The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Criminal Justice

BILL:	SB 1002
INTRODUCER:	Senators Perry and Rouson
SUBJECT:	Controlled Substances
DATE:	March 24, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Erickson	Hrdlicka	CJ	**Pre-meeting**
2.			JU	
3.			AP	

I. Summary:

SB 1002 amends Florida's controlled substance schedules to provide that ioflupane (123I)[1] is not included as a Schedule II controlled substance.

Currently, ioflupane (123I) 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 (123I) was also a Schedule II controlled substance under the federal Controlled Substances Act. However, effective September 11, 2015, the U.S. Drug Enforcement Administration removed ioflupane (123I) from that schedule because the drug is not subject to abuse and currently has a medically acceptable use in DaTscan, a drug product used to visualize striatal dopamine transporters in the brains of adult patients with suspected Parkinsonian syndromes.

The Criminal Justice Impact Conference estimates that the bill will not have a prison bed impact.

II. Present Situation:

Florida's Controlled Substance Schedules and Scheduling of Ioflupane (123I)

Section 893.03, F.S., classifies controlled substances into five categories, known as schedules. These schedules regulate the manufacture, distribution, preparation, and dispensing of the substances listed in the statute. The most important factors in determining which schedule may

[1] The bill refers to the substance as "Ioflupane (123I)." An analysis of the bill by the Florida Department of Law Enforcement refers to the substance as "Ioflupane I 123." 2017 FDLE Legislative Bill Analysis (SB 1002) (January 26, 2017), Florida Department of Law Enforcement (on file with the Senate Committee on Criminal Justice). However, FDLE's analysis does not indicate that the chemical nomenclature used in the bill to describe this substance is incorrect. This bill analysis uses the nomenclature used in the bill.

apply to a substance is 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 described 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.[4]
- 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.[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. This schedule includes substances such as stimulants and anabolic steroids.[6]
- 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.[7]
- 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.[8]

The majority of provisions criminalizing behavior relating to controlled substances 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.[9] 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 (123I) is a Schedule II controlled substance because it is derived from cocaine via ecgonine, both of which are Schedule II controlled substances. The substance falls under s. 893.03(2)(a)(4), F.S., (cocaine or ecgonine, including any of their stereoisomers, and any salt, compound, derivative, or preparation of cocaine or ecgonine).

Federal Controlled Substance Schedules

The federal Controlled Substances Act[10] also classifies certain substances into schedules based on potential for abuse of the substance and whether there is a currently accepted medical use for it. Until 2015, federal law recognized ioflupane (123I) as a Schedule II controlled substance

[2] Pursuant to s. 893.035(3)(a), F.S., "potential for abuse" means a substance has properties as a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of the substance 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.
[3] See s. 893.03, F.S.
[4] Section 893.03(1), F.S.
[5] Section 893.03(2), F.S.
[6] Section 893.03(3), F.S.
[7] Section 893.03(4), F.S.
[8] Section 893.03(5), F.S.
[9] *See, e.g.*, s. 893.13(1)(a) and (c), F.S.
[10] 21 U.S.C. section 812.

because of its derivation from cocaine via ecgonine, both of which are Schedule II controlled substances.[11]

Ioflupane (123I) is the active pharmaceutical ingredient in the drug product DaTscan.[12] The U.S. Food and Drug 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.[13]

In 2010, the U.S. Department of Health and Human Services recommended to the U.S. Drug Enforcement Administration (DEA) that ioflupane (123I) be removed from the list of Schedule II substances.[14] In response, the DEA completed a review of FDA-approved diagnostic products containing ioflupane (123I), which at the time was only DaTscan.[15] The DEA agreed to remove ioflupane (123I) 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 (123I). 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 (123I) 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 (123I) or seizures as a result of ioflupane (123I).
- Because of the limited amounts of manufactured DaTscan, the low concentration of ioflupane (123I) 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 (123I).
- Ioflupane (123I) is not an immediate precursor of a substance already controlled under the federal Controlled Substances Act.[16]

Accordingly, ioflupane (123I) was removed from the schedule of the federal Controlled Substances Act on September 11, 2015.[17]

---

[11]. "Schedules of Controlled Substances: Removal of [123I] Ioflupane Ioflupane I 123 from Schedule II of the Controlled Substances Act," FR 2015-13455, U.S. Drug Enforcement Administration, *available at* https://www.deadiversion.usdoj.gov/fed_regs/rules/2015/fr0603.htm (last visited on March 14, 2017).
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] "Schedules of Controlled Substances: Removal of [123I] Ioflupane from Schedule II of the Controlled Substances Act," FR 2015-22919, U.S. Drug Enforcement Administration, *available at* https://www.deadiversion.usdoj.gov/fed_regs/rules/2015/fr0911.htm (last visited on March 14, 2017).

III. Effect of Proposed Changes:

The bill provides that ioflupane (123I) is not included as a Schedule II controlled substance under s. 890.03(2)(a)4., F.S., (cocaine or ecgonine, including any of their stereoisomers, and any salt, compound, derivative, or preparation of cocaine or ecgonine).

The bill takes effect July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Criminal Justice Impact Conference, which provides the final, official estimate of the prison bed impact, if any, of legislation, estimates that the bill will not have a prison bed impact.[18]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[18] Impact information was provided by staff of the Office of Economic and Demographic Research on March 6, 2017, via e-mail (on file with the Senate Committee on Criminal Justice).

VIII. Statutes Affected:

This bill substantially amends section 893.03 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.