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 Health Regulation Committee

BILL:	SB 1156
INTRODUCER:	Senator Garcia
SUBJECT:	Dextromethorphan
DATE:	March 23, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Stovall	HR	**Favorable**
2.			CJ	
3.			JU	
4.				
5.				
6.				

I. Summary:

The bill creates the "Andy Maxfield Dextromethorphan Act." The bill amends Florida Statutes relating to the retail sale of ephedrine and related compounds by including dextromethorphan in many provisions of current law that limit the conditions under which ephedrine and related compounds may be sold by commercial retailers, including those relating to the commission of misdemeanors and felonies under certain conditions.

This bill substantially amends the following section of the Florida Statutes: 893.1495.

II. Present Situation:

Ephedrine, Pseudoephedrine, Phenylpropanolamine, and Methamphetamine

Ephedrine, pseudoephedrine, and phenylpropanolamine are drugs found in both prescription and nonprescription products used to relieve nasal or sinus congestion caused by the common cold, sinusitis, hay fever, and other respiratory allergies. However, these chemicals are also used in the unlawful production of methamphetamine, a Schedule II controlled substance under state and federal law.[1]

Methamphetamine is a central nervous system stimulant drug that is similar in structure to amphetamine. Methamphetamine is a white, odorless, bitter-tasting crystalline powder that easily

[1] Section 893.03(2)(c)(4), F.S., and 21 C.F.R. s. 1308.12(d)(2). The drug "has limited medical uses for the treatment of narcolepsy, attention deficit disorders, and obesity." U.S. Drug Enforcement Administration, *Methamphetamine, available at* http://www.justice.gov/dea/concern/meth.html (citing by footnote to the National Institute on Drug Abuse, Research Report - Methamphetamine Abuse and Addiction, www.drugabuse.gov/) (last visited March 23, 2011).

dissolves in water or alcohol and is taken orally, intranasally (snorting the powder), by needle injection, or by smoking. Methamphetamine increases the release and blocks the reuptake of the brain chemical (or neurotransmitter) dopamine, leading to high levels of the chemical in the brain—a common mechanism for most drugs of abuse. Dopamine is involved in reward, motivation, the experience of pleasure, and motor function. Methamphetamine's ability to release dopamine rapidly in reward regions of the brain produces the intense euphoria, or "rush," that many users feel after snorting, smoking, or injecting the drug.[2]

Taking even small amounts of methamphetamine can result in many of the same physical effects as those of other stimulants, such as cocaine or amphetamines, including increased wakefulness, increased physical activity, decreased appetite, increased respiration, rapid heart rate, irregular heartbeat, increased blood pressure, and hyperthermia. Long-term methamphetamine abuse has many negative health consequences, including extreme weight loss, severe dental problems ("meth mouth"), anxiety, confusion, insomnia, mood disturbances, and violent behavior. Chronic methamphetamine abusers can also display a number of psychotic features, including paranoia, visual and auditory hallucinations, and delusions.[3]

Ephedrine, pseudoephedrine, and phenylpropanolamine are listed precursor chemicals under Florida law.[4] A "listed precursor chemical" is a chemical that may be used in manufacturing a controlled substance in violation of ch. 893, F.S., and is critical to the creation of the controlled substance, and includes any salt, optical isomer, or salt of an optical isomer, whenever the existence of such salt, optical isomer, or salt of optical isomer is possible within the specific chemical designation. These chemicals are also listed chemicals. A "listed chemical" is any precursor chemical or essential chemical named or described in s. 893.033, F.S.[5]

Ephedrine, pseudoephedrine, and phenylpropanolamine are also "list 1" chemicals under federal law.[6] A "list 1" chemical is a chemical specified by regulation of the U.S. Attorney General as a chemical that is used in manufacturing a controlled substance in violation of federal drug abuse prevention and control laws and is important to the manufacture of controlled substances, and includes (until otherwise specified by regulation of, or upon petition to, the U.S. Attorney General) ephedrine, pseudoephedrine, and phenylpropanolamine, and other listed chemicals.[7] These chemicals, including their salts, optical isomers, and salts of optical isomers, are also designated methamphetamine precursor chemicals.[8]

Current Florida law defines "ephedrine or related compounds" as ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers.[9] The law regulates the retail sale of ephedrine or related compounds by preventing persons from displaying products containing such compounds or offering them for retail sale other than behind

[2] U.S. Department of Health & Human Services, National Institute on Drug Abuse, *InfoFacts: Methamphetamine*, March 2010, p. 1.
[3] *Id.*
[4] Section 893.033(1)(f),(v), and (z), F.S.
[5] Section 893.02(13), F.S. The inclusion of a chemical as a listed precursor chemical does not bar, prohibit, or punish legitimate use of the chemical.
[6] 21 U.S.C. s. 802(34)(c)(I) and (K). Many of the federal list 1 chemicals are also precursor chemicals under s. 893.033, F.S.
[7] *Id.*
[8] 6 U.S.C. s. 220(c).
[9] *See* s. 893.1495(1), F.S.

a checkout counter where the public is not permitted or other such location that is not otherwise accessible to the general public.[10] The quantity of such products that may be purchased is strictly limited.[11] The owner or primary operator of a retail outlet that sells such products is required to properly train employees engaged in their sale.[12] Retailers are required, unless exempted, to utilize an electronic recordkeeping system, approved by the Florida Department of Law Enforcement (FDLE) for the purpose of recording and monitoring the real-time purchase of such products and for the purpose of monitoring this information in order to prevent or investigate illegal purchases of these products.[13] Violations of provisions of the law related to the sale or display of such products and employee training regarding the sale of such products, amount to misdemeanors or felonies, depending on the nature of the violation.[14]

In terms of restrictions on quantity, current law specifically provides that a person may not knowingly obtain or deliver to an individual in any retail OTC sale any nonprescription compound, mixture, or preparation containing ephedrine or related compounds in excess of the following amounts:

- In any single day, any number of packages that contain a total of 3.6 grams of ephedrine or related compounds;
- In any single retail OTC sale, three packages, regardless of weight, containing ephedrine or related compounds; or
- In any 30-day period, in any number of retail OTC sales, a total of 9 grams or more of ephedrine or related compounds.

Dextromethorphan

Dextromethorphan (DXM) is one of the most widely used antitussive (cough suppressant) agents worldwide. It was approved for use by the federal Food and Drug Administration (FDA) in 1958 as a non-prescription cough medication. Currently, DXM is found in more than 125 over-the-counter (OTC) patented products to treat cough and cold symptoms. Medications are available in pills, gel caps, lozenges, liquids, and syrups, either alone or in combination with other active ingredients such as antihistamines, decongestants, and/or expectorants.[15]

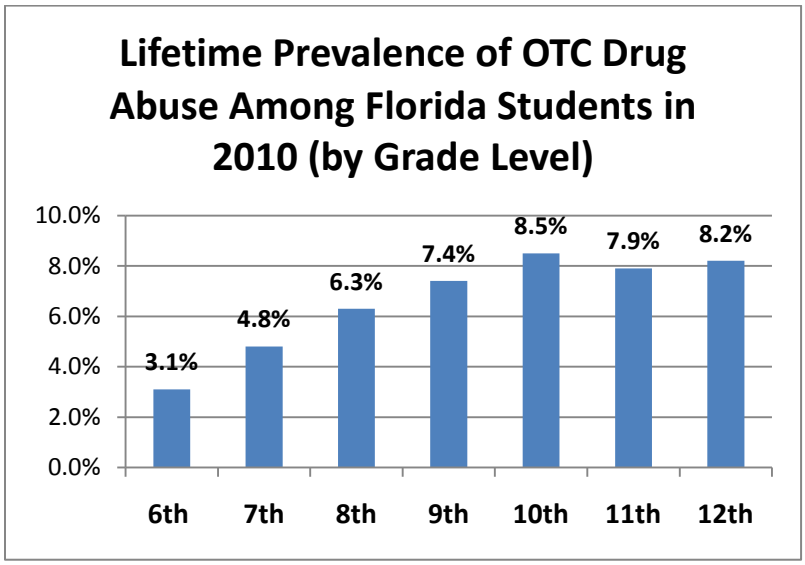
The U.S. Justice Department's Drug Enforcement Administration (DEA) has reported an increasing abuse of DXM in recent years, especially among adolescents.[16] DXM-containing cough suppressants are abused for their euphoriant, hallucinogenic, and "out-of-body experience" properties, which is generally associated with doses 10 to 20 times greater than the dose recommended for cough suppression (10-30 mg).[17] In high enough doses, the abuse of

[10] *See* s. 893.1495(3), F.S.
[11] *See* s. 893.1495(2), F.S.
[12] *See* s. 893.1495(4), F.S.
[13] *See* s. 893.1495(5), F.S.
[14] *See* s. 893.1495(11), F.S.
[15] U.S. Department of Justice, Drug Enforcement Administration, "Dextromethorphan: Drug Fact Sheet," July 14, 2010, p. 1, available at http://www.drugabuse.gov/pdf/infofacts/Methamphetamine10.pdf (last visited March 24, 2011).
[16] Section 877.111, F.S., makes it unlawful for any person to inhale or ingest, or to possess with intent to breathe, inhale, or drink, any compound, liquid, or chemical containing certain substances for the purpose of inducing a condition of intoxication or which distorts or disturbs the auditory, visual, or mental processes. DXM is not included in the statute's list of substances subject to this provision.
[17] *Supra,* note 15.

DXM can cause serious adverse events, such as psychosis, brain damage, seizure, loss of consciousness, irregular heartbeat, and even death.[18] Cases of long-term DXM abuse exhibit features of dependence, including tolerance and physical withdrawal symptoms.[19]

DXM is not presently a scheduled substance or listed precursor chemical under the Controlled Substances Act, nor is DXM a known precursor chemical in the production of methamphetamine. However, in August 2010, the DEA listed DXM as a drug and chemical of concern and federal authorities have indicated that DXM could be added to the Controlled Substances Act if warranted.[20]

The Department of Children and Families began surveying students in middle-school about their use of OTC drugs in 2008, with the Florida Youth Substance Abuse Survey (FYSAS).[21] Students were asked, "On how many occasions (if any) have you used drugs that can be purchased from a store without a prescription – such as cold and cough medication – in order to get high" in your lifetime and in the past 30 days? It is important to note that this question does not specifically ask about OTC drugs containing DXM and only cites "cold and cough medication" as one example. Since 2008, the FYSAS has indicated that approximately 5 percent of Florida's middle school students report that they used drugs like cold and cough medications to get high at least once in their lifetime. Among middle school students, the lifetime prevalence of OTC drug abuse is higher than nearly all illicit drugs on the survey. The same question was added to the high school survey in 2010, allowing comparisons of lifetime prevalence across all grade levels. As depicted in the figure below, the prevalence of OTC drug abuse increases across successively higher grade levels, with the highest lifetime prevalence (8.5 percent) reported by 10th graders:



[18] Terrie, Yvette C., "Dextromethorphan Abuse," *Pharmacy Times*, November 1, 2008.
[19] Chyka, P.A., Erdman, A.R., Manoguerra, A.S., et al., "Dextromethorphan Poisoning: An Evidence-based Consensus Guideline for Out-of-Hospital Management," *Clinical Toxicology*, 2007, vol. 45, no. 6, pp. 662-677.
[20] U.S. Dept. of Justice, Drug Enforcement Administration, "Drugs and Chemicals of Concern: Dextromethorphan," August 2010, available at http://www.deadiversion.usdoj.gov/drugs_concern/dextro_m/dextro_m.htm (last visited March 24, 2011).
[21] Results are available at http://www.dcf.state.fl.us/programs/samh/publications/fysas/ (last visited March 24, 2011).

III. Effect of Proposed Changes:

Section 1 provides that this act may be cited as the "Andy Maxfield Dextromethorphan Act." Andy Maxfield was a Miami Lakes resident who died from an overdose of an OTC product containing DXM on August 6, 2010, at the age of 19, according to a web site created by his parents following his death.[22] Andy's death was the subject of a television news story in Miami and Fort Lauderdale.[23]

Section 2 amends s. 893.1495, F.S., to provide that the term "ephedrine, dextromethorphan, or related compounds" means ephedrine, pseudoephedrine, phenylpropanolamine, dextromethorphan, or any of their salts, optical isomers, or salts of optical isomers.

The bill goes on to change all instances of "ephedrine or related compounds" to "ephedrine, dextromethorphan, or related compounds" within the statute that are related to the sale or display of such products, and employee training regarding the sale of such products, except for one instance. In s. 893.1495(5), F.S., the bill separates DXM from ephedrine and its related compounds by maintaining the requirement that any person purchasing or acquiring any nonprescription product containing ephedrine or related compounds must sign his or her name on a record of the purchase, but persons purchasing or acquiring products containing DXM are not required to sign a record of the purchase. Those purchasing or acquiring DXM-containing products are required by the bill to be at least 18 years of age and produce a government-issued photo identification, as are persons purchasing or acquiring products containing ephedrine or its related compounds under current law.

The bill does not include DXM in any provisions of current law relating to the FDLE electronic recordkeeping system for products containing ephedrine or related compounds.

Section 3 of the bill provides an effective date of July 1, 2011.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

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[22] *See* http://www.andymaxfield.com/ (last visited March 23, 2011).
[23] *See* http://www.wsvn.com/features/articles/investigations/MI89843/ (last visited March 23, 2011).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill could cause an indeterminate increase in the cost of doing business for retailers who sell DXM-containing products due to the requirements in the bill related to product sales, product display, and employee training. (Also see section VII. Related Issues.)

C. Government Sector Impact:

To the extent that criminal violations of the bill's restrictions on DXM occur, the bill could cause an indeterminate increase of expenses and costs in the criminal justice system.

VI. Technical Deficiencies:

The bill eliminates the current-law definition of "ephedrine or related compounds" in favor of the bill's definition of "ephedrine, dextromethorphan, or related compounds." However, certain portions of s. 893.1495, F.S., that are not amended by the bill rely on the existing definition of "ephedrine or related compounds," and without that existing definition, those provisions would contain an undefined term if the bill becomes law. The provisions in question are:

- FDLE is required to approve an electronic recordkeeping system for the purpose of monitoring the real-time purchase of products containing ephedrine or related compounds.[24]
- In order to be granted an exemption from electronic reporting, a retailer must maintain a sales volume of less than 72 grams of ephedrine or related compounds in a 30-day period.[25]
- The electronic recordkeeping system must record the name of the product containing ephedrine or related compounds.[26]
- A nonprescription product containing any quantity of ephedrine or related compounds may not be sold over the counter unless reported to the FDLE electronic recordkeeping system.[27]
- The requirements of s. 893.1495, F.S., relating to the marketing, sale, or distribution of products containing ephedrine or related compounds supersede any local ordinance or regulation.[28]

VII. Related Issues:

The bill places the same restrictions on the quantity of DXM-containing products that may be sold as are currently in law for products containing ephedrine or related compounds. However, the bill exempts the sale of DXM-containing products from the FDLE electronic recordkeeping system, which will leave retailers without a real-time mechanism for tracking the quantity of

[24] *See* s. 893.1495(5)(b), F.S.
[25] *Id.*
[26] *See* s. 893.1495(5)(b)3., F.S.
[27] *See* s. 893.1495(6), F.S.
[28] *See* s. 893.1495(9), F.S.

DXM-containing products sold to certain purchasers in any single day or over a 30-day period, as required by the bill. How retailers will keep track of those data in a reliable, practical, and affordable manner in order to comply with the requirements of the bill is indeterminate.

VIII. Additional Information:

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

None.

B. Amendments:

None.