May 14, 2020

Utah Department of Commerce
Division of Occupational and Professional Licensing
Utah Board of Pharmacy
Attn: Jennifer Falkenrath - Bureau Manager
P.O. Box 146741
Salt Lake City, Utah 84114-6741

**Re: Descheduling of Epidiolex® in Utah**

Dear Jennifer:

Greenwich Biosciences (a subsidiary of GW Pharmaceuticals plc, hereinafter referred to as "Greenwich") is the developer of Epidiolex®. Epidiolex is a highly purified cannabidiol ("CBD") oral solution prescription medicine approved by the Food and Drug Administration ("FDA") in June 2018 for the treatment of seizures associated with Dravet Syndrome and Lennox Gastaut Syndrome in patients two years of age and older.

On behalf of Greenwich, I am pleased to inform you that the Drug Enforcement Administration ("DEA") has removed Epidiolex from control under the federal Controlled Substances Act ("CSA"). In light of this positive development for Epidiolex patients in Utah, and for the reasons described below, I write to ask that the Attorney General please confirm that Epidiolex is now considered a non-controlled substance in Utah.

## I. Federal Descheduling of Epidiolex.

In September 2018, the DEA placed Epidiolex in Schedule V of the CSA. Because Utah incorporates federal scheduling laws, Epidiolex has been treated in Utah as a Schedule V substance under Utah Code § 58-37-4(2)(e)(ii).

On March 20, 2020, Greenwich received correspondence from the DEA—attached here as **Exhibit 1**—confirming that, as a result of the federal 2018 Agricultural Improvement Act ("AIA"), ***Epidiolex has been descheduled under the CSA*** by operation of law**.** The AIA defined the term "hemp" to "mean the plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 U.S.C. § 1639o. Under the AIA, hemp (as defined) is no longer a controlled substance—it is now excluded from the definition of "marihuana" under 21 U.S.C. § 802(16) and the listing of tetrahydrocannabinols under 21 U.S.C. § 812(c). Pub. L. 115-334, § 12619. Accordingly, as explained in the DEA's letter, the DEA determined that because Epidiolex is a cannabis derivative containing less than 0.1% delta-9-THC content, Epidiolex is no longer a controlled substance under the CSA.

As a consequence of the DEA's letter, the FDA recently removed the Schedule V designation from the Epidiolex label. This means that Epidiolex is no longer considered a Schedule V drug, and it can be treated as any other non-scheduled prescription drug. The revised FDA-approved label is attached as **Exhibit 2,** along with Epidiolex's listing on DailyMed[1] as **Exhibit 3**, which states that the drug is no longer scheduled by the DEA. The FDA's National Drug Code directory likewise shows the current status of Epidiolex as a descheduled drug.[2]

## II. Uniformity Between Utah's Controlled Substances Laws and Federal Law Necessitates Descheduling of Epidiolex in Utah.

Utah law incorporates the federal CSA into its controlled substances laws. Utah Code § 58-37-2(1)(f) ("controlled substance" includes drug or substances "included in Schedules I, I, III, IV, or V of the federal Controlled Substances Act"). This uniformity is particularly important when considering the controlled status of Epidiolex, or any other future FDA-approved cannabis-derived substance, in Utah. Under Utah law, an FDA-approved drug containing "any component of marijuana" is automatically scheduled in Utah according to the schedule it is placed in by the DEA under federal law. Utah Code § 58-37-4(2)(e)(ii) (Schedule V); *id.* § 58-37-4(2)(d)(vi) (Schedule IV); *id.* § 58-37-4(2)(c)(viii) (Schedule III); *id.* § 58-37-4(2)(b)(vii) (Schedule II).

Now that the DEA has descheduled Epidiolex and removed it from Schedule V of the CSA, it is Greenwich's understanding that Epidiolex should no longer be considered a scheduled substance in Utah. Utah Code § 58-37-4(2)(e)(ii). In other words, since Epidiolex is no longer "scheduled by the [DEA] in Schedule V of the federal [CSA]," Epidiolex would not fall under the definition of a Schedule V FDA-approved cannabis-derived substance under Utah Code § 58-37-4(2)(e)(ii). Epidiolex would also not fall under the definition of marijuana under Utah's Controlled Substances Act since Epidiolex is no longer scheduled under federal law. Utah Code § 58-37-2(1)(aa) (marijuana does not include "any compound, mixture, or preparation approved by the [FDA] under the federal Food, Drug, and Cosmetic Act . . . that is not listed in a schedule of controlled substances in Section 58-27-4 or in the federal [CSA]").

Finally, like the federal government, Utah excludes hemp and hemp-derived substances, including CBD, from control under Utah's controlled substances laws. Utah Code § 26-61a-113; *id.* § 4-41-402. Under Utah's Hemp and Cannabinoid Act, hemp is defined as "any part of a cannabis plant, whether growing or not, with a concentration of less than 0.3% tetrahydrocannabinol by dry weight." Utah Code § 4-41-102(2). Utah's hemp program expressly permits for the cultivation and processing of hemp and hemp-derived products containing less than 0.3% delta-9-THC.[3] Indeed, the Department of Agriculture maintains a list

[1] DailyMed is the National Institute of Health's website providing real time labeling information, as officially approved by the FDA.
[2] This database is available at https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm.
[3] As Utah's Department of Agriculture states: "Cannabidiol (CBD) products may be sold around the state of Utah, provided they are registered with the Department." Utah Department of Food and Agriculture, Industrial Hemp Program Laws and Rules,4-41 Hemp and Cannabidiol Act, *available at* https://ag.utah.gov/office-of-the-commissioner/industrialhempprogram/.

of hundreds of registered CBD products that may be sold, purchased, and consumed in Utah.[4] Again, Epidiolex is a highly purified CBD product derived from cannabis and contains less than 0.1% delta-9-THC concentration on a dry weight basis.

It would make little sense for Utah to continue to treat Epidiolex, and any future FDA-approved CBD drugs, as a Schedule V substance while other hemp products, including CBD, are currently excluded from control under Utah law. Indeed, it would allow for the decontrol of substances that are not in FDA-approved drug products (and which contain more THC than those approved drug products (up to 0.3% THC)), such as Utah-registered CBD products, while keeping FDA-approved drug products containing the same substances, like Epidiolex, in Schedule V.

For these reasons, Greenwich respectfully requests that the Attorney General confirm that Epidiolex is no longer considered a scheduled drug in Utah. Several other states have already taken this step since the DEA descheduled Epidiolex in March. Examples from Missouri and Ohio are attached as **Exhibits 4 and 5**.

## III. Compelling Policy Considerations Further Warrant Descheduling in Utah.

The descheduling of Epidiolex in Utah is important because it will remove barriers for patients, pharmacies, and licensed prescribers related to your state's controlled substance laws and regulations. In Utah, descheduling will allow for the following improvements in patient access and lessen the prescriber and pharmacist burdens in the following ways:

- **Burdens of Prescribing/Dispensing Controlled Substances** – Patients often encounter problems if they need to change pharmacies because current governing rules only grant permission to transfer controlled substance prescriptions on a one-time basis or not at all if the prescription needs to transfer to a retail pharmacy from a specialty pharmacy. Additionally, if a prescription needs to be transferred to another pharmacy before the initial fill, a new prescription must be written. In some cases, specialty pharmacies must obtain a controlled substance dispensing license from the DEA that they did not previously carry before patients needing an early refill can obtain one. Descheduling Epidiolex will eliminate these burdensome requirements.

- **Expensive and Cumbersome Storage and Handling Requirements** – Controlled substances must be stored in locked and secure safes, which are costly to install and burdensome for smaller, less sophisticated care settings like group homes and schools. The storage and handling of controlled substances places significant administrative burdens on staff, who must carefully document, report, track, and keep records for all uses of controlled substances. The descheduling of Epidiolex will allow for additional support personnel to more easily administer and handle this important medicine for vulnerable and medically fragile patients.

[4] This list is available on the Utah Department of Agriculture's website at https://ag.utah.gov/wp-content/uploads/2020/05/May-8th-Product-List-Final.pdf.

- **Telemedicine Limits on Initial Prescriptions and Refills** – In the COVID-19 pandemic environment, many healthcare practices and provider offices are attempting to shift to mostly telemedicine visits to limit in-person interactions. A consequence of this change is that starting new patients on Epidiolex or writing refill prescriptions is more difficult and may even be prohibited depending upon state telemedicine laws that apply to prescribing controlled substances. In many states, patients are required to have live, in-person visits for initial prescriptions and in some instances, refills.

- **Lower Patient Out-of-Pocket Prescription Costs** – We believe that descheduling will help lower patient copay and/or co-insurance costs for Epidiolex patients where insurers have placed controlled substances on higher cost specialty tiers or place additional, cumbersome prior authorization requirements on controlled substance prescriptions.

- **Confusion and Uncertainty Within Supply Chain –** The misalignment of state and federal rules create significant risks of supply disruptions to patients caused by wholesalers, pharmacies, institutions, and electronic medical records ("EMR") companies applying different requirements to Epidiolex prescriptions. For example, EMR systems used for prescribing are being updated to remove the Schedule V designation for Epidiolex, in accordance with federal law. However, when these EMR systems send electronic Epidiolex prescriptions to pharmacies as a non-controlled drug, some pharmacies reject them due to state scheduling laws, leading to delays in patients receiving their medication. These delays can be resolved by harmonizing state descheduling of Epidiolex with federal law.

If additional information would be helpful, or if you have questions, please do not hesitate to contact me at the contact information provided below.

Thank you for your assistance, and I look forward to your response.

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