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Developing Cannabis-Derived Products as Modern Prescription Medications

Alice Mead, Vice President, U.S. Public Policy & Public Affairs
Greenwich Biosciences
GW Pharmaceuticals (Greenwich Biosciences in the US)

• Founded in the UK in 1998 by Drs. Geoffrey Guy and Brian Whittle
  - Goal was to develop a range of prescription medications derived from the cannabis plant or its individual components
  - Developed under conventional regulatory standards for pharmaceutical products
Sativex®

- **Sativex®** is a 1:1 cannabidiol (CBD) to tetrahydrocannabinol (THC) ratio (of its main cannabinoids);
  - Retains minor cannabinoids and other active plant components;
- Delivered as an oromucosal spray
- Approved in Canada in 2005 and is now approved in 28 countries **ex-US** for spasticity in multiple sclerosis;
- First cannabis-derived product approved as a prescription medicine in modern times
Epidiolex®

- Comprised of cannabidiol (CBD) purified from a high-CBD extract;
- Approved by FDA on June 25, 2018, for the treatment of seizures in two types of catastrophic childhood onset epilepsies
- First cannabis-derived product ever approved by FDA
Production of Botanical Raw Material (BRM)
Quality

• Plants bred to express very precise cannabinoid content;
  - cannabidiol (CBD)-rich plants very high in CBD

• Grown in computer controlled greenhouses
  - Temperature, humidity, and lighting controlled

• Natural, proprietary growth medium devoid of heavy metals

• No pesticides or fungicides used

• Propagation by clones; no genetically modified plants

• Manufacturing done under GMP for pharmaceutical products; FDA inspects
Epidiolex Commercial Growing (45 acres): CBD-rich Chemovars for Efficient Production
Safety and Efficacy

• Large body of safety and toxicology studies in animals
• Phase 1-3 studies in human subjects/patients including large randomized, double blind, placebo controlled trials
• Multiple drug/drug studies
• Full package of abuse potential studies, e.g., receptor binding, animal studies, human abuse liability study
Schedule I Research & Development—It Can be Done!

• The research steps are the same as for any other investigational prescription product.
  - Preclinical
  - Phase 1
  - Phase 2
  - Phase 3

• However, all researchers must secure special Schedule I research registrations from DEA and additionally Schedule I licenses from the state controlled drugs authority.
  - Special security provisions for handling, storage (safe), recordkeeping, etc.
Moving Out of Schedule I

• Sponsor must provide data to FDA from abuse liability studies.
• At the end of the approval process, FDA will make a scheduling recommendation to DEA.
• Upon FDA approval, a cannabinoid product must be moved to a lower schedule (II-V).
  - FDA approval constitutes “accepted medical use”
• DEA will issue an interim final rule (IFR) within 90 days of approval, after which time the product can be marketed and dispensed.
  - A full rescheduling administrative process follows

• **Rescheduling under state law then required**
What Can States Do To Facilitate The Development Of New RX Cannabis-Derived Medications?

- Reschedule or make other changes to state law promptly following FDA approval and DEA rescheduling so Rx products can be dispensed in pharmacies
  - This would have no effect on laws allowing access to cannabis for medical or adult use.

- State laws and regulations that govern state-authorized vernacular cannabis products should not be interpreted to apply to FDA approved products

- Ensure that manufacturers and vendors of state-authorized, non-FDA approved cannabis products do not make medical claims if they have not conducted their own controlled clinical trials

- State laws should not prevent manufacturers of either FDA approved products or state-authorized vernacular products from enforcing whatever intellectual property and other rights they may have
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