Small Step or Giant Leap? FDA Approves Cannabis-Derived Drug for the First Time

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By Darren Grady on June 27, 2018

On June 25, 2018, for the first time in its history, the Food and Drug Administration approved the use of a drug derived directly from cannabis. The drug, called Epidiolex, treats two specific epileptic syndromes – Dravet syndrome and Lennox-Gastaut syndrome – both of which can affect infants and children under the age of five. This decision comes following extensive clinical studies of the cannabis based medicine. In the past, the FDA has only approved *synthetic* variations of Tetrahydrocannabinol (THC) and other cannabis compounds (typically for use in combatting nausea and weight loss in cancer and AIDS patients).

So, does this mean that the FDA is going to start approving, at the federal level, marijuana use for a panoply of conditions from back pain to PTSD? Not quite. Epidiolex contains a very specific and highly purified cannabidiol (CBD), a compound found in Cannabis which does not induce the "high" often associated with marijuana use. THC, *not CBD*, is the principal psychoactive compound in marijuana. It is widely believed that many parents of children with these epileptic conditions have already been supplementing their children's treatment with non-pharmaceutical grade (and non-FDA approved) CBD products. Following the FDA's approval of Epidiolex, children can now be prescribed a pharmaceutical grade medicine that has been extensively tested and vetted by the FDA.

It remains to be seen how the FDA approval of Epidiolex will affect the myriad of CBD products that anyone can purchase without a prescription, the legality of which is somewhat unclear, *for now*. Although many CBD products are readily available, CBD (and all other components in marijuana) remains a Schedule I drug under the Controlled Substances Act (along with heroin, LSD, ecstasy, Quaaludes, and peyote). This means that that CBD has "no currently accepted medical use" in the eyes of the Drug Enforcement Administration. The FDA often works with the DEA regarding the scheduling of substances and the FDA approval of Epidiolex is a likely indicator that CBD will soon be rescheduled. In fact, CBD will have to be removed from Schedule I by the DEA for Epidiolex to be sold legally under federal law.

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Although the proverbial dam has not totally broken for federal approval of more cannabis based medicines, the approval of Epidiolex has been hailed as a "historic milestone" by manufacturer GW Pharmaceuticals. The FDA's decision shows, for the first time, the federal government's willingness to review scientifically legitimate and accepted clinical studies for the specific use of cannabis based drugs for a narrow set of medical conditions that are in need of more effective treatments. The importance of that willingness cannot be understated as the medical benefits of cannabis continue to be studied and acknowledged by medical professionals nationwide. The approval of Epidiolex may very well be seen as the point where the formal federal approach to cannabis based medicine pivots away from politics to a focus on sound medical science.

Epidiolex will likely be available for prescription and sale later this year (pending reclassification) and will become a much needed option for patients who have not had success with other treatment plans. Should patients begin seeing the results that were shown in the clinical studies that led to the FDA's approval, and should competing pharmaceutical companies see the obvious financial benefit that GW Pharmaceuticals is likely to reap for being the first to market, we can expect other large pharmaceutical companies to accelerate their research and testing on cannabis based medicines for more conditions that are otherwise ill served by current treatment options.

For now, the FDA approval of Epidiolex is a small but highly significant step in the ever evolving and fast growing world of cannabis based medicine. However, if FDA approval of cannabis based medications continues, one day the approval of Epidiolex will be viewed at as a giant leap for the medical community and cannabis industry.