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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 medicines 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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