State of Utah
Controlled Substances Advisory Committee

29 September 2022

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—2023 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 for your consideration for action during the 2023 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 two times this year to identify, evaluate and discuss issues related to the use and misuse of 'recreational' drugs and 'legend' drugs. 'Recreational' drugs does not have a universally accepted definition. The term is commonly associated with narcotics, stimulants, depressants, and hallucinogens, which do not have a legally authorized use. These agents are frequently not regulated within the Controlled Substances Act (CSA), and may be considered potentially dangerous to the health and well-being of the public. 'Legend' drugs are Food and Drug Administration (FDA) 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.

In accordance with Utah Code Annotated (UCA) 58-38a-203(3), the CSAC is charged by the Legislature to evaluate substances and make recommendations based on the following criteria:

- Actual or probable abuse of the substance, including:
  - History and current pattern of abuse in Utah and other states
  - Scope, duration, and significance of abuse
  - Degree of actual or probable detriment to public health which may result from abuse of the substance
  - Probable physical and social impact of widespread abuse of the substance
- Biomedical hazard of the substance, including:
  - Pharmacology, including the effects and modifiers of the effects
  - Toxicology – acute and chronic toxicity
  - Risk to public health
- Whether the substance is an immediate precursor to a substance that is currently controlled

- Current state of scientific knowledge regarding the substance, including whether any acceptable means to safely use the substance under medical supervision
- Relationship between use of the substance and criminal activity
- Whether the substance has been scheduled by any other states
- Whether the substance has any accepted medical use in the United States

The coronavirus pandemic is a persistent challenge to society, however the CSAC continues to monitor misuse and illicit trends with numerous medications, drugs and chemical substances. In particular, the CSAC has been closely following the use patterns for fentanyl, synthetic opioids and gabapentin (brand name: Neurontin), as further described in the body of this letter. For the 2023 legislative session the CSAC is *recommending no changes to the Utah CSA*.

Illicit use of Fentanyl and synthetic opioids continue to be monitored.

The United States Drug Enforcement Administration (DEA) has recently described alarming patterns regarding 'illicit' fentanyl.[1] In particular, the intentional targeting of younger Americans by drug cartels, with colorful fentanyl products being identified as 'rainbow fentanyl'. Fentanyl continues to be one of the top chemicals identified in substances submitted to the Department of Public Safety – Bureau of Forensic Services Lab for identification of controlled substances.

The Bureau of Forensic Services informed the CSAC about a class of synthetic opioids referred to as 'nitazene' compounds. These compounds also may be referred to as 'benzimidazole-opioids'.[2] Based on initial information, these substances are more difficult to produce than fentanyl, however, they are at least as potent as fentanyl, with several being more potent than fentanyl. As more scientific and epidemiological data become available, the public health risk of these agents is likely to increase. At this time, the Bureau of Forensic Services reports there have been no nitazene compounds identified in samples submitted to the lab. The DEA has included at least ten (10) nitazene compounds as Schedule I controlled substances, including but not limited to, butonitazene, clonitazene, etodesnitazene, flunitazene, isotonitazine, metodesnitazene, and metonitazene.

The CSAC continues to monitor the illicit use of fentanyl and synthetic opioids.

Gabapentin (2-[1-(aminomethyl) cyclohexyl] acetic acid) continues in monitoring by multiple entities in the State.

As described in the CSAC recommendations provided in Fall 2020 and Fall 2021, concerns about misuse of gabapentin in Utah have been expressed. This medication is approved in the United States for treatment of epilepsy and post-herpetic neuralgia, however, it is widely used for many off-label conditions, including chronic, non-specific pain.[3]

[1] https://www.dea.gov/press-releases/2022/08/30/dea-warns-brightly-colored-fentanyl-used-target-young-americans
[2] Montanari E, Madeo G, Pichini S, Paolo Busardò F, Carlier J. Acute Intoxications and Fatalities Associated With Benzimidazole Opioid (Nitazene Analog) Use: A Systematic Review. *Ther Drug Monit*. 2022 Aug 1;44(4):494-510. doi: 10.1097/FTD.0000000000000970.
[3] Goodman CW, Brett AS. A clinical overview of off-label use of gabapentinoid drugs. JAMA Intern Med 2019;179(5):695-701. doi: 10.1001/jamainternmed.2019.0086

In January 2020, The Drug Regimen Review Center (DRRC) published a report on behalf of Utah Medicaid Drug Utilization Review program, titled, "Abuse and Misuse of Gabapentin." The report includes information on toxic exposures involving gabapentin. 'Exposure' is a common term in clinical toxicology and emergency medicine, wherein a chemical substance comes into contact with the body, or is otherwise introduced into the body of a human. The most common routes for toxic 'exposure' are contact with skin (dermatological), mouth (oral ingestion), or lungs (respiratory inhalation). The DRRC report is available to the public at: https://medicaid.utah.gov/pharmacy/drugutilization/files/Criteria%20Review%20Documents/2020/2020.01%20Gabapentin.pdf

This report draws information from a plurality of sources, including: Medicaid claims data, Pubmed, Epistemonikos, DEA, CDC, FDA, Substance Abuse and Mental Health Services Administration (SAMSHA), University of Maryland Center for Substance Abuse Research (CESAR), and data from the Utah Poison Control Center (UPCC). Key findings from this report are summarized, as follows:

- Gabapentin is among the top 15 drugs most frequently involved in drug overdose deaths in the US
- The UPCC has 2,011 exposures (between 2014-2019) which include gabapentin, and accounts for 1% of total exposures during this time period. Sixty-three percent (63%) of these exposures were intentional ingestions. One-half of these exposures were intentional harmful overdoses (i.e., suicide).
- Systematic reviews suggest the prevalence of gabapentin abuse appears low (~1%). In those persons who abuse other substances (e.g., opioids, benzodiazepines, cannabis, heroin) the abuse of gabapentin increases to 15-22%.

To assess use patterns in Utah, a rule for data collection on gabapentin prescribing and dispensing in Utah was implemented, effective April 1, 2020. This was done in conjunction with the Division of Occupational and Professional Licensing, and the Utah Office of Administrative Rules. For purposes of this data collection, gabapentin is classified as non-controlled 'agent of concern'.

The Controlled Substance Database (CSD) administrator provided a summary of available data on gabapentin dispensing, including 554,879 prescriptions dispensed between Q3 2020, and Q2 2021 (i.e., first year of monitoring). Based on Q2 2022 data in the CSD, there is a slight increase in the number of new prescriptions (3,912) for gabapentin compared to the previous quarter. These data also indicate that gabapentin is dispensed most commonly to patients in the 55-65 year age group (21%), followed by 45-55 year age group (17%), and 35-45 age group (15%). The majority of prescriptions are dispensed to patients aged 35 and older, and while these percentages do not necessarily inform on abuse, they are consistent with labeled and off-label uses.

Gabapentin is prescribed to patients who are receiving other controlled substances. However, there can be many appropriate clinical reasons why patients receiving gabapentin would also be receiving prescriptions for other pain medications (e.g., analgesics), and other central nervous system depressants (e.g., benzodiazepines). The following controlled substances were the top 4

medications also present on the database profile for patients receiving gabapentin: oxycodone (23.8%), hydrocodone (15.4%), tramadol (13.4%) and clonazepam (9.6%)

Some members of the CSAC expressed their professional observations of substantial clinical impacts of gabapentin misuse. In particular, gabapentin is commonly present in pathologic and laboratory analysis of toxic drug exposures, but *gabapentin is rarely the sole or primary agent of toxicity*. National trends indicate gabapentin is frequently misused along with opiates, buprenorphine/naltrexone, and benzodiazepines. Although gabapentin has not been designated a controlled substance by the Drug Enforcement Administration (DEA), there have been some initiatives at state levels. Seven (7) states – Alabama, Kentucky, Michigan, North Dakota, Tennessee, Virginia, and West Virginia have scheduled gabapentin as a state controlled substance – Schedule V. Twelve (12) states, including Utah, have not controlled gabapentin, but have required monitoring through a prescription monitoring database (e.g., Controlled Substance Database). Three (3) states are contemplating monitoring or controlling gabapentin.[4]

The DEA is also monitoring gabapentin for patterns of abuse. The DEA reported that from 2011 to 2017, the number of prescriptions for 'licit' uses of gabapentin doubled – 33.4 million to 64.8 million.[5] This monitoring data was from the IQVIA database. The DEA and the United States Food and Drug Administration (FDA) have received petitions to designate gabapentin as a schedule V controlled substance.[6,7] As yet, there is no strong indicator from these federal agencies regarding a decision to schedule gabapentin, but its abuse potential is clearly being monitored and evaluated by federal agencies.

Some members of the CSAC expressed their professional observations about clinical consequences of scheduling gabapentin as a controlled substance in Utah. In particular, an action to schedule gabapentin could reduce access to this medication therapy for patients in chronic pain, as well as patients located in rural and medically underserved areas. These concerns were supported by rational professional justifications.

As identified in this letter, there are mixed observations and data about actual abuse of gabapentin in Utah, as well as concerns about scheduling gabapentin as a controlled substance in Utah. National trends and data are noted above, and suggest a potential for abuse of gabapentin. The Controlled Substances Database is a helpful tool to better understand actual use patterns in Utah. The CSAC remains vigilant, but feels the collection of gabapentin prescribing and dispensing data into the CSD should be continued. The Office of the Medical Examiner, as well as the State Bureau of Forensic Services, and the Utah Poison Control Center continue to monitor for patterns of gabapentin misuse, as well as many other substances. The CSAC will re-evaluate data from these state resources as well as national trends next year. Accordingly, if these data sources indicate, a recommendation on scheduling will be provided in the Fall 2023 CSAC letter to the HHS Interim Committee.

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[4] Campbell LS, Coomer TN, Jacob GK, Lenz RJ. Gabapentin controlled substance status. *J Am Pharm Assoc* 2021;61:e218-e224. Doi.org/10.1016/j.japh2021.01.025

[5] https://deadiversion.usdoj.gov/drug_chem_info/gabapentin.pdf

[6] https://www.citizen.org/article/petition-to-the-dea-and-fda-to-classify-the-drug-gabapentin-as-a-schedule-v-controlled-substance/

[7] https://www.citizen.org/wp-content/uploads/2567_FDA-Interim-Response-Letter_Gabapentin-Petition_August-4-2022.pdf

The CSAC respectfully acknowledges the Controlled Substances Database administration, the Office of the Medical Examiner, the Bureau of Forensic Services, and the Utah Poison Control Center. The CSAC mission could not be fulfilled without the efforts and collaboration of these Utah resources.

The CSAC Committee is grateful to 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.
Respectfully Submitted,

The Controlled Substances Advisory Committee

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