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Senate Bill 801 (as introduced 1-31-18)

Sponsor: Senator Rick Jones

Committee: Judiciary

Date Completed: 2-6-18

## 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, 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. (A Schedule 2 substance is a substance that meets all of the following: it 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 the abuse of the substance may lead to severe psychic or physical dependence.) 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

Page 1 of 2 sb801/1718 drug also is used recreationally for its anxiolytic (anxiety-reducing) effects, and, in sufficiently high doses, affects the body like a narcotic.

Tianeptine is not approved for treatment in the United States. As an unscheduled substance under Federal law, tianeptine is available for purchase online.

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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