SB0614_FAV_JOTF.pdf
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JOTF JOB OPPORTUNITIES TASK FORCE

Advocating better skills, jobs, and incomes

TESTIMONY IN SUPPORT OF SENATE BILL 614:

Criminal Law - Controlled Dangerous Substances - Schedules - Adjustment

TO: Hon. William C. Smith, Jr., Chair, and members of the Senate Judicial Proceedings Committee

FROM: Caleb Jasso, Policy Advocate

DATE: February 23, 2022

The Job Opportunities Task Force (JOTF) is an independent, nonprofit organization that develops and advocates policies and programs to increase the skills, job opportunities, and incomes of low-skill, low-wage workers and job seekers in Maryland. JOTF supports **Senate Bill 614** because it will allow for the Maryland Legislature to update and adjust controlled dangerous substances (CDS) with greater frequency and in a more streamlined process.

Under the Maryland Controlled Dangerous Substances Act, if the federal government places a substance on Schedules I through V, it is automatically considered a substance on the same schedule under Maryland law unless MDH objects to the designation. Although this process is automatic, currently, Maryland Department of Health, MDH is only able to update what is listed on schedules once per year, which poses potential scheduling issues. Additionally, this puts the state of Maryland behind and provides for the opportunity for drugs scheduled at a certain level to remain as they are even if the federal government de-schedules the drug. This can create unnecessary confusion and frustration for residents of Maryland who may be experiencing detrimental health problems made more bearable by a drug de-scheduled at the federal level and not at the state level.

An essential part of **Senate Bill 614**, is that Maryland does not lose the ability to reject or expand what is listed on drug schedules. The state retains the ability to remain semi-autonomous in this manner but is simply able to address the changes more quickly. Furthermore, MDH can object to federal government action immediately for drug scheduling, and therefore Maryland could act separately from the federal government. It should be noted that the bill also removes from statute those substances that Maryland regulates more stringently than the federal government. It does not appear that those substances are listed in Maryland regulations. However, those substances can still be found listed on MDH's website under the title "Maryland Supplemental CDS List " that must be updated and republished on an annual basis.

Senate Bill 614 allows for the Maryland Legislature to update and adjust controlled dangerous substances (CDS) with greater frequency in regard to the rate at which the federal government currently updates them. For these reasons, we urge a favorable report.

For more information, contact:
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SB0614_FAV_EF,TSC,Dravets,LGS_Criminal Law - CDS
Uploaded by: Christine Krone
Position: FAV

TO: The Honorable William C. Smith, Jr., Chair
Members, Senate Judicial Proceedings Committee
The Honorable Jeff Waldstreicher

FROM: Epilepsy Foundation
TSC Alliance
LGS (Lennox-Gastaut Syndrome) Foundation
Dravet Syndrome Foundation

DATE: February 23, 2022

RE: **SUPPORT** – Senate Bill 614 – *Criminal Law – Controlled Dangerous Substances – Schedules – Adjustment*

On behalf of the Epilepsy Foundation, TSC Alliance, LGS (Lennox-Gastaut Syndrome) Foundation, and Dravet Syndrome Foundation, we submit this letter of support for Senate Bill 614.

Tuberlous sclerosis complex (TSC) is a rare genetic disease that causes non-cancerous (benign) tumors to grow in the brain and other parts of the body such as the eyes, heart, kidneys, lungs, and skin. TSC usually affects the central nervous system and can result in a combination of symptoms including seizures, developmental delay, and behavioral problems, although the signs and symptoms of the condition, as well as the severity of symptoms, vary widely. TSC affects about 1 in 6,000 people and is the leading genetic cause of epilepsy and autism.

LGS is a rare and debilitating form of early childhood-onset epilepsy that is characterized by highly treatment resistant seizures, multiple seizure types, moderate to severe cognitive impairment, and increased risk of premature death. Individuals living with LGS experience an increased risk of serious injury because of frequent falls associated with uncontrolled seizures. Despite other FDA-approved treatments for LGS, the majority of individuals living with this rare epilepsy do not achieve seizure control and experience lifelong cognitive impairments that severely limit quality of life.

Dravet syndrome is a rare and catastrophic form of intractable epilepsy that begins in infancy and is highly treatment resistant. It is a debilitating, life-long condition characterized by frequent and

prolonged seizures, poor seizure control, and developmental delays, as well as an increased risk of premature death, including sudden unexpected death in epilepsy (SUDEP). This condition affects 1 in 15,700 to 20,900 individuals globally.

Epidiolex, initially approved by the FDA for treatment of Dravet syndrome and Lennox-Gastaut syndrome (LGS) and subsequently approved for the treatment of TSC in individuals one year of age and older has been an extraordinary breakthrough in the ability to effectively treat these catastrophic conditions. While Epidiolex was initially designated by the DEA as a Schedule V substance. It was subsequently descheduled in July 2020 which dramatically enhanced access.

Unfortunately, Maryland's current controlled dangerous substances (CDS) scheduling system created unnecessary confusion and access to Epidiolex after it was descheduled. While Maryland generally follows the federal scheduling, they are only able to update their actual statute annually during the Legislative Session. Because Epidiolex was descheduled during the interim it resulted in confusion and access challenges. Thankfully, the Maryland Department of Health issued a letter essentially saying they would not enforce it as a scheduled drug as they planned to deschedule it when they updated their statute this Session.

Our organizations and the families we represent want to ensure that similar confusion does not occur in the future. Senate Bill 614 would amend Maryland's CDS statute to reference Federal CDS schedules as opposed to listing all of the compounds in each of the schedules. It will allow Maryland to stay current with the federal government's schedules and prevent future access and management issues for scheduled and descheduled drugs due to timing as occurred with Epidiolex.

The Epilepsy Foundation, TSC Alliance, LGS Foundation, and Dravet Syndrome Foundation request your support for Senate Bill 614 to ensure that Marylanders living with epilepsy and seizure disorders do not face future State barriers to lifechanging treatments.

For more information:
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SB0614_FAV_Jazz Pharmaceuticals_CDS - Schedules -

Uploaded by: Pam Kasemeyer

Position: FAV

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TO: The Honorable William C. Smith, Jr., Chair
Members, Senate Judicial Proceedings Committee
The Honorable Jeff Waldstreicher

FROM: Pamela Metz Kasemeyer
J. Steven Wise

DATE: February 23, 2022

RE: **SUPPORT** – Senate Bill 614 – *Criminal Law – Controlled Dangerous Substances – Schedules – Adjustment*

On behalf of Jazz Pharmaceuticals, we wish to register support for Senate Bill 614. 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.

Senate Bill 614, 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.

Senate Bill 614, if enacted, will prevent the challenges created, relative to Epidiolex for future substances. Senate Bill 614 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 Senate Bill 614 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:
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