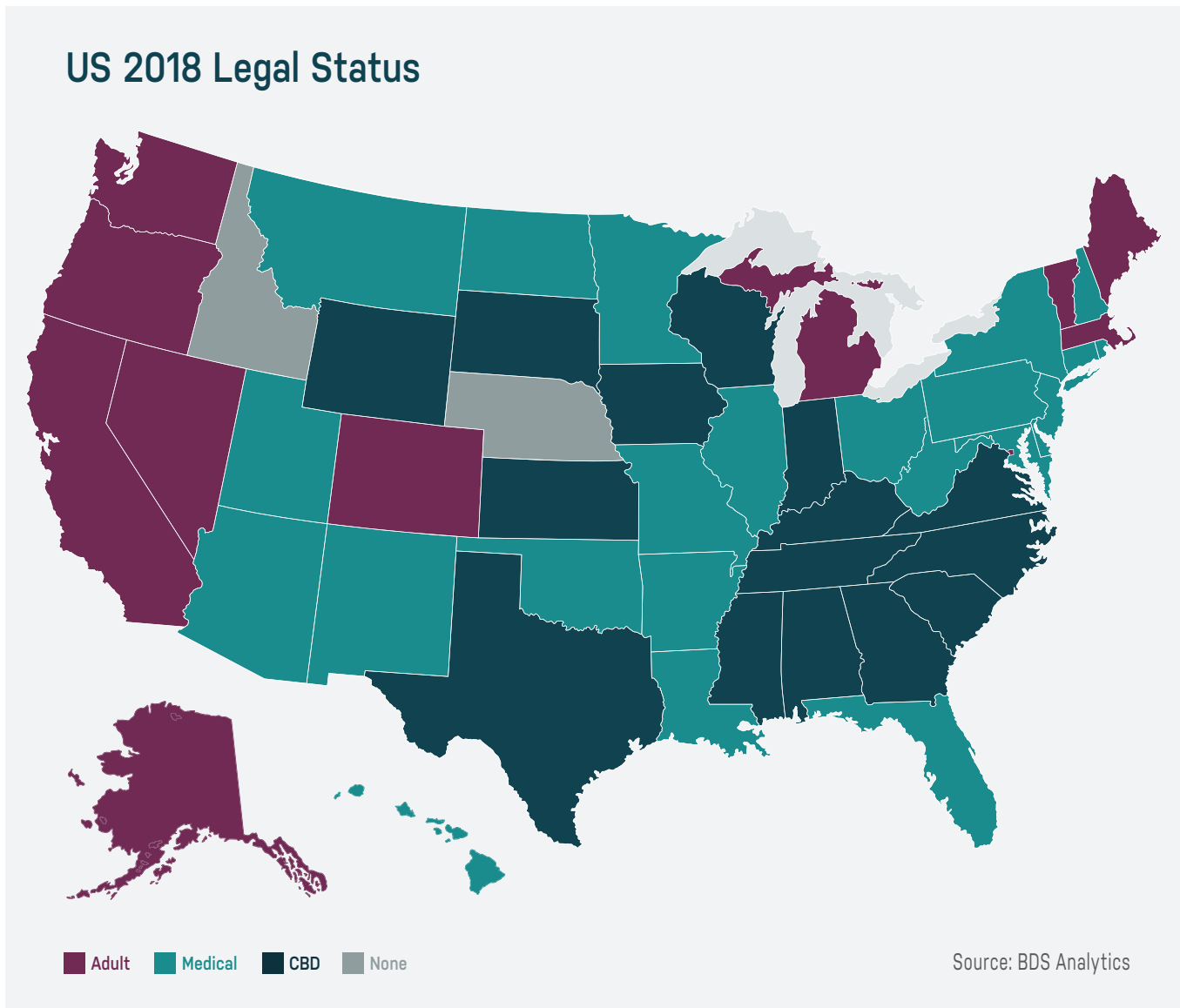
and how fast the existing medical cannabis market can go in treating those conditions before the pharmaceutical industry can get products through the regulatory hoops and to patients will be a key determinant of the relative success of the two related, but very different, industries.

The June 2018 FDA approval of Epidiolex from UK-based GW Pharmaceuticals was a turning point; it is the first approved pharmaceutical drug naturally derived from cannabis plants in the US. Previous pharmaceutical cannabinoid drugs have been synthetic or semi-synthetic. Equally important, the FDA’s action forced the Drug Enforcement Administration (DEA) to reschedule the

In states that have legalized medical cannabis, opioid drug use has decreased significantly, up to a reported 30%, in statistics tracked through the government’s Medicaid programs

Epidiolex formulation on the Controlled Substances Act (CSA) scheduling from I to V. This does not mean the floodgates will open to a blanket approval for plant-based cannabis products. Any other drug from the pharmaceutical channel will have to go through the same rigorous process.

This event brought light to a very serious battle that has been going on in state legislatures as pharmaceutical cannabinoid makers push local authorities to write laws requiring FDA approval for CBD products. It is shaping up to be one of the most consequential battles in the legal cannabis industry's short history.



Thirty-three states and the District of Columbia have passed medical cannabis laws in the US. In those states where medical cannabis possession is legal, it is up to a physician's discretion to recommend cannabis to patients. Cannabis remaining classified as a Schedule I drug at the federal level contributes greatly to physician reluctance to recommend it to, or even discuss it with, their patients.

Even so, cannabis has been recognized for years for its ability to help manage many conditions (see "The Botany and Chemistry of Cannabis"). Now studies are showing that in states that have legalized medical cannabis, opioid drug use has decreased significantly, up to a reported 30%, in statistics tracked through the government's Medicaid programs. But there are still significant political hurdles for pharmaceutical cannabis medicines, particularly in the US where strict prohibitions remain in place regarding cannabis use throughout the medical system.

Now that Epidolex has FDA approval, however, doctors will have more freedom. Off-label use, the practice of doctors prescribing a drug for conditions other than those explicitly approved, is one area of freedom. Off-label uses are typically not reimbursed by insurance companies, so the expense would be borne by the patient.

Most of the already-approved cannabis-related products are in current clinical trials for multiple other indications. Proper pharmaceutical life-cycle planning to include those future uses can help expedite paths that would decrease time to market for pharmaceutical cannabis drugs for those potential uses.

The FDA approval process is strict and doesn't lend itself to a product that is a naturally grown plant. While many plant-based drugs have been approved prior to Epidolex, there are no standardized tests for plants. Therefore we will continue to see such products approved one by one.

The legal cannabis market has been characterized by two main channels: medical and adult use. Medical cannabis is typically available via retail or mail order in 30-plus countries with the recommendation of a medical professional. Laws requiring payers to cover cannabis exist in some markets (see "Medical Cannabis Lays the Groundwork"), and this will be a key factor in the battle to come between pharmacies and dispensaries. The adult-use market consists of highly regulated, heavily taxed retail sales to adult consumers in four countries and 10 US states plus the District of Columbia.

The pharmaceutical cannabis market, in contrast, is disease-specific, clinically trialed, government approved and payer eligible (e.g. covered by insurance) use of pharmaceutical cannabinoid products (see "Approved Pharmaceutical Cannabis Drugs"). It is the wild card in the already complicated cannabis market.

There are a host of outright facts we just don't know yet about cannabis science that will profoundly affect the medical, pharmaceutical and even adult-use markets. But the approval of Epidolex for distribution through the pharmaceutical channel has given the questions explored in this report a whole new sense of urgency.

Subscribe Today to the Cannabis Intelligence Briefing Series

Intelligent data and insights for the cannabis industry at your fingertips

Our annual subscribers receive:

- Every briefing as soon as it is released during the yearlong subscription
- *The State of Legal Cannabis Markets, 7th Edition* + Mid-Year Update
- Instant access to all historical intelligence reports

Briefings Available Today



Subscribe Today!
shop.bdsanalytics.com



Visit shop.bdsanalytics.com to purchase individual reports for \$297 each or to subscribe to the Cannabis Intelligence Briefing Series for \$1,975. For questions, please contact info@bdsanalytics.com.

Cannabis, meet capital.

Prohibition is crumbling. Invest in what comes next.

197

Funded Companies

\$225M+

Invested

1200+

Investors



THE
ARCVIEW
GROUP

Arcview is the #1 source of deal flow in the fastest growing industry. If you qualify as a high net worth accredited investor or if you are an entrepreneur raising capital, Arcview might be right for you.

The Pharmacy vs. Dispensaries: The Future of Cannabinoids as Medicine report was published as part of our Cannabis Intelligence Briefing Series.

Other recently released reports from the Series include:

- Cannabis Retail: The \$23 Billion Opportunity
- Cultivation: Capitalizing on a Tripling of Legal Demand
- US Legal Cannabis: Driving \$40 Billion Economic Output
- The Road Map to a \$57 Billion Worldwide Market
- California: The Golden Opportunity?
- Concentrates: The Hottest Product Category in Cannabis
- The Tasty Future of Cannabis Edibles
- Flower: The Foundation of the Cannabis Industry

Additionally, subscribers to our Cannabis Intelligence Briefing Series gain access to the comprehensive, annually released *The State of Legal Marijuana Markets* book and the corresponding mid-year update.

For more information on purchasing a Series subscription, or to learn about any of the specific reports listed, please visit shop.bdsanalytics.com.



The leader in cannabis business intelligence and market share tracking

**It's simple. We provide answers.
You make more money.**

We answer the **WHO, WHAT, WHEN, WHERE, WHY, HOW MUCH**, and **WHAT'S NEXT** in cannabis.

“BDS Analytics has been a great partner from Day 1. The retail data they provide our business helps us in so many ways. We're able to track trends, more smartly merchandise our dispensary, and just make better business decisions all-around.”

Debby Goldsberry, Executive Director, Magnolia Wellness



Ready to build a successful cannabis business?

We recommend you subscribe to our industry-leading GreenEdge™ Platform which powers our retail sales tracking data, unrivaled cannabis consumer research, and industry intelligence reports and services.

And for dispensaries across the US, we are actively recruiting GreenEdge dispensary partners in medical-only and adult-use markets.

Contact us today to learn more.

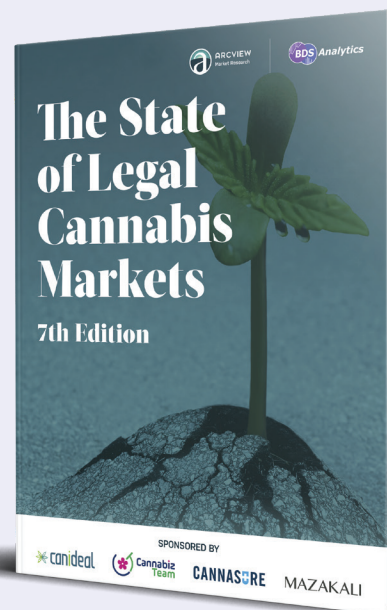
info@bdsanalytics.com | bdsanalytics.com | 720.465.9692

Just Released



The State of Legal Cannabis Markets, 7th Edition

The #1 cited market research for the cannabis industry, co-produced by Arcview Market Research and BDS Analytics



The report is a must-read for serious players in the cannabis industry looking for a competitive advantage.

Featuring:

- You'll receive digital and hardbound versions of the 352 page report
- 178 data-rich charts and graphs/tables
- Downloadable slides of selected charts

“The depth and breadth of this report is unsurpassed and simply not available anywhere else.”

Mark Passerini, Om of Medicine



As Seen In

THE
WALL STREET
JOURNAL

FORTUNE

Forbes

Bloomberg

Get Yours Today!

Purchase at shop.bdsanalytics.com