HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: HB 1595 Controlled Substances
SPONSOR(S): Plakon and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1512

FINAL HOUSE FLOOR ACTION: 112 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

HB 1595 passed the House on March 6, 2024, as SB 1512.

Federal and state law both classify controlled substances into five schedules. The scheduling determination for a controlled substance is based on a substance's potential for abuse and whether the substance has a currently accepted medical use. The classifications range from a Schedule I substance, which has a high potential for abuse and no accepted medical use; to a Schedule V substance, which has a low potential for abuse and an accepted medical use. These schedules regulate the manufacture, distribution, preparation, and dispensing of the substances listed therein.

The Legislature has delegated to the Florida Attorney General the authority to adopt rules to add a substance to a schedule established under s. 893.03, F.S., or transfer a substance between schedules, if the substance has the potential for abuse and meets other requirements, or to remove a scheduled substance if it no longer meets the requirements for inclusion in that schedule. If the Attorney General finds that the scheduling of a substance in Schedule I of s. 893.03, F.S., on a temporary basis is necessary to avoid an imminent hazard to the public safety, he or she may bypass certain requirements and by rule schedule such substance in Schedule I.

Tianeptine, sometimes referred to as "gas station heroin," was developed in the 1960s for use as an antidepressant. Although it is approved in low doses for that purpose in some countries outside of the United States, the United States Food and Drug Administration (FDA) has never approved tianeptine for any medical use, and both its potency and dosage are unregulated. When used in high doses, tianeptine produces effects similar to those produced by an opioid and delivers short-lived euphoria. Tianeptine comes in both powder and pill forms but has also been found in counterfeit pills mimicking other pharmaceutical products and individual stamp bags commonly used to distribute heroin.

On September 20, 2023, Florida's Attorney General issued Emergency Rule 2ER23-1, temporarily scheduling tianeptine as a Schedule I controlled substance and concluding that tianeptine was "an immediate danger to the public" by producing side effects including respiratory depression, loss of consciousness, death, nausea, vomiting, agitation, decreased blood pressure, rapid heartbeat, slowed or stopped breathing, drowsiness, mental confusion, and dependence. The emergency rule and the temporary scheduling of tianeptine will expire on June 30, 2024.

The bill amends s. 893.03, F.S., to add tianeptine to the list of Schedule I controlled substances. As such, under the bill, the manufacture, distribution, preparation, and dispensing of tianeptine will be regulated by Florida law.

The bill may have a positive indeterminate impact on jail and prison beds by making the possession, distribution, sale, or manufacture of more substances illegal which may result in more jail and prison admissions.

The bill was approved by the Governor on March 22, 2024, ch. 2024-20, L.O.F., and will become effective on July 1, 2024.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

Florida Law

Controlled Substance Schedules

Chapter 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, classifies controlled substances[1] into five categories, called schedules. These schedules regulate the manufacture, distribution, preparation, and dispensing of the substances listed therein. The distinguishing factors between the different controlled substance schedules are the "potential for abuse"[2] of the substance and whether there is a currently accepted medical use for the substance.[3]

The controlled substance schedules are as follows:

- Schedule I substances have a high potential for abuse and currently have no accepted medical use in the United States and their use under medical supervision does not meet accepted safety standards.[4]
- Schedule II substances have a high potential for abuse and have a currently accepted but severely restricted medical use in the United States, and abuse of the substance may lead to severe psychological or physical dependence.[5]
- Schedule III substances have a potential for abuse less than the substances contained in Schedules I and II and have a currently accepted medical use in the United States, and the abuse of the substance may lead to moderate or low physical dependence or high psychological dependence, or in the case of anabolic steroids, may lead to physical damage.[6]
- Schedule IV substances have a low potential for abuse relative to substances in Schedule III and have a currently accepted medical use in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III.[7]
- Schedule V substances, compounds, mixtures, or preparation of substances have a low potential for abuse relative to the substances in Schedule IV and have a currently accepted medical use in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.[8]

Attorney General Emergency Scheduling Authority

The Legislature delegated to the Florida Attorney General the authority to adopt rules to add a substance to a schedule established under s. 893.03, F.S., or transfer a substance between schedules, if the substance has the potential for abuse and meets other classification requirements, or to remove a substance previously added to a schedule if it no longer meets the requirements for inclusion in that schedule.[9] Proof of potential for abuse can be based upon a showing that these activities are already taking place, or upon a showing that the nature and properties of the substance make it reasonable to

[1] "Controlled substance" means any substance named or described in Schedules I-V of s. 893.03, F.S. S. 893.02(4), F.S.
[2] "Potential for abuse" means that a substance has properties of a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of its being: 1) used in amounts that create a hazard to the user's health or safety of the community; 2) diverted from legal channels and distributed through illegal channels; or 3) taken on the user's own initiative rather than on the basis of professional medical advice. S. 893.02(22), F.S.
[3] *See* s. 893.03, F.S.
[4] S. 893.03(1), F.S.
[5] S. 893.03(2), F.S.
[6] S. 893.03(3), F.S.
[7] S. 893.03(4), F.S.
[8] S. 893.03(5), F.S.
[9] S. 893.035(2), F.S.; "Potential for abuse" has the same meaning as provided in s. 893.02(22), F.S.

assume that there is a substantial likelihood that such activities will take place, in other than isolated or occasional instances.[10] Any findings and conclusions provided by the U.S. Attorney General with respect to any substance is admissible as evidence in any rulemaking proceeding, including an emergency rulemaking proceeding.[11]

If the Attorney General finds that the scheduling of a substance in Schedule I of s. 893.03, F.S., on a temporary basis is necessary to avoid an imminent hazard to public safety, he or she may by rule[12] schedule such substance in Schedule I if the substance is not listed in any other schedule of s. 893.03, F.S. The Attorney General must consider, with respect to his or her finding of imminent hazard to public safety, only:

- The substance's potential for abuse;[13]
- The substance's history and current pattern of abuse;
- The scope, duration, and significance of abuse;
- What, if any, risk there is to the public health;[14]
- Diversion from legitimate channels, if any; and
- Clandestine importation, manufacture, or distribution.[15]

The Attorney General must provide specific facts and reasons for finding an immediate danger to the public health, safety, or welfare.[16] The Attorney General shall report to the Legislature by March 1 of each year concerning any rules adopted to schedule or reschedule any substance during the previous year. Each such rule expires on the following June 30 unless the Legislature adopts the provisions in statute.[17]

Federal Law

The federal Controlled Substances Act[18] (CSA) also classifies controlled substances into schedules based on the potential for abuse and whether there is a currently accepted medical use for the substance. The U.S. Attorney General is required to consider the following when determining where to schedule a substance:[19]

- The substance's actual or relative potential for abuse;
- Scientific evidence of the substance's pharmacological effect, if known;
- The state of current scientific knowledge regarding the substance;
- The substance's history and current pattern of abuse;
- The scope, duration, and significance of abuse;
- What, if any, risk there is to public health;
- The substance's psychic or physiological dependence liability; and
- Whether the substance is an immediate precursor of a substance already controlled.

Tianeptine

[10] S. 893.035(3)(a), F.S.
[11] *Id*.
[12] In an emergency rulemaking proceeding, the Attorney General may proceed without regard to the requirements to request a medical and scientific evaluation of the substance from and consider recommendations regarding scheduling from the Department of Health and the Department of Law Enforcement. S. 893.035(5) and (7), F.S.
[13] S. 893.035(3)(a), F.S.
[14] S. 893.035(4)(d-f), F.S.
[15] S. 893.035(7), F.S.
[16] S. 120.54(4)(a)3., F.S.
[17] These expiration provisions are notwithstanding the 90-day expiration described in s. 120.54(4)(c), F.S.
[18] 21 U.S.C. § 812.
[19] 21 U.S.C. § 811(c).

General Information

Tianeptine, sometimes referred to as "gas station heroin," was developed in the 1960s for use as an antidepressant.[20,21] Although it is approved in low doses for that purpose in some countries outside of the United States, the United States Food and Drug Administration (FDA) has never approved tianeptine for any medical use, and both its potency and dosage are unregulated.[22] When used in high doses, tianeptine produces effects similar to those produced by an opioid and delivers short-lived euphoria.[23] Tianeptine comes in both powder and pill forms but has also been found in counterfeit pills mimicking other pharmaceutical products and individual stamp bags commonly used to distribute heroin.[24]

Reports have indicated that people may be taking tianeptine under the widespread, mistaken belief that it is a safe alternative to street opioids like fentanyl or heroin, or even as a way to taper off using those other drugs.[25] Tianeptine is also relatively cheap and accessible to consumers, with capsules costing slightly more than $30 for a package of 15 and liquid solutions costing around $15 for a single 10mL bottle.[26]

Tianeptine is similar to opioids in terms of side effects, withdrawal symptoms, and overall addiction potential.[27] At low dosages, common side effects include headaches, dizziness, constipation, dry mouth, drowsiness, insomnia, and nightmares.[28] At higher doses, side effects, some of which may cause death, may include increased blood pressure and other cardiovascular effects; liver and kidney damage; addiction and dependence; and irregular heartbeat, difficulty breathing, seizures, hallucinations, and loss of consciousness.[29] Withdrawal symptoms related to tianeptine initially last five to seven days and are similar to those seen with opioids, including nausea or vomiting, flu-like illness, muscle aches, and tremors; depression and anxiety; strong cravings for tianeptine; and seizures.[30]

Florida's poison control center had 15 exposure calls for tianeptine in the first half of 2023, 24 calls in 2022, and 54 calls over the last 4 years combined.[31] Five deaths in the United States have been attributed to tianeptine intoxication.[32]

Federal Tianeptine Regulation

The United States Food and Drug Administration (FDA) has never approved tianeptine to treat depression or for any other medical use, and both its potency and dosage are unregulated.[33] Additionally, the FDA considers tianeptine to be an unsafe food additive that does not meet the statutory definition of a dietary ingredient.[34]

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[20] Cleveland Clinic, *Know the Dangers of 'Gas Station Heroin'* (May 25, 2023), https://health.clevelandclinic.org/gas-station-heroin-tianeptine (last visited Mar. 6, 2024).
[21] *See also* United States Drug Enforcement Agency (DEA), *Tianeptine* (May 2023), https://www.deadiversion.usdoj.gov/drug_chem_info/tianeptine.pdf (last visited Mar. 6, 2024).
[22] *Supra* note 20.
[23] Jan Hoffman, *'Gas-Station Heroin' Sold as Dietary Supplement Alarms Health Officials* (Jan. 10, 2024), The New York Times, https://www.nytimes.com/2024/01/10/health/gas-station-heroin-tianeptine-addiction.html (last visited Mar. 6, 2024).
[24] Florida Department of State, *Emergency Rule 2ER23-1* (Sep. 20, 2023), https://www.myfloridalegal.com/sites/default/files/2023-09/2er23-1.pdf (last visited Mar. 6, 2024).
[25] *Supra* note 23.
[26] *Id.*
[27] Carmen Pope, BPharm, *Tianeptine* (Jan. 12, 2024), Drugs.com, https://www.drugs.com/illicit/tianeptine.html (last visited Mar. 6, 2024).
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] *Supra* note 24.
[32] *Id.*
[33] *Supra* note 20.
[34] DEA, *Tianeptine in Dietary Supplements* (Feb. 22, 2023) https://www.fda.gov/food/dietary-supplement-ingredient-directory/tianeptine-dietary-supplements (last visited Mar. 6, 2024). A "dietary ingredient" is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract,

On November 21, 2023, after receiving severe adverse event reports from the public, the FDA issued a warning to consumers not to purchase or use any products containing tianeptine—which it characterized as a potentially dangerous substance that is not FDA-approved for any medical use but is nonetheless sold with unauthorized and unsubstantiated claims that it improves brain function and treats anxiety, depression, pain, opioid use disorder and other conditions.[35] The FDA's warning noted that products containing tianeptine "may contain other harmful ingredients not listed on the label,"[36] in line with prior consumer warnings about the overall risks of using tianeptine.[37]

Despite the FDA's warnings, as of January 2024, tianeptine is still not a controlled substance under federal law.

Florida Tianeptine Regulation

On September 20, 2023, Florida's Attorney General issued Emergency Rule 2ER23-1, temporarily scheduling tianeptine as a Schedule I controlled substance and concluding that tianeptine was "an immediate danger to the public" by producing side effects including respiratory depression, loss of consciousness, death, nausea, vomiting, agitation, decreased blood pressure, rapid heartbeat, slowed or stopped breathing, drowsiness, mental confusion, and dependence.[38,39]

Prior to the issuance of Emergency Rule 2ER23-1, tianeptine was sold by some private businesses, including gas stations and other convenience stores. The Emergency Rule currently classifies tianeptine as a Schedule I controlled substance, prohibiting its sale or distribution by such private businesses.

Emergency Rule 2ER23-1 and the temporary scheduling of tianeptine will expire on June 30, 2024.[40]

Effect of the Bill

The bill amends s. 893.03, F.S., to add tianeptine to the list of Schedule I controlled substances.

As such, under the bill, the manufacture, distribution, preparation, and dispensing of tianeptine will be regulated by Florida law.

The effective date of the bill is July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

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or combination of any dietary ingredient from the preceding categories. Non-dietary ingredients intended for use in dietary supplements must be used in accordance with a food additive regulation or be generally recognized as safe, unless they meet one of the other listed exceptions to the food additive definition.

[35] FDA, *FDA warns consumers not to purchase or use Neptune's Fix or any tianeptine product due to serious risks* (Nov. 21, 2023), https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-neptunes-fix-or-any-tianeptine-product-due-serious-risks (last visited Mar. 6, 2024).

[36] *Id.*

[37] FDA, *Tianeptine Products Linked to Serious Harm, Overdoses, Death* (Feb. 10, 2022), https://www.fda.gov/consumers/consumer-updates/tianeptine-products-linked-serious-harm-overdoses-death (last visited Mar. 6, 2024).

[38] Office of the Attorney General, *Video: Attorney General Moody Outlaws Gas Station Heroin in Florida* (Sep. 21, 2023) https://www.myfloridalegal.com/newsrelease/video-attorney-general-moody-outlaws-gas-station-heroin-florida (last visited Mar. 6, 2024).

[39] Tianeptine is a controlled substance in Alabama, Georgia, Indiana, Kentucky, Michigan, Minnesota, Mississippi, Ohio, and Tennessee.

[40] *Supra* note 24.

None.

2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may have an indeterminate negative impact on private businesses that sold tianeptine prior to the issuance of the Emergency Rule. Such businesses may continue to experience reduced profits associated with the continued prohibition on selling tianeptine or tianeptine products under the bill.

D. FISCAL COMMENTS:

The bill may have a positive indeterminate impact on jail and prison beds by making the possession, distribution, sale, or manufacture of more substances illegal which may result in more jail and prison admissions.