SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/SB 232

SPONSOR: Criminal Justice Committee and Senator Brown-Waite

SUBJECT: Controlled Substances

DATE: March 7, 2001 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Erickson	Cannon	CJ	Favorable/CS
2.			APJ	
3.			AP	
4.				
5.				

I. Summary:

Committee Substitute for Senate Bill 232 lists materials, compounds, mixtures, or preparations containing hydrocodone in limited quantities per milliliters or dosage unit as controlled substances under Schedule III of s. 893.03, F.S. The CS further references in s. 893.135, F.S., the trafficking statute, this Schedule III reference in order to indicate that prosecution for trafficking in hydrocodone, as listed under Schedule III, is intended. The CS further provides that, for the purpose of charging trafficking, the weight of the hydrocodone, or any other controlled substance, in a mixture is the total weight of the mixture.

This CS substantially amends ss. 893.03(3)(c) and 893.135(1)(c), F.S. This CS also reenacts s. 921.0022(3)(b), (c), and (e), F.S.

II. Present Situation:

A. Hydrocodone

Hydrocodone is legitimately prescribed and sold as an analgesic (pain reliever) and antitussive (cough suppressant) under such registered trademark names as Tussionex, Vicodin, Hycodan, Lortab, and Lorcet. Hydrocodone is often, though not exclusively, distributed in the form of tablets or pills that also contain acetaminophen, ibuprofen, aspirin, or other non-controlled substances. Hydrocodone (combined with acetaminophen) is listed as #5 of the 200 most popular prescriptions for 1999 (latest year reported), as ranked by RxList, an Internet drug information source. Rx.list.com, 2000 (website).

"The usual adult dose of hydrocodone is 5 to 10 mg. every 4 to 6 hours as needed, not to exceed 40 mg. per day with the 5 mg. dose and 60 mg. per day with the 10 mg. dose. The maximum recommended dose for hydrocodone when used in combination with ibuprofen is 37.5 mg. per

day . . . and when used in combination with acetaminophen is 60 mg. per day." *Texas Medicaid Drug Use Review Criteria for Outpatient Use* (revised March 2000), Drug Information Service, The University of Texas Health Science Center at San Antonio and the College of Pharmacy, The University of Texas (review by the Texas Medicaid Drug Use Review Board). According to the U.S. Drug Enforcement Administration (DEA), "[t]he therapeutic dose of 5-10 mg. [of hydrocodone] is the pharmacological equivalent to 60 mg. of oral morphine." *Drugs of Abuse*, U.S. Drug Enforcement Administration (website).

According to the National Institute on Drug Abuse (NIDA) (see NIDA website), hydrocodone can depress breathing, and is used with caution in elderly, debilitated patients and in patients with serious lung disease. It can impair thinking and the physical abilities required for driving or operating machinery. Alcohol and sedatives can produce further brain impairment and even confusion when combined with hydrocodone. Pregnant and nursing mothers and children should generally avoid hydrocodone use. There are also numerous possible side effects of varying degrees of seriousness, such as severe allergic reaction, that might be avoided in an appropriate medical setting (as contrasted with the illegal use of the drug where the user's medical history has not been reviewed and where the dosage used is not appropriately patient-specific and in accord with appropriate dosage-level standards).

NIDA further reports that hydrocodone overdosage may occur if the medication containing hydrocodone is not taken appropriately. Symptoms of overdosage of acetaminophen and hydrocodone include slow breathing, seizures, dizziness, weakness, loss of consciousness, coma, confusion, tiredness, cold and clammy skin, small pupils, nausea, vomiting and sweating.

NIDA further reports that using certain medications containing hydrocodone, in combination with various other drugs, can lead to serious or even dangerous interactions. For example, taking acetaminophen and hydrocodone with a monamine oxidase inhibitor can result in dangerous side effects, and taking acetaminophen and hydrocodone with certain antihistamines, tricyclic antidepressants, anticholinergics, phenothiazines, tranquilizers, and sedatives can result in serious interactions. Such usages would be avoided in a medical setting. The problem is with illegal use of medications containing hydrocodone. Many substance abusers are multiple substance abusers.

NIDA also reports that physical dependence on hydrocodone assumes clinically significant proportions only after several weeks of continued use, although some mild degree of physical dependence may develop after a few days of use. The rate of development of tolerance varies among patients. (Recent research findings indicate that "the abuse potential of opioid medications is generally low in healthy, non-drug abusing volunteers." Robert Mathias, "Research Eases Concern About Use of Opioids to Relieve Pain," *NIDA Notes*, V. 15, Number 1 (March 29, 2000))

Hydrocodone is illegally possessed and sold. Unlike, for example, methamphetamines obtained from illicit manufacturing, hydrocodone is almost without exception obtained from the diversion of prescription medications containing hydrocodone. *The Diversion of Drugs and Chemicals*, U.S. Drug Enforcement Administration (website). According to the DEA, approximately 2.4 billion prescriptions were written in 1998 (the most recent year reported), of which 254 million were controlled substances. *Id*. The DEA believes that pharmaceuticals diverted into illicit traffic

account for over 30 percent of all reported deaths and injuries associated with drug abuse. The DEA lists hydrocodone among the most diverted pharmaceuticals. *Id.*

According to the National Narcotics Intelligence Consumers Committee (NNICC), a committee that includes the DEA and FBI, "[t]he most commonly abused pharmaceutical drugs were hydrocodone products such as Lortab and Vicodin. Only 3 out of 20 DEA field divisions did not mention hydrocodone product abuse in their reports." *The NNICC Report 1996/The Supply of Illicit Drugs to the United States*, U.S. Drug Enforcement Administration (website). *See The DEA Diversion-Industry Communicator*, U.S. Drug Enforcement Administration (website) (under the subtitle "National Trends," the DEA reports that "[h]ydrocodone products remained the often reported abused pharmaceuticals."). The 1994 Southeastern Conference on Prescription Drug Abuse concluded that hydrocodone was among the most diverted prescription drugs. Ronald J. Dougherty, M.D, "Prescription Drug Use and Abuse," *Psychiatric Times*, V. XII, Issue 1 (January 1995). *See* Sharon Samber, "Questions Surface About Hydrocodone," *The NCADI Reporter* (October 29, 1997) (" '[Hydrocodone] is the most diverted forged prescription in the U.S.,' [Dr. Dougherty] says.")

Diversion of pharmaceuticals is accomplished in many different ways: second-hand sale of legitimately prescribed medication; theft of medication from hospitals, pharmacies, doctor's offices and homes; forged prescriptions; phone-in prescription fraud; falsifying symptoms to obtain prescriptions ("doctor shopping"); and unscrupulous practices by certain professionals. *See* Appendix H-2 Additional Drugs of Abuse Reported by Criminal Intelligence Division, Maryland Department of State Police, *Assessing Drug Abuse Within and Across Communities*, National Institute on Drug Abuse (website). *See also The Diversion of Drugs and Chemicals*, U.S. Drug Enforcement Administration (website) ("Typical diversion cases involve physicians who sell prescriptions to drug dealers or abusers, pharmacists who falsify records and subsequently sell the drugs, employees who steal from inventory, executives who falsify orders to cover illicit sales, prescription forgers, individuals who commit armed robbery of pharmacies and drug distributors, and 'doctor shoppers.' ")

Diverted pharmaceuticals, including products containing hydrocodone, are popular with substance abusers for several reasons in addition to the effects of the drugs. Quality of pharmaceuticals is assured and dosages and effects are consistent. The drugs are also relatively inexpensive and easy to obtain. Further, abuse of these drugs often goes undetected as law enforcement agencies' attention and resources are focused on illicit non-prescription drugs or these agencies are not well informed on diverted pharmaceuticals. *See* Appendix H-2 Additional Drugs of Abuse Reported by Criminal Intelligence Division, Maryland Department of State Police, *Assessing Drug Abuse Within and Across Communities*, National Institute on Drug Abuse (website).

Federal data is collected on emergency room episodes in which hydrocodone has been mentioned. ". . . [H]ydrocodone mentions [as reported in federal survey data] increased 173 percent from 1990 to 1997." *Epidemiological Trends in Drug Abuse/Advance Report June 1999*, Community Epidemiology Workgroup, National Institute on Drug Abuse.

On February 9, 2001, the Florida Department of Law Enforcement (FDLE) and the Florida Office of Drug Control (ODC) issued a press release (referred to as a "safety alert") In that press release, the FDLE and the ODC stated in part the following:

> Preliminary reports from the state medical examiners indicate that there have been 191 deaths related to the abuse of the prescription drugs oxycodone and hydrocodone. These numbers do not include reports from Miami-Dade and Broward counties. While the total number of 191 deaths reflects both drugs, the primary danger lies in the abuse of the drug oxycodone. Of the 191 deaths, 68 cases involving these drugs were overdose deaths. These numbers are significant, and the danger of death posed by the abuse of this drug warrants an immediate notification to the public.

A caveat to this information is that the press release indicates that the "safety alert" was not generated by the abuse of hydrocodone, though the FDLE and the ODC appear to have found something significant enough in the preliminary data to include mention of hydrocodone and find some correlation between the 191 deaths and "the abuse of prescription drugs oxycodone and hydrocodone." It is not indicated what number, if any, of the 191 deaths reported or the subset of 68 deaths by overdose, were directly the result of abuse of hydrocodone.

B. 1999 Controlled Substance Scheduling of Hydrocodone

In 1999, hydrocodone was listed as a Schedule II and Schedule III controlled substance. Section 893.03(2)(a)1.j., F.S., listed hydrocodone as a Schedule II controlled substance. However, s. 893.03(3)(c) 3. and 4. listed hydrocodone as a Schedule III controlled substance as provided:

> 3. Not more than 300 milligrams of hydrocodone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.
>
> 4. Not more than 300 milligrams of hydrocodone per 100 milliliters or nor more than 15 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

C. Trafficking in Hydrocodone

Section 893.135(c)1., F.S., makes it a first degree felony to traffic in 4 grams or more of hydrocodone or any salt, derivative, isomer, or salt of an isomer thereof, or 4 grams or more of any mixture containing hydrocodone. If the quantity involved is 4 grams or more but less than 14 grams, a 3-year mandatory minimum term and a $50,000 fine apply. If the quantity involved is 14 grams or more but less than 28 grams, a 15-year mandatory minimum term and a $100,000 fine apply. If the quantity involved is 28 grams or more but less than 30 kilograms, a 25-year mandatory minimum term and a $500,000 fine apply. There is no specific reference to Schedule III in this provision, only reference to Schedule I and Schedule II.

Section 893.135(c)2., F.S., makes it a first degree felony punishable by life imprisonment to traffic in 30 kilograms or more of hydrocodone or any salt, derivative, isomer, or salt of an isomer thereof, or 30 kilograms or more of any mixture containing hydrocodone. A person sentenced for

this crime is ineligible for any form of discretionary early release except pardon, executive clemency, or conditional medical release. There is no specific reference to Schedule III in this provision, only reference to Schedule I and Schedule II.

Committing an act in violation of s. 893.135(c)2., F.S., is a capital felony if the court determines that in addition to committing the act: the person intentionally killed an individual or counseled, commanded, induced, procured, or caused the intentional killing of an individual and such killing was the result; or the person's conduct in committing the act led to a natural, though not inevitable, lethal result. A person sentenced for this capital felony is also required to pay a $500,000 fine. There is no specific reference to Schedule III in this provision, only reference to Schedule I and Schedule II.

Section 893.135(c)3., F.S., makes it a capital felony to knowingly bring into this state 60 kilograms or more of hydrocodone or any salt, derivative, isomer, or salt of an isomer thereof, or 30 kilograms or more of any mixture containing hydrocodone, knowing that the probable result of such importation would be the death of any person. A person sentenced for this capital felony is also required to pay a $500,000 fine. There is no specific reference to Schedule III in this provision, only reference to Schedule I and Schedule II.

D. *Hayes v. State*

In *Hayes v. State*, 750 So.2d 1 (Fla. 1999), the Florida Supreme Court determined whether prescription tablets containing hydrocodone and non-controlled substances met the trafficking threshold under s. 893.135(1)(c)1., F.S. (Supp. 1996), which made it a crime to traffic in certain weights of hydrocodone or mixtures containing hydrocodone. The Court stated that s. 893.135(1)(c)1. (Supp.1996), applied only to Schedule I and Schedule II controlled substances; Schedule III controlled substances were not referenced there. Hydrocodone, the Court noted, was both a Schedule II and Schedule III controlled substance. The provision scheduling hydrocodone in Schedule III set forth specific limitations on quantity. s. 893.03(3)(c), F.S. (Supp. 1996). These limitations controlled the determination of whether a person is trafficking in hydrocodone. Specifically, these limitations excluded from prosecution trafficking persons possessing prescription tablets containing not more than 15 mg. of hydrocodone "per dosage unit" (e.g., tablet or pill). Because the tablets possessed by Hayes contained not more than 15 mg. per dosage unit, Hayes was not subject to the trafficking statute.

The *Hayes* decision effectively prohibited determining hydrocodone trafficking weight based upon the aggregate weight of the tablets possessed. Prior to the *Hayes* decision, both the Fourth District Court of Appeals and the Fifth District Court of Appeals approved this aggregation. *See States v. Hayes*, 720 So.2d 1095 (Fla. 4th DCA 1998), quashed, *Hayes v. State, supra,* and *State v. Baxley*, 684 So.2d 831 (Fla. 5th DCA 1996), abrogated, *Hayes v. State, supra*. The Fifth District Court of Appeals concluded that the aggregate weight of the tablets possessed by Hayes and not the amount of hydrocodone per dosage unit was the determinative weight for prosecution of Hayes for trafficking in a controlled substance. The Court relied on the Legislature's intent to punish hydrocodone trafficking and on *Chapman v. United States*, 500 U.S. 453 (1991).

> In *Chapman*, the defendant was convicted of selling 10 sheets of blotter paper containing 1,000 doses of LSD in violation of 21 U.S.C. [section] 841(a). *Id*. at 455, 111 S.Ct. 1919.

> The law called for "a mandatory minimum sentence of five years for the offense of distributing more than one gram of a 'mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD).'" *Id.* The Supreme Court held that the weight of the blotter paper, and not just the weight of the pure LSD which the paper contained was to be used in determining the sentence. *Id*. The Court concluded that this interpretation was compatible with Congress' " 'market-oriented' approach to punishing drug trafficking, under which the total quantity of what is distributed, rather than the amount of pure drug involved, is used to determine the length of the sentence." *Id*. at 461, 111 S.Ct. 1919 (citing H.R.Rep. No. 99-845, pt. 1, pp. 11-12, 17 (1986)).

State v. Hayes 720 So.2d at 1097.

More important, *Hayes v. State* effectively nullified the trafficking provision as it relates to hydrocodone because, almost without exception, the trafficking that occurs in hydrocodone is trafficking in prescription medications containing not more than 15 mg. of hydrocodone per dosage unit. It is not clear from the *Hayes* decision if the Court was aware of the preclusive effect of its decision.

Subsequent to *Hayes*, there has been conflict between the district courts as to whether the Florida Supreme Court intended in *Hayes* to prohibit aggregate weighing of a mixture containing oxycodone, a Schedule II controlled substance. *See Eagle v. State*, 2000 WL 898070 (Fla. 2d DCA, July 7, 2000) (supported aggregation) and *Travis v. State*, 754 So.2d 59 (Fla. 5th DCA 2000) (did not support aggregation).

E. 2000 Legislation on Hydrocodone Scheduling

During the 2000 Legislative Session, the Legislature enacted into law legislation (HB 2085) that, among other things, eliminated the Schedule III scheduling of hydrocodone. Sec. 2, ch. 2000-320, L.O.F.

The deletion of the Schedule III scheduling of hydrocodone was in response to the Florida Supreme Court's decision in *Hayes v. State*, 750 So.2d 1 (Fla. 1999). Hydrocodone was to become only a Schedule II controlled substance pursuant to s. 893.03(2)(a)1.j., F.S. The effective date of ch. 2000-320, L.O.F., was October 1, 2000.

F. Reaction to 2000 Legislation

Following the passage of HB 2085, the Office of the Attorney General was contacted by a number of individuals and associations, including legislators, physicians and pharmacists, expressing their concern that the deletion of the Schedule III scheduling of hydrocodone posed a danger to the public. Letter from the Honorable Robert A. Butterworth, Florida Attorney General to the Honorable Gus M. Bilirakis, Florida House of Representatives, dated August 29, 2000. (The following correspondence was identified by General Butterworth: Letter from James R. McDonough, Director, Office of Drug Control, dated August 24, 2000; Letter from the Honorable Mike Fasano, Florida House of Representatives, dated August 24, 2000; Letter from Marcia Foreman, President, Escambia County Pharmacy Association, dated August 20, 2000; Letter from the Honorable Mark Flanagan, Florida House of Representatives, dated August 16, 2000; Letter

from William J. Phelan, Executive Director, Florida Health Care Association, dated, August 8, 2000; Letter from the Honorable Charles Clary, Florida Senate, dated August 7, 2000; Letter from Barbara Lumpkin, Associate Executive Director, Florida Nurses Association, dated August 3, 2000; Letter from Delbert D. Konner, President, Pharmaceutical Care Management Association; and Letter from Luanne S. Stark, Director, of Pharmacy Practice, Merck-Medco Rx Services of Florida, L.C., dated July 31, 2000.)

The Senate and House sponsors of the legislation removing the Schedule III scheduling of hydrocodone indicated that it was not their intent to burden patients legitimately using prescription medications containing hydrocodone. *In Re: Proposed Rule 2-40.005, F.A.C.*, Office of the Attorney General (August 29, 2000); "Public outcry puts new law on hold for painkiller," *St. Petersburg Times* (August 31, 2000).

General Butterworth identified what appears to be the main concern regarding the deletion of the Schedule III scheduling of hydrocodone:

> Among the concerns expressed about the schedule change is that patients would be required to obtain a new written prescription from their physician for each refill of this pain medication. Many of the patients receiving hydrocodone mixtures are suffering from chronic illnesses such as AIDS, cancer, and arthritis and may need to receive up to five refills in six months. As a result of the rescheduling, a patient's drug therapy could be delayed or disrupted. *See*, Letter from Delbert D. Conner, Pharmaceutical Care Management, *supra*, and Letter from William Phelan, Florida Health Care Association, *supra*.

Id.

The requirements relating to prescriptions containing Schedule II controlled substances are federal requirements. *See* 21 C.F.R. Section 1308.13(e).

General Butterworth also noted that the Florida Board of Medicine and the Florida Board of Pharmacy voted to request the Attorney General to exercise his authority under s. 893.0355, F.S., to retain the Schedule III scheduling of hydrocodone. *Id*. (The Attorney General noted that he received a letter from John D. Taylor, Executive Director, Florida Board of Pharmacy, Department of Health, dated August 22, 2000.)

The Attorney General exercised his rulemaking authority under s. 893.0355, F.S., and on August 29, 2000, an emergency rule was issued retaining the Schedule III scheduling of hydrocodone (Committee staff conversation with Attorney General staff, February 28, 2001). On November 27, 2000, a permanent rule was issued (*id.*). Section 893.0355(6) provides that "[r]ules adopted pursuant to this section shall be reviewed each year by the Legislature" and "[e]ach rule shall remain in effect until the effective date of legislation that provides for a different scheduling of a substance than that set forth in the rule."

G. Definition of "Mixture"

Section 1 of ch. 2000-320, L.O.F., amended s. 893.02, F.S., to add a new subsection (14) that contains a new definition of the term "mixture." A mixture, as defined, is "any physical

combination of two or more substances." Since a prescription medication containing hydrocodone is a "physical combination of two or more substances" (combining hydrocodone and non-controlled substances, such as acetaminophen), it is clearly a "mixture," as defined in s. 893.02(14), F.S.

III. Effect of Proposed Changes:

Committee Substitute for Senate Bill 232 amends s. 893.03(3)(c), F.S., to reinstate the former listing under that paragraph of materials, compounds, mixtures, or preparations containing hydrocodone in limited quantities per milliliters or dosage unit as Schedule III controlled substances. This amendment addresses the concerns of the medical community and others regarding refilling orders for prescription medications containing hydrocodone.

The CS also amends s. 893.135(1)(c), F.S., which prohibits trafficking in hydrocodone, to reference the Schedule III scheduling references for hydrocodone. This amendment is to indicate that this trafficking provision applies to hydrocodone, regardless of whether it is a Schedule II or Schedule III substance. A persuasive factor in the Court reaching its holding in *Hayes, supra*, was the fact that there was no Schedule III reference in this trafficking provision. This change, combined with the new definition of "mixture" in s. 893.02(14), F.S., should indicate to the Court the Legislature's intent to treat hydrocodone, for trafficking purposes, the same as other trafficking drugs. In other words, for determining whether the trafficking threshold for hydrocodone or mixtures containing hydrocodone is met, the weight of the hydrocodone should be the aggregate weight of the hydrocodone or prescription medication containing hydrocodone that is possessed, not the amount of hydrocodone per dosage unit. The new definition of "mixture" indicates that a prescription medication containing hydrocodone is indistinguishable from any other mixture containing a controlled substance, e.g., cut cocaine.

The CS further clarifies legislative intent regarding the weighing of hydrocodone, or any other controlled substance, in a mixture, for the purpose of charging trafficking. The weight of the hydrocodone or other controlled substance is the weight of the mixture containing hydrocodone or other controlled substance. In other words, the weight includes both the controlled substance and the non-controlled substances in the mixture. If there is more than one mixture containing the same controlled substance, the weight of the controlled substance is calculated by aggregating the total weight of each mixture.

Finally, the CS provides legislative findings regarding the weighing of hydrocodone, or any other controlled substance, in a mixture, for the purpose of charging trafficking. The Legislature finds that *Hayes v. State, supra,* does not correctly construe such legislative intent but *State v. Hayes, supra,* and *State v. Baxley, supra,* do. Accordingly, the Legislature is indicating through these findings that hydrocodone or mixtures containing hydrocodone, whether listed in Schedule II or Schedule III are, for the purpose of charging trafficking, to be weighed no differently than any other controlled substances, e.g., cocaine or cut cocaine.

The CS also reenacts s. 921.0022(3)(b), (c), and (e), F.S., relating to the offense severity ranking chart in the Criminal Punishment Code, to incorporate the amendment in s. 893.03, F.S., in reference thereto.

The CS takes effect on July 1, 2001.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

There should be no impact on the private sector, because the CS addresses the concerns of members of the private sector regarding the deletion of the Schedule III scheduling of hydrocodone.

C. Government Sector Impact:

The Criminal Justice Estimating Conference estimates that CS/SB 232 will not have an impact.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.