Testimony HB 1213

January 18, 2021

Dear Chairman Weisz

Position on HB 1213 – Neutral but with concerns

Greenwich Biosciences is the US leader in the development and commercialization of prescription cannabinoid medicines to address serious medical conditions. Along with parent company GW Pharmaceuticals, we have been advancing cannabinoid science for more than two decades, with much of what is known about cannabinoids discovered by our researchers. In addition to lead product - EPIDIOLEX® (cannabidiol) oral solution, indicated for the treatment of seizures associated with three rare disorders - we have a robust pipeline of cannabinoid-derived therapies for serious illnesses (e.g., Rett syndrome, spasticity associated with multiple sclerosis and spinal cord injury, post-traumatic stress disorder, schizophrenia and autism spectrum disorders).

Concerns and Proposed Amendment to HB 1213

HB 1213, Section 1, states that a "cannabinoid solution" is a "solution consisting of a mixture created from cannabinoid concentrate and other ingredients" and that such a container may not exceed thirty milliliters. There is no exception in this provision for a prescription medication approved by the FDA, such as Epidiolex, which is dispensed in 100 milliliter vials. This provision would therefore potentially prohibit Epidiolex from being made available to patients in North Dakota. If so applied, patients would be denied a treatment that has been approved to treat serious and intractable seizures associated with three types of childhood-onset seizure conditions. Patient access to additional future FDA-approved cannabinoid medicines would also potentially be impacted.

Nothing in North Dakota's underlying medical marijuana statute, Chapter 19-24.1, excepts an FDA-approved product from its coverage. Indeed, the law broadly defines a cannabinoid product intended for medical use: Under 94-24.1-01(24), "'medical cannabinoid product' means a product intended for human consumption or use which contains cannabinoids," and includes cannabinoid solutions, capsules, transdermal patches and topicals.

As a result, the law imposes a number of restrictions and requirements on patients who have been prescribed FDA-approved cannabinoid products, which do not apply to patients using any other type of FDA-approved product. For example, only a patient with a specific

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"qualifying condition" may be certified to use a cannabinoid product, but an FDA-approved medicine may be approved for a condition not on that list. A person may not produce, process, dispense or use medical marijuana unless authorized by the state's medical marijuana law. However, a pharmaceutical product is likely to be manufactured outside of the state by an entity that is not licensed by the state and dispensed within the state by pharmacies, rather than by licensed dispensaries. Qualifying patients must become part of a patient registry and must annually pay for a registry identification card, but this requirement does not apply to patients using other types of FDA-approved products.
In short, the state's medical marijuana is likely intended to apply to cannabis/cannabinoid products that have not been approved as prescription medications by the FDA, but the law inadvertently sweeps such FDA-approved products into its purview.

Proposed Amendment

In order to ensure that physicians and pharmacies in North Dakota are not restricted in their ability to prescribe and dispense FDA-approved cannabinoid drugs to appropriate patients, and to ensure that such patients are not subject to burdens and limitations that other patients to whom non-cannabinoid FDA-approved medications have been prescribed, the following amendment should be included in HB 1213:

"Nothing in this chapter shall apply to a drug approved by the Food and Drug Administration pursuant to section 505 of the federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et. Seq."

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