S M W K
Schwartz, Metz, Wise & Kauffman, P.A.
Attorneys

20 West Street
410-244-7000 Annapolis, Maryland 21401 smwpa.com

TO: The Honorable Luke Clippinger, Chair
Members, House Judiciary Committee
The Honorable Emily Shetty

FROM: Pamela Metz Kasemeyer
J. Steven Wise

DATE: January 25, 2022

RE: **SUPPORT** – House Bill 33 – *Criminal Law – Controlled Dangerous Substances – Schedules – Adjustment*

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On behalf of Jazz Pharmaceuticals, we wish to register support for House Bill 33. Jazz Pharmaceuticals is a global biopharmaceutical company with a focus on developing life-changing medicines for people with serious disease – often with limited or no options – so they can live their lives more fully. Jazz Pharmaceuticals has particular expertise in two key therapeutic areas; neuroscience and oncology and is an industry leader in treating sleep disorders and epilepsy. Greenwich Biosciences, the developer of Epidiolex, is a part of Jazz Pharmaceuticals.

House Bill 33, if enacted, will eliminate the unnecessary confusion and access to medication issues that can occur under the current controlled dangerous substance (CDS) scheduling statute framework. While Maryland generally follows the federal scheduling, they are only able to update their actual statute annually during the Legislative Session, which can lead to confusion when the federal government schedules, reschedules, or deschedules a substance during the interim. The recent descheduling of Epidiolex provides a clear example of the negative impact on access to life-changing medecines that can occur as a result of that confusion and timing mismatch.

In June 2018, the Food and Drug Administration (FDA) approved Epidiolex to treat seizures associated with two rare forms of epilepsy – Dravet syndrome and Lennox-Gastaut syndrome – for those aged two years of age and older. While Epidiolex was initially designated by the DEA as a Schedule V substance, it was subsequently descheduled in July 2020 which dramatically enhanced access by removing barriers for patients, physicians, and pharmacies.

Because Epidiolex was descheduled during the interim, it resulted in confusion and access challenges. The attached letter from Johns Hopkins to the Maryland Department of Health (MDH) reflects the negative impact which Maryland's current scheduling process created. Thankfully, MDH issued a letter (attached) stating they would not enforce Epidiolex as a scheduled drug as they planned to deschedule it when they updated their statute this Session.

House Bill 33, if enacted, will prevent the challenges created, relative to Epidiolex for future substances. House Bill 33 references the federal lists rather than listing all of the compounds in each of the schedules. This will allow Maryland to stay current with the federal government's schedules and prevent access and management issues for substances due to timing with Maryland's General Assembly Session. The bill retains any language that Maryland has added to their statute separate from the federal lists and retains Maryland's current authority to take exception to federal decisions and/or add additional provisions/substances. Passage of House Bill 33 will make it much more straightforward for all affected parties – patients, health care professionals, pharmacies, health care facilities, and law enforcement – to know what Maryland law is with respect to CDS scheduling. A favorable report is requested.

**For more information call**:
Pamela Metz Kasemeyer
J. Steven Wise
410-244-7000

**Carl Stafstrom, M.D., Ph.D.**
Director, Pediatric Neurology

**Sarah Aminoff Kelley, M.D.**
Associate Professor of Clinical Neurology & Pediatrics
Director, Pediatric Epilepsy Monitoring Unit

**Eric H. Kossoff, M.D.**
Professor of Neurology & Pediatrics

**Christa Habela, M.D., PhD.**
Assistant Professor of Neurology & Pediatrics

**Ahmad Marashly, M.D.**
Assistant Professor of Neurology & Pediatrics

JOHNS HOPKINS
MEDICINE

October 13, 2021

To the Office of Controlled Substances,

I am writing in support of the de-scheduling of Epidiolex (CBD), from Drug Enforcement Administration in the state of Maryland. In June 2018, Epidiolex became the only FDA-approved form of CBD for the treatment of seizures for specific epilepsy syndromes and was placed in schedule V of the Controlled Substances Act. In April 2020, the US DEA de-scheduled Epidiolex on a national level, however the state of Maryland remains one of the few states that has kept the schedule V designation. As a member of the healthcare team for one of the most prestigious academic medical centers in the world for epilepsy, Johns Hopkins Hospital, we strive to consistently provide the best quality care for our patients. A large number of our pediatric patients rely on Epidiolex for seizure control, and the downstream effects of the continued schedule V designation not only affect our patients and their families, but also interfere with our ability to provide quality and timely care.

As an outlier amongst the other states that house the specialty pharmacies, our electronic prescription capabilities were severely limited by our electronic medical record for a period of time in 2020. We were not able to electronically send new prescriptions and refills for Epidiolex as a result of our scheduled status, causing delays in filling prescriptions. One of the greatest impacts to our patients remains the inability to receive the medication in a timely manner. DEA regulations for controlled substances dictate that refills can only be dispensed after exactly 30 days from the last refill, however since Epidiolex can only be dispensed from specialty pharmacies, the shipping time is not accounted for in this time frame. Since we first started prescribing Epidiolex in 2018, we have rarely experienced a month in which at least one patient has not missed doses due to the refill constraint. As any parent with a child with epilepsy can attest, the panic of running out of a medication that prevents seizures is palpable, as even one dose of missed medication can cause devastating sequalae including breakthrough seizures, emergency treatment, and inpatient admission.

As the front-line team member who not only directly handles the initiation, maintenance, and prior authorization process for our patients on Epidiolex but helps manage the care of our patients when they become de-stabilized as a result of this process, it is difficult to understand whom this scheduled designation is benefitting. To our numerous patients on Epidiolex, this current system not only misaligns with our commitment to provide quality care, but directly negatively impacts their ability to access an essential treatment option. Your consideration in removing Epidiolex as a controlled substance in the state of Maryland is greatly appreciated. Please do not hesitate to contact me with questions.

Sincerely,

Meghan Cronk, MSN RN CNRN CNL

Meghan Cronk, MSN RN CNRN CNL
*Pediatric Epilepsy Nurse Coordinator*

The John M. Freeman Pediatric Epilepsy Center
Johns Hopkins Hospital
600 North Wolfe St., Meyer 2-147, Baltimore, Maryland 21287
Phone: 410-955-9100
Fax: 410-367-2521
Mcronk1@jhmi.edu

Maryland
DEPARTMENT OF HEALTH

# Update: Suspension of disciplinary actions - Epidiolex
# December 22, 2021

Purpose – The purpose of this statement is to provide clarification to Maryland pharmacists, pharmacies and other licensees dealing with patient prescriptions for Epidiolex on or after December 22, 2021.

As a result of actions under the federal Agriculture Improvement Act (AIA), the drug Epidiolex was descheduled under the federal Uniform Controlled Substances Act (CSA). On August 21, 2020, the U.S. Drug Enforcement Administration (DEA) issued an Interim Final Rule incorporating the AIA into DEA regulations officially removing any federal controlled substance designation from the prescribing and dispensing of the drug, Epidiolex. Following descheduling by Congress, the FDA approved the drug's revised non-scheduled label. The FDA's National Drug Code directory also shows the current status of the drug as non-scheduled. Accordingly, pursuant to the AIA, Epidiolex is not a controlled substance under the CSA and is therefore no longer subject to the CSA and its implementing regulations.

The Maryland Uniform Controlled Substances Act still lists the drug's ingredient as a Schedule V controlled substance (See, MD Code Ann. Crim. Law §5-406(f)) and cannot be updated until the 2022 legislative session, as such this has created a temporary conflict between federal and state law. In order to maintain alignment with the federal government, until the Maryland Legislature can take action to deschedule Epidiolex, MDH will exercise its regulatory discretion.

Effective December 22, 2021, MDH and the Office of Controlled Substance Administration will no longer pursue disciplinary action against licensees or registrants that appropriately receive, process, and dispense Epidiolex prescriptions as a non-controlled drug.