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Research Recap: Potential Cannabis-Based Medicines

Updated January 5, 2017

Background

A small, but growing, number of cannabis extracts with possible therapeutic benefits have been isolated for federally-authorized clinical trials testing to determine safety and efficacy as potential medicines, with one closely watched product nearing consideration for approval by the FDA. Two cannabis-based synthetic products are currently on the market, and available by prescription. Additional cannabis derivatives are being eyed for possible future study.

Clinical Trials to Market Status

Epidiolex

Made by GW Pharmaceuticals (GW), *Epidiolex* is a nearly pure cannabidiol (CBD) product with almost no psychoactive tetrahydrocannabinol (THC). The first physician-sponsored Expanded Access program was opened for *Epidiolex* in the spring of 2013, followed by an Investigational New Drug exemption for clinical trials research—including in Iowa—in the spring of 2014 to study two forms of intractable epilepsy: Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS). The FDA has granted GW Orphan designation for both syndromes.

Results of two Phase 3 studies of *Epidiolex* for LGS released by GW in 2016 showed 44% and 42% reductions in seizure frequency respectively vs. 22% and 17% for corresponding placebos. Results of the first Phase 3 study of *Epidiolex* for DS, released by GW in 2016, showed a 39% reduction in seizure frequency vs. 13% for placebos.

Based on these results, GW plans to submit a New Drug Application to the FDA in the first half of 2017. If the FDA approves and the DEA and affected states reschedule *Epidiolex*, GW estimates *Epidiolex* could be on the U.S. market as a prescription drug in early 2018.

Sativex

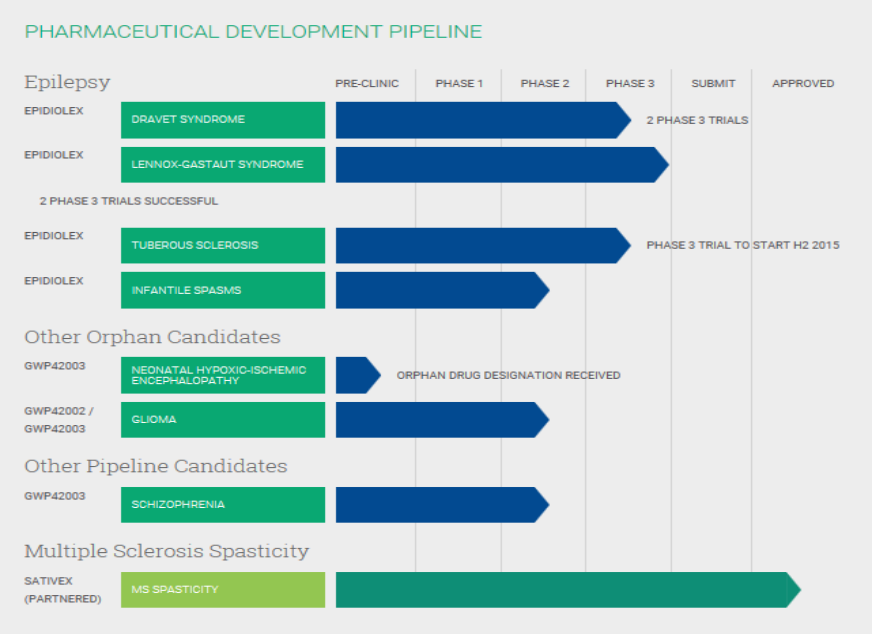
Sativex is a cannabis-based mouth spray product, containing CBD and THC. Made by GW, it was initially tested in U.S. clinical trials for treating cancer pain. However, in 2015 those trials failed to produce positive results necessary for FDA approval. GW says it's starting a new set of clinical trials to test *Sativex* for the treatment of MS and related spasticity conditions, uses for which the product has already been approved in Canada and some European nations.

Marinol and *Cesamet*

These orally-administered medicines contain a synthetic version of THC found in the cannabis plant. *Marinol* and *Cesamet* are formulated to treat nausea and vomiting caused by cancer chemotherapy, and *Marinol* is also used to treat appetite and weight loss in patients with HIV infection. Both medicines are FDA-approved, and available by prescription in the U.S.

Other Cannabis-Based Products

GW is working to clinically test *Epidiolex* and other pharmaceutical product formulations of cannabis derivatives in the U.S. as possible treatments for other conditions, including: Tuberous Sclerosis; Infantile Spasms; Neonatal Hypoxic-Ischemic Encephalopathy (a.k.a. Perinatal Asphyxia); Glioma; and Schizophrenia.



The University of Iowa Children's Hospital reports 11 studies are recruiting patients for epilepsy treatments involving cannabis-based derivatives, and a few studies will soon be published.

Iowa Medical Cannabidiol (CBD) Act Registration Card Program

The Department of Public Health reports the following results for approximately the first two years of Iowa's legislatively-approved Medical CBD Program, implemented January 30, 2015.

2016 CBD Card Activity-Year 2 (1/30/16-1/5/17)	**2015 CBD Card Activity-Year 1** (1/30/15-1/29/16)
Apps Approved/Received = 45 of 48	Apps Approved/Received = 53 of 56
Renewal Apps Approved/Received = 27 of 27	Renewal Apps Approved/Received = NA
Cards Issued/Approved = 107 of 142	Cards Issued/Approved = 96 of 130

Other Developments in U.S. Marijuana-Related Research

In 2015, HHS eliminated an extra layer of Public Health Service review for non-government funded CBD research and the DEA eased regulatory requirements for FDA-approved CBD clinical trials requiring additional product. The USDOJ and HHS are currently evaluating CBD to determine whether it can be classified on a lower controlled substance schedule under federal law than the entire marijuana plant, which may further ease CBD research.

The National Institutes of Health invested $111 million in 281 cannabinoid research projects in FY15, including 49 projects ($21m) to examine potential therapeutic properties of cannabinoids and 15 CBD projects ($9m). This is in addition to 17 independently funded research projects approved since 1999 to study possible therapeutic uses of marijuana and its derivatives.

In 2016, the DEA published a rule requiring a separate drug code for researching marijuana extracts such as CBD. The DEA also announced a policy change to allow additional entities to apply to become registered to grow and distribute marijuana for FDA-authorized research purposes. As of 2016, the DEA reported 350 individuals currently registered to conduct research on marijuana and its components.

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