



State of Utah Controlled Substances Advisory Committee

September 24, 2020

Health and Human Services Interim Committee
Office of Legislative Research and General Counsel
W210 State Capital Complex
Salt Lake City, Utah 84114

SUBJECT: Controlled Substances Advisory Committee—2021 Legislative Recommendations

Dear Members of the Health and Human Services (HHS) Interim Committee:

The Controlled Substances Advisory Committee (CSAC) is pleased to provide for you, as required by law, a report and recommendations for your consideration for action during the 2021 Legislative session. The CSAC is composed of individuals with a broad range of expertise and/or experience in public health, clinical care, public safety, state laboratory, and academia. The CSAC met three times this year to identify, evaluate and discuss issues related to the use and misuse of “recreational drugs” and “legend” drugs. “Recreational” drugs are substances not currently regulated by the Controlled Substances Act (CSA), but may be considered potentially dangerous to the health and well-being of the public. “Legend” drugs are approved prescription only drugs that potentially merit inclusion in a designated schedule in the CSA due to new evidence of health risks to the people of the State of Utah.

Even though the coronavirus pandemic is impacting every sector of society, the CSAC continues to monitor misuse and illicit trends with numerous medications and chemical substances. The status of two of these FDA approved medications – gabapentin (brand name: Neurontin) and cannabidiol (brand name: Epidiolex) – is further described in the body of this letter. However, for the 2021 legislative session the CSAC is recommending no changes to the Utah CSA.

(1) Gabapentin (2-[1-(aminomethyl) cyclohexyl] acetic acid) continues in monitoring

As described in the CSAC recommendations last Fall, there are concerns about misuse of gabapentin in Utah. This medication is approved in the United States for treatment of epilepsy and post-herpetic neuralgia, however, it widely used for many other off-label conditions, including chronic, non-specific pain.

In collaboration with the Division of Occupational and Professional Licensing, and the Utah Office of Administrative Rules, a rule for data collection on gabapentin prescribing and dispensing in Utah was implemented effective April 1, 2020. Several pharmacies voluntarily provided information on gabapentin dispensing during the 2019 calendar year. The quantity of data collected on gabapentin prescriptions is rapidly growing.

The Controlled Substance Database administrator provided a summary of available data on gabapentin dispensing, including more than 300,000 prescriptions dispensed. The initial data suggests a Utah trend in polypharmacy use involving gabapentin and tramadol (schedule IV). Some members of the CSAC expressed their observations of substantial clinical impacts of gabapentin misuse. In particular, gabapentin is commonly present in pathologic and laboratory analysis of toxic drug exposures, but it is rarely the sole or primary agent of toxicity. National trends indicate gabapentin is frequently misused along with opiates and benzodiazepines. At least five (5) states – Kentucky, Michigan, Tennessee, Virginia, and West Virginia have scheduled gabapentin as a state controlled substance. It is not a federal controlled substance.

There are mixed concerns about scheduling gabapentin as a controlled substance in Utah. National trends and data are noted above. The CSAC remains vigilant, but feels that another 6-12 months of data collection from the Controlled Substances Database, as well as additional information from national trends and toxicological surveillance will provide a sufficient foundation to re-consider gabapentin scheduling. Accordingly, if these data sources indicate, a recommendation on scheduling will be provided in the October 2021 CSAC letter to the HHS Interim Committee.

(2) Cannabidiol (brand name: Epidiolex)

A manufactured pharmaceutical formulation of cannabidiol, marketed under the name Epidiolex, was approved by the FDA in June 2018 for severe forms of epilepsy. At the time of FDA approval, Epidiolex was also listed in Schedule V of the Federal Controlled Substance Act. In the CSAC letter to the HHS Interim Committee for the 2020 legislative session, it was recommended to list Epidiolex as a Schedule V controlled substance in the Utah CSA, for compliance with federal law.

In the 2020 legislative session, the Utah Controlled Substances Act was amended, at UCA 58-37-4(2)(e)(ii), with the following language:

(ii) A drug product or preparation that contains any component of marijuana, including cannabidiol, and is approved by the United States Food and Drug Administration and scheduled by the Drug Enforcement Administration in Schedule V of the federal Controlled Substances Act, Title II, P.L. 91-513. (emphasis added)

On August 21, 2020, the DEA published an interim final rule (Federal Register 51639), to codify statutory amendments to the Controlled Substances Act made by the Agricultural Improvement Act (AIA) of 2018. More particularly, cannabidiol products with a residual Δ^9 -THC concentration no more than 0.1% (w/w) have been delisted as controlled substances.

There are no data available to indicate Epidiolex is being misused in Utah. The CSAC voted in favor of delisting Epidiolex in Utah. However, upon further reading of the Utah Code section identified above, it appears that no action is required by the Legislature, and Epidiolex no longer meets the qualification for listing as Schedule V controlled substance in Utah.

The CSAC Committee thanks the Health and Human Services Interim Committee for its attention to these important issues and looks forward to continuing to serve as a consultative and advisory body to the Legislature.

Respectively Submitted,

The Controlled Substances Advisory Committee

James Ruble, PharmD, JD, Committee Chair

Erik D. Christensen, MD

Colonel Brian Redd

Byron J. Talbot, DDS

Katherine Carlson, MD

Barbara Hurst, MD

Byron F. Burmester, JD

Julie Balk, APRN

Kate Barton Miyagi, ND

Craig William Davis, MD

Amberly Johnson, PharmD

Jennifer McNair, BS

Christopher Sheard, PharmD

Trey E. Hansen (public member)

Jeff Busjahn, Committee Administrator