A year of Epidiolex: The first FDA-approved medical marijuana drug for epilepsy

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On June 25th the FDA-approved Epidiolex (GW Pharmaceuticals plc), a cannabidiol (CBD) based drug to treat both Lennox-Gastaut and Dravet syndromes, two rare forms of epilepsy. Epidiolex is the first drug product based on an active ingredient in marijuana approved for use in the US and is the first drug approved to treat Dravet syndrome. The FDA's approval of Epidiolex indicates that CBD will have to be rescheduled under the Drug Enforcement Agency (DEA) and that marijuana-based compounds have a legitimate path to the US market.

CBD is a component derived from marijuana that does not elicit the intoxication effects typically associated with the use of the plant. Alongside its determined effectiveness at treating certain forms of epilepsy, preclinical data exists to suggest that CBD could be a potent anti-inflammatory treatment in combating osteoarthritis, a common arthritic condition. CBD is currently classified as a Schedule I drug according to the DEA, a classification that implies a drug has a high potential for abuse and has no accepted medicinal value.

With the FDA's recent approval of Epidiolex, CBD must be rescheduled, which will have a profound impact on future marijuana-based pharmaceutical products. In a statement released on June 25th, GW Pharmaceuticals plc stated that it expects CBD to be rescheduled within 90 days. In the US, marijuana is illegal at the federal level and has only been fully legalised in nine US states and for medicinal purposes in an additional 21 states. It is currently unclear how Epidiolex will enter the remaining states where marijuana and its derivatives remain illegal.

Another major aspect of the launch of Epidiolex will be if patients will use the drug over medicinal marijuana preparations of CBD. When faced with this question at the Bank of America Merrill Lynch Healthcare Conference, GW Pharmaceuticals CEO Justin Grover stressed that these epileptic conditions aren't trivial and that taking approved therapeutics is vital. Grover also indicated that the therapeutic concentrations of CBD required were substantial and this would not be cheap to produce from medical marijuana.

An independent look into the price of non-FDA approved CBD oils demonstrated that the cost could be as high as $2,835 per ounce. To ensure Epidiolex's affordability, GW Pharmaceuticals is currently seeking payer coverage and stated at the Bank of America Merrill Lynch Healthcare Conference that payers "get the science" and "understand the value" of the drug.

If Epidiolex gets the coverage from payers that it expects, individuals on Medicare or Medicaid, approximately 55% of all estimated patients, would have a co-pay of between $5-10 and others in the commercial insurance space would have a co-pay of approximately $50-200, on par with competitor drugs ONFI (clobazam) and Banzel (rufinamide).

As Epidiolex continues to make headway into forging a legitimate pathway for marijuana-derived pharmaceuticals, the potential markets surrounding these compounds will continue to grow and gain social and legal acceptance.