



Senate Fiscal Agency
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BILL ANALYSIS



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Senate Bill 801 (as enrolled)
Sponsor: Senator Rick Jones
Senate Committee: Judiciary
House Committee: Law and Justice

Date Completed: 3-28-18

RATIONALE

Consistent with Federal law, Michigan's Public Health Code classifies controlled substances under five schedules. A Schedule 2 substance is a substance that has a high potential for abuse, has currently accepted medical use in treatment in the United States or currently accepted medical use with severe restrictions, and whose abuse may lead to severe psychic or physical dependence. Schedule 2 substances currently include opium, amphetamines, and medical marijuana, among other drugs.

Some have raised concerns about the recreational use of a substance called tianeptine sodium, which is approved in other countries for the treatment of major depressive disorder. Since the drug is unscheduled for use in the United States, it is available online. Individuals reportedly have purchased the drug and taken it in sufficient doses to achieve an opioid-like high, which has resulted in several cases of overdose. To prevent these incidents, and enable the State to control the drug, it has been suggested that tianeptine sodium be added to Schedule 2.

CONTENT

The bill would amend the Public Health Code to classify tianeptine sodium as a Schedule 2 controlled substance.

Article 7 of the Code governs the manufacture, distribution, and possession of controlled substances, and prescribes a range of criminal penalties for violations. The requirements, prohibitions, and penalties depend, in part, on whether a drug is a Schedule 1, 2, 3, 4, or 5 controlled substance. Article 7 identifies specific drugs in each schedule and authorizes the Michigan Board of Pharmacy to add controlled substances to the schedules. The placement of a substance in a particular schedule depends on the drug's potential for abuse, its acceptance for medical use in treatment in the United States, and the extent to which abuse of the drug may lead to physical or psychological dependence.

Section 7214 designates certain substances as Schedule 2 controlled substances. The bill would add tianeptine sodium to those listed in Section 7214.

The bill would take effect 90 days after its enactment.

MCL 333.7214

BACKGROUND

Tianeptine sodium is drug that was commercialized in France beginning in 1987. Since 2016, it has been available in approximately 66 countries in Europe, Asia, and Latin America under a number of tradenames, including Stablon and Coaxil. In the United States, various uses of

tianeptine have received patent protection since the early 1990s. Some pharmaceutical companies have developed formulations of tianeptine for treatment of major depressive disorder. In 2009, Johnson & Johnson completed phase I clinical trials in the United States, but discontinued development of the drug in 2012. Currently, Tonix Pharmaceutical is enrolling participants for phase III clinical trials of a formulation of tianeptine sodium for treatment of military-related post-traumatic stress disorder.

In doses of approximately 25 to 50 milligrams, tianeptine sodium is prescribed (in countries where it can be prescribed) to reduce symptoms of mild to moderate-to-severe major depression, as well as depression-associated anxiety. There is evidence to suggest that the drug also is used recreationally for its anxiolytic (anxiety-reducing) effects, and, in sufficiently high doses, affects the body like a narcotic.

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Tianeptine sodium binds to opioid receptors in the brain in a manner similar to oxycodone. Recently, countries that have approved the drug have restricted its use in a manner similar to opioid painkillers. Where it has been approved, the recommended dose is roughly 25 milligrams. Reportedly, however, there have been cases in which individuals have taken doses in the hundreds, or thousands, of milligrams. At such doses, tianeptine sodium's effects simulate the effect of opioid painkillers, and the drug can become addictive. Withdrawals from tianeptine sodium at these doses can be painful and violent. According to testimony before the Senate Committee on Judiciary, current drug tests do not effectively detect tianeptine sodium, making it difficult to ascertain whether an overdose patient has used the drug.

Because tianeptine sodium is an unscheduled drug, it is currently available for purchase online, where it is marketed as a supplement. Such a dangerous substance should not be readily available. Designating tianeptine sodium as a Schedule 2 drug would effectively end the legal manufacture, distribution, and sale of the drug in Michigan. Substances on the list of Schedule 2 drugs can be prescribed, however. While not currently approved, there have been, and continue to be, efforts to have the drug approved for use in the United States. If the drug were eventually approved by the Food and Drug Administration for use in the United States, it could be prescribed by a physician while on Schedule 2.

Legislative Analyst: Jeff Mann

FISCAL IMPACT

The bill could have a negative fiscal impact on State and local government. There are no data available to indicate how many people would be convicted of manufacturing, delivering, or possessing a Schedule 2 drug if tianeptine sodium were added to the drugs listed on the schedule. More misdemeanor and felony arrests and convictions could increase resource demands on law enforcement, court systems, community supervision, jails, and correctional facilities. The average cost to State government for felony probation supervision is approximately \$3,024 per probationer per year. For any increase in prison intakes, in the short term, the marginal cost to State government is approximately \$3,764 per prisoner per year. Any associated increase in fine revenue increases funding to public libraries.

Fiscal Analyst: Ryan Bergan

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.