Rescheduling of hydrocodone

Number: INFORMAL

Date: August 30, 2000

The Honorable Gus M. Bilirakis
Representative, District 48
31608 US Highway 19 North
Palm Harbor, Florida 34684

Dear Representative Bilirakis:

As one of the sponsors of House Bill 2085 (passed as Chapter 2000-320, Laws of Florida), you ask about the effect of this law on hydrocodone derivatives. Hydrocodone is a controlled substance that is often sold as a prescription analgesic (pain reliever) and antitussive (cough suppressant) under such registered trademark names as Tussionex, Vicodin, Hycodan, and Lorcet.[1]

In 1999, hydrocodone was listed as a Schedule II and a Schedule III controlled substance. Section 893.03(2)(a)1.j., Florida Statutes 1999, listed hydrocodone as a Schedule II drug. Section 893.03(3)(c)3., Florida Statutes 1999, however, provided that the following constituted a Schedule III controlled substance:

"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 not more than 15 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances."

During the 2000 legislative session, in response to the decision of the Supreme Court of Florida in *Hayes v. State,*[2] the Legislature enacted Chapter 2000-320, Laws of Florida, which in section 2 deletes the reference to certain mixtures containing hydrocodone from Schedule III.[3] By removing the mixtures of hydrocodone from Schedule III, the drug, including mixtures thereof, is treated strictly as a Schedule II substance. Chapter 2000-320 becomes effective October 1, 2000.[4]

Since the passage of Chapter 2000-320, Laws of Florida, this office has been contacted by a number of individuals[5] and associations,[6] including physicians and pharmacists, expressing their concern that the reclassification of any and all compounds of hydrocodone as a Schedule II drug poses a danger to the public.[7] Additionally, the Florida Board of Medicine and the Florida Board of Pharmacy have voted to request the Attorney General to exercise his authority under section 893.0355, Florida Statutes, to reschedule certain mixtures of hydrocodone to Schedule III.[8]

Section 893.0355, Florida Statutes, delegates to the Attorney General the authority to adopt rules rescheduling specified substances to a less controlled schedule if such reduction is found to be in the public interest, based upon the statutory criteria set forth in section 893.0355.[9] The statute requires that great weight be given to the scheduling rules adopted by the United States Attorney General in order to achieve the original legislative purpose of the Florida Comprehensive Drug Abuse Prevention and Control Act of maintaining uniformity between the laws of Florida and the laws of the United States with respect to controlled substances.[10] Currently, the federal government classifies hydrocodone as both a Schedule II and Schedule III drug.[11]

In light of the concerns expressed by the medical community, this office anticipates initiating rule-making under the delegated authority of section 893.0355, Florida Statutes, regarding the rescheduling of certain mixtures of hydrocodone to a Schedule III controlled substance. This, however, is only a temporary solution to this serious problem that should be addressed by the Florida Legislature prior to the conclusion of its next regular session.

In taking steps towards reclassification, I am deeply concerned about the potential for abuse of hydrocodone. This office, therefore, is working closely with the Florida Prosecuting Attorneys Association to ensure that the Legislature has language for a proposed bill to readdress the decision in *Hayes v. State*[12] when the regular legislative session convenes.

I trust that the above comments may be of assistance to you in this matter.

Sincerely,

Robert A. Butterworth
Attorney General

RAB/tgk

cc: The Honorable John Thrasher
Speaker, Florida House of Representatives

The Honorable Toni Jennings
President, Florida Senate

The Honorable Brad King
State Attorney, 5th Judicial Circuit
President, Florida Prosecuting Attorneys Association

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[1] *See* House of Representatives, as revised by the Committee on Crime and Punishment, Final Analysis on CS/HB 2085 (Chapter 2000-320, Laws of Florida), dated June 21, 2000, p. 4.

[2] 750 So. 2d 1 (Fla. 1999).

[3] *See* s. 2, Ch. 2000-320, Laws of Florida.

[4] *See* s. 29, Ch. 2000-320, *supra.*

[5] *See* Letter from James R. McDonough, Director, Governor's Office of Drug Control, dated August 24, 2000; Letter from the Honorable Mike Fasano, Florida House of Representatives, dated August 24, 2000; Letter from the Honorable Mark Flanagan, Florida House of Representatives, dated August 16, 2000; Letter from the Honorable Charlie Clary, Florida Senate, dated August 7, 2000.

[6] *See* Letter from William J. Phelan, Executive Director, Florida Health Care Association, dated August 8, 2000; Letter from Marcia Foreman, President, Escambia County Pharmacy Association, dated August 20, 2000; Letter from Barbara Lumpkin, Associate Executive Director, Florida Nurses Association, dated August 3, 2000; Letter from Luanne S. Stark, Director of Pharmacy Practice, Merck-Medco Rx Services of Florida, L.C., dated July 31, 2000; Letter from Delbert D. Konner, President, Pharmaceutical Care Management Association, dated August 3, 2000.

[7] 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. Konner, Pharmaceutical Care Management Association, *supra,* and Letter from William Phelan, Florida Heath Care Association, *supra.*

[8] *See* Letter from John D. Taylor, Executive Director, Florida Board of Pharmacy, Department of Health, dated August 22, 2000.

[9] *See* s. 893.0355(2), Fla. Stat., which sets forth the criteria the Attorney General must consider in making that determination:

"(a) Whether the substance has been rescheduled or deleted from any schedule by rule adopted by the United States Attorney General pursuant to s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811.
(b) The substance's actual or relative potential for abuse.
(c) Scientific evidence of the substance's pharmacological effect, if known.
(d) The state of current scientific knowledge regarding the substance.
(e) The substance's history and current pattern of abuse.
(f) The scope, duration, and significance of abuse.
(g) What, if any, risk there is to the public health.
(h) The substance's psychic or physiological dependence liability."

[10] *See* s. 893.0355(3), Fla. Stat.

[11] *See* 21 CFR s. 1308.12, Schedule II, refers in (b)(1) to:

"(10) Hydrocodone"

And see, 21 CFR s. 1308.13, Schedule III, stating in subsection (e) Narcotic Drugs:

"Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

* * *

(3) Not more than 300 milligrams of dihydrocodeinone (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 dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts."

[12] 750 So. 2d 1 (Fla. 1999).