HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 505 Controlled Substances
SPONSOR(S): Trumbull
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Criminal Justice Subcommittee		Fields	White
2) Justice Appropriations Subcommittee			
3) Judiciary Committee			

SUMMARY ANALYSIS

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act and classifies controlled substances into five categories, known as schedules I through V. These schedules regulate the manufacture, distribution, preparation, and dispensing of the substances listed therein. The distinguishing factors between the different drug schedules are the "potential for abuse" of the substances listed therein and whether there is a currently accepted medical use for the substance.

Currently, ioflupane I 123 is a schedule II controlled substance in Florida because of its derivation from cocaine via ecgonine, both of which are schedule II substances. Prior to September 2015, ioflupane I 123 was also a schedule II controlled substance under the federal Controlled Substances Act; however, it was removed from that schedule by the U.S. Drug Enforcement Administration effective September 11, 2015, because the drug is not subject to abuse and currently has a medical acceptable use in DaTscan, a drug product used to visualize striatal dopamine transporters in the brains of adult patients with suspected Parkinsonian syndromes.

The bill amends s. 893.03, F.S., to remove ioflupane I 123 from the list of substances that are classified under schedule II in Florida.

The bill does not appear to have a fiscal impact on state or local governments.

The bill is effective July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Regulating Controlled Substances

The Florida Comprehensive Drug Abuse Prevention and Control Act

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

- Schedule I substances have a high potential for abuse and have no currently accepted medical use in the United States. This schedule includes substances such as cannabis and heroin.[3]
- Schedule II substances have a high potential for abuse and have a currently accepted but severely restricted medical use in the United States. This schedule includes substances such as raw opium, cocaine, and codeine.[4]
- 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. This schedule includes substances such as stimulants and anabolic steroids.[5]
- Schedule IV substances have a low potential for abuse relative to the substances in Schedule III and have a currently accepted medical use in the United States. This schedule includes substances such as benzodiazepines and barbiturates.[6]
- Schedule V 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. This schedule includes substances such as mixtures that contain small quantities of opiates and codeine.[7]

Chapter 893, F.S., contains a variety of provisions criminalizing behavior related to controlled substances. Most of these provisions are found in s. 893.13, F.S., which criminalizes the possession, sale, purchase, manufacture, and delivery of controlled substances. The penalty for violating these provisions depends largely on the schedule in which the substance is listed.[8] Other factors, such as the quantity of controlled substances involved in a crime or the location where the violation occurs can also affect the penalties for violating the criminal provisions of ch. 893, F.S.

Ioflupane I 123

Federal Law

Federal Law, pursuant to the Controlled Substances Act,[9] also classifies certain substances into schedules based on potential for abuse and whether there is a currently accepted medical use for it. Until 2015, federal law recognized ioflupane I 123 as a schedule II controlled substance because of its derivation from cocaine via ecgonine, both of which are schedule II substances.[10] Ioflupane I 123 is the active pharmaceutical ingredient in the drug product DaTscan.[11] The U.S. Food and Drug

[1] Section 893.035(3)(a), F.S., defines "potential for abuse" to mean that a substance has properties as 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 the 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.
[2] *See* s. 893.03, F.S.
[3] s. 893.03(1), F.S.
[4] s. 893.03(2), F.S.
[5] s. 893.03(3), F.S.
[6] s. 893.03(4), F.S.
[7] s. 893.03(5), F.S.
[8] *See, e.g.*, s. 893.13(1)(a) and (c), F.S.
[9] 21 U.S.C. § 812.
[10] Department of Justice, *Schedules of Controlled Substances: Removal of Ioflupane I 123 from Schedule II of the Controlled Substances Act*, https://www.deadiversion.usdoj.gov/fed_regs/rules/2015/fr0603.htm (last visited Feb. 6, 2017).
[11] *Id.*

Administration (FDA) approved the New Drug Application for DaTscan, for the indication of visualizing striatal dopamine transporters in the brains of adult patients with suspected Parkinsonian syndromes.[12]

In 2010, the U.S. Department of Health and Human Services (HHS) recommended to the U.S. Drug Enforcement Administration (DEA) that ioflupane I 123 be removed from the list of schedule II substances.[13] In response, the DEA completed a review of FDA-approved diagnostic products containing ioflupane I 123, which at the time was only DaTscan.[14] The DEA agreed to remove ioflupane I 123 from the federal Controlled Substances Act based on the following:

- There is no data demonstrating that individuals are administering quantities of DaTscan sufficient to create a hazard to their health or to the safety of other individuals or to the community. Approximately 6,000 vials of DaTscan would be required to produce a subjective "high" in humans from exposure to ioflupane I 123. The volume of 6,000 vials is about 15 liters of fluid, an amount that would be lethal if administered intravenously.
- Over 168,000 doses of DaTscan were administered to patients worldwide and there was no clinical evidence of pharmacological effects.
- Meaningful extraction of ioflupane I 123 from DaTscan would be impossible due to its limited production and availability and because extraction is technically complex and would require advanced equipment not available to the general public.
- There have been no reports of abuse of ioflupane I 123 or seizures resulting from its use.
- Because of the limited amounts of manufactured DaTscan, the low concentration of ioflupane I 123 per vial, and the existence of stringent regulatory controls on the manufacturing and handling of DaTscan, abuse of DaTscan is not possible as a practical matter.
- There was no psychic or physiological dependence potential of FDA-approved diagnostic products containing ioflupane I 123.
- Ioflupane I 123 is not an immediate precursor of a substance already controlled under the Controlled Substances Act.[15]

Accordingly, ioflupane I 123 was removed from schedule II of the federal Controlled Substances Act on September 11, 2015.[16]

Florida Law
Ioflupane I 123 is a schedule II substance under s. 893.03(2)(a)(4), F.S.

Effect of the Bill
The bill amends s. 893.03, F.S., to remove ioflupane I 123 from the list of substances classified under Schedule II.

The bill also reenacts ss. 893.0301, 893.055, and 893.13, F.S., to incorporate the amendment made by the bill to s. 893.03, F.S.

The bill takes effect July 1, 2017.

B. SECTION DIRECTORY:

Section 1. Amends s. 893.03, F.S., relating to standards and schedules.

Section 2. Reenacts s. 893.0301, F.S., relating to death resulting from apparent drug overdose; reporting requirements.

Section 3. Reenacts s. 893.055, F.S., relating to prescription drug monitoring programs.

[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] Department of Justice, *Schedules of Controlled Substances: Removal of Ioflupane I 123 from Schedule II of the Controlled Substances Act*, https://www.deadiversion.usdoj.gov/fed_regs/rules/2015/fr0911.htm (last visited Feb. 7, 2017).

Section 4. Reenacts s. 893.13, F.S., relating prohibited acts; penalties.

Section 5. Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues: The bill does not appear to have an impact on state revenues.

2. Expenditures: The bill does not appear to have an impact on state expenditures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues: The bill does not appear to have an impact on local government revenues.

2. Expenditures: The bill does not appear to have an impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR: None.

D. FISCAL COMMENTS: None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision: This bill appears to be exempt from the requirements of article VII, section 18 of the Florida Constitution because it is a criminal law.

2. Other: None.

B. RULE-MAKING AUTHORITY: The bill does not appear to create the need for rulemaking or rulemaking or rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS: None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

N/A