OPINION NO. 2001-014

Syllabus:

Pursuant to R.C. 3719.43 and 65 Fed. Reg. 13,235 (Mar. 13, 2000) (amending, *inter alia*, 21 C.F.R. §§ 1308.11(e) and 1308.13(c)), for purposes of Ohio law gammahydroxybutyrate (GHB) is a Schedule I controlled substance and FDA-

approved drugs containing GHB are Schedule III controlled substances, notwithstanding the provisions of Am. H.B. 428, 123rd Gen. A. (1999) (eff. May 17, 2000).

To: William T. Winsley, R.Ph., M.S., Executive Director, State Board of Pharmacy, Columbus, Ohio
By: Betty D. Montgomery, Attorney General, April 2, 2001

We have received your request for an opinion concerning the classification of the drug gammahydroxybutyrate (GHB)[1] as a controlled substance. You have raised questions concerning the controlled substance schedule in which GHB appears under Ohio law. We note, as a general matter, that a controlled substance is a drug, compound, mixture, preparation, or substance that is placed in a schedule for extensive regulation under state or federal law because it has a potential for abuse, or because either it has no accepted medical use in treatment or its abuse may lead to dependence. *See* 21 U.S.C.A. §§ 811 and 812 (West Group 1999); R.C. 3719.01(C); R.C. 3719.41; R. C. 3719.44; *see also* notes 2 and 8, *infra.*

GHB is a fast-acting central nervous system depressant that can produce drowsiness, dizziness, nausea, visual disturbances, unconsciousness, seizures, severe respiratory depression, and coma. GHB is abused to produce euphoric and hallucinogenic states and for sedative and body building effects. It has been associated with occurrences of sexual assaults and date rape situations. Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Pub. L. No. 106-172, 114 Stat. 7 (2000); H.R. Rep. No. 106-340 (Sept. 27, 1999); 65 Fed. Reg. 13,235, at 13,236 (Mar. 13, 2000); Ohio Legislative Service Comm'n, Final Analysis, 123rd Gen. A. (Am. H.B. 428, eff. May 17, 2000).

Your concerns have arisen in light of federal and state actions relating to GHB. Under both federal and state law, controlled substances are listed in Schedules I through V, with Schedule I providing the most stringent control.[2] On December 9, 1999, the General Assembly enacted Am. H.B. 428, which amended the controlled substance schedules appearing in R.C. 3719.41, *inter alia*, to designate GHB as a Schedule II controlled substance. *See* Am. H.B. 428, 123rd Gen. A. (1999) (eff. May 17, 2000). Am. H.B. 428 was signed by Governor Taft on February 15, 2000, and filed with the Secretary of State on February 16, 2000. *See* Ohio Const. art. II, § 16. By operation of law, it became effective on May 17, 2000. Id.; *see* Ohio Const. art. II, § 1c; *see also* R.C. 1.471.[3]

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[1]Alternate spellings include gamma-hydroxybutyrate and gamma-hydroxy-butyrate. *See* 21 C.F.R. § 1308.11(e)(1) (2000); Am. H.B. 428, 123rd Gen. A. (1999) (eff. May 17, 2000). Other names include gamma-hydroxybutyric acid, sodium oxybate, Liquid X, Liquid Ecstasy, and Grievous Bodily Harm. *See* Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Pub. L. No. 106-172, 114 Stat. 7 (2000); 21 C.F.R. § 1308.11(e)(1) (2000).

[2]The federal schedules of controlled substances appear in 21 C.F.R. §§ 1308.11 to 1308.15 (2000). *See* 21 U.S.C.A. § 812 (West Group 1999). The Ohio schedules of controlled substances appear in R.C. 3719.41 and are subject to modification pursuant to federal action as provided in R.C. 3719.43 or action by the State Board of Pharmacy pursuant to R.C. 3719.44. *See* R.C. 3719.41; R.C. 3719.43; R.C. 3719.44. *See generally* 21 U.S.C.A. § 829 (West Group 1999); 21 U.S.C.A. §§ 841 to 843 (West Group 1999); R.C. 3719.99; *Touby v. United States*, 500 U.S. 160 (1991); *State v.Reed*, 14 Ohio App. 3d 63, 470 N.E.2d 150 (Ross County 1983); 1991 Op. Att'y Gen. No. 91-038.

[3]Absent the manifestation of a contrary intention, an act of the General Assembly speaks and operates only from its effective date. *See, e.g., Patterson Foundry & Machine Co. v. Ohio*

Between the time when Am. H.B. 428 was filed and its effective date, there appeared in the Federal Register notice that the United States Attorney General, through the Deputy Administrator of the Federal Drug Enforcement Administration in the Department of Justice, adopted a final rule designating GHB as a Schedule I controlled substance, with limited exceptions. 65 Fed. Reg. 13,235 (Mar. 13, 2000) (amending 21 C.F.R. §§ 1301.72(a) and (b), 1308.11(e), and 1308.13(c)); *see* 21 C.F.R. § 1308.11(e)(1) (2000). The basic exception is that any drug product including GHB that receives approval by the Federal Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act[4] will be included in Schedule III.[5] 65 Fed. Reg. 13,235 (Mar. 13, 2000); *see* 21 C.F.R. § 1308.13(c)(5) (2000); *see also* 21 U.S.C.A. §§ 301 and 355 (West Group 1999 & Supp. 2000). In addition, GHB that is used in a properly approved research program is subject to Schedule III physical security requirements for storage by registered manufacturers and distributors. 65 Fed. Reg. 13,235 (Mar. 13, 2000); *see* 21 C.F.R. § 1301.72(a) and (b) (2000); *see also* 21 U.S.C.A. § 355(i) (West Group 1999).[6]

The confusion regarding the classification of GHB arises from statutes governing the relationship between federal and state classifications of controlled substances.[7] R.C. 3719.43 provides that, when the United States Attorney General adds a substance to the federal drug abuse controlled substance schedules, transfers a substance between schedules, or removes a substance from the schedules, "then such addition, transfer, or removal is automatically effected in the corresponding schedule or schedules in [R.C. 3719.41], subject to amendment

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River Power Co., 99 Ohio St. 429, 124 N.E. 241 (1919); *Mott v. Fulton*, 21 Ohio L. Abs. 366, 368-69 (Ct. App. Summit County 1935), *aff'd*, 131 Ohio St. 500, 3 N.E.2d 404 (1936).

[4]No drug product including GHB had been approved by the FDA when the federal rule was adopted or when this opinion was prepared. *See* 65 Fed. Reg. 13,235, at 13,237 (Mar. 13, 2000); note 11, *infra*.

[5]Under federal law, drug products coming within this exception will be subject to the same criminal penalties for illicit manufacturing or distribution that apply to a Schedule I controlled substance. *See* Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Pub. L. No. 106-172, 114 Stat. 7 (2000); H.R. Rep. No. 106-340 (Sept. 27, 1999); 65 Fed. Reg. 13,235, at 13,237 (Mar. 13, 2000).

[6]This exception is mandated by federal statute and affects the manner in which GHB is treated under federal law, but it does not appear in the federal controlled substance schedules and thus does not appear to be automatically effected in the Ohio schedules pursuant to R.C. 3719.43. *See* Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Pub. L. No. 106-172, 114 Stat. 7 (2000); H.R. Rep. No. 106-340 (Sept. 27, 1999); 21 C.F.R. §§ 1308.11 to 1308.15 (2000); 65 Fed. Reg. 13,235, at 13,237 (Mar. 13, 2000); R.C. 3719.43.

[7]The federal drug abuse prevention and control statutes allow state regulation of drugs, as follows:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C.A. § 903 (West Group 1999).

pursuant to [R.C. 3719.44]." R.C. 3719.43; *see State v. Klinck*, 44 Ohio St. 3d 108, 109, 541 N.E.2d 590, 592 (1989) (drug classification made by the United States Attorney General on the federal schedules "was automatically incorporated into" the Ohio schedules).[8] The matter to be determined is how this automatic classification affects the action taken by the General Assembly.

Pursuant to R.C. 3719.43, the federal action designating GHB a controlled substance placed GHB itself in Schedule I and placed any FDA-approved drug containing GHB in Schedule III. However, the state action, if found valid, effective, and not superseded by federal law, would place both GHB and any FDA-approved drug containing GHB in Schedule II.

In order to address your question, it is necessary to examine the procedure by which Ohio's controlled substance schedules were modified. *See* note 2, *supra*.[9] In the instant case, the General Assembly enacted Am. H.B. 428, which included as one of its purposes: "to make gamma-hydroxy-butyrate a schedule II controlled substance." Am. H.B. 428, 123rd Gen. A. (1999) (eff. May 17, 2000). The relevant language of Schedule II, including the preexisting statutory language preceding the reference to GHB, states:

> (D) Depressants
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> Unless specifically excepted under federal drug abuse control laws or *unless listed in another schedule*, any material, compound, mixture, or preparation that contains any quantity of the following substances having a

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[8]R.C. 3719.44 permits the State Board of Pharmacy to add or remove controlled substances or to transfer controlled substances from one schedule to another, but it does not permit the State Board of Pharmacy to take action that results in less stringent control than is provided under federal drug abuse control laws. R.C. 3719.44(A); *see Sterling Drug, Inc. v. Wickham*, 63 Ohio St. 2d 16, 406 N.E.2d 1363 (1980); 1994 Op. Att'y Gen. No. 94-083. The Board is given factors to consider and standards to meet in determining whether to add, remove, or transfer substances. R.C. 3719.44(B) to (H). Those factors are similar to standards established by federal law. *See* 21 U.S.C.A. §§ 811 and 812 (West Group 1999). In particular, substances are appropriately included in Schedule I when it appears that there is a high potential for abuse and either no accepted medical use in treatment or a lack of accepted safety for use in treatment. R.C. 3719.44(C). Substances are appropriately included in Schedule II when it appears that there is a high potential for abuse, a currently accepted medical use in treatment, and the possibility of severe physical or severe psychological dependence if the drug is abused. R.C. 3719.44(D). Substances are appropriately included in Schedule III when it appears that there is a currently accepted medical use in treatment, less potential for abuse than in Schedules I and II, and the possibility that abuse may lead to moderate or low physical or high psychological dependence. R.C. 3719.44(E).

[9]From time to time the General Assembly incorporates in R.C. 3719.41 changes to the controlled substance schedules made by the federal government as provided in R.C. 3719.43 or by the State Board of Pharmacy pursuant to R.C. 3719.44. *See, e.g.*, Am. H.B. 428, 123rd Gen. A. (1999) (eff. May 17, 2000) (*inter alia*, revising state controlled substances schedules according to federal drug laws). The General Assembly also acts on occasion to add to the controlled substance schedules drugs that have not been placed there by federal action or by the State Board of Pharmacy. *See, e.g.*, 1991-1992 Ohio Laws, Part II, 2834, 2860 (Am. Sub. H.B. 62, eff. May 21, 1991) (adding anabolic steroids to Schedule III); 1994 Op. Att'y Gen. No. 94-083 (discussing Sub. H.B. 391, 120th Gen. A. (1994) (eff. July 21, 1994) [1993-1994 Ohio Laws, Part III, 5768, 5816], which added ephedrine to Schedule V).

> depressant effect on the central nervous system, including their salts, isomers, and salts of isomers, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:
>
> (2) Gamma-hydroxy-butyrate ....

R.C. 3719.41 (emphasis added). The language of the statute clearly states that the substances listed therein are included in Schedule II unless they are specifically excepted under federal drug abuse control laws or unless they are listed in another of Ohio's controlled substance schedules.

Pursuant to R.C. 3719.43, the action of the federal government appearing in the Federal Register on March 13, 2000, automatically modified Ohio's controlled substance schedules by placing GHB in Schedule I and placing FDA-approved drugs containing GHB in Schedule III.[10] 65 Fed. Reg. 13,235 (Mar. 13, 2000). Thus, when Am. H.B. 428 became effective on May 17, 2000, GHB had already been listed in Schedule I and FDA-approved drugs containing GHB had already been listed in Schedule III. Pursuant to the express language of R.C. 3719.41, therefore, the language of Am. H.B. 428 placing GHB in Schedule II was inoperative, because at the time of the effective date of the statute GHB was "listed in another schedule." R.C. 3719.41. The result is that the federal designations currently prevail under Ohio law.[11] Therefore, pursuant to R.C. 3719.43 and 65 Fed. Reg. 13,235 (Mar. 13, 2000) (amending, *inter alia*, 21 C.F.R. §§ 1308.11(e) and 1308.13(c)), for purposes of Ohio law GHB is a Schedule I controlled substance and FDA-approved drugs containing GHB are

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[10]R.C. 3719.43, which provides for automatic revision of the Ohio controlled substance schedules to correspond to revisions of the federal schedules, has been upheld against the challenge that it constitutes an unconstitutional delegation of state legislative authority. *State v. Klinck*, 44 Ohio St. 3d 108, 541 N.E.2d 590 (1989). Its validity is based on the fact that the State Board of Pharmacy has authority to transfer a drug to another schedule, provided that control is not less stringent than provided under federal law. *Id.*

[11]This conclusion is consistent with the following note appearing in the supplement to Baldwin's Ohio Revised Code Annotated:

> *House Bill 428 was passed and signed by the Governor in February, 2000. This bill placed GHB into Schedule II and was set to take effect on May 17, 2000. Since the Federal Government has placed GHB into Schedule I effective March 13, 2000, and since Ohio has an automatic roll-over statute for scheduling, House Bill 428 regarding GHB will not take effect. Ohio's Schedules of Controlled Substances will reflect the more restrictive scheduling. Therefore, all analysis for GHB should be reported as a Schedule I controlled substance.*

2 *Baldwin's Ohio Legislative Service Annotated*, 123rd Gen. A., at L-319 (West Group complete to Apr. 10, 2000). This note follows language indicating that there currently are no FDA-approved drugs containing GHB; hence, there currently are no substances containing GHB that should be reported as Schedule III controlled substances. With respect to the effectiveness of Am. H.B. 428, this note states only that "*House Bill 428 regarding GHB will not take effect.*" Other portions of that bill, relating to the scheduling of other substances, took effect in the ordinary manner. *See* Am. H.B. 428, 123rd Gen. A. (1999) (eff. May 17, 2000).

Schedule III controlled substances, notwithstanding the provisions of Am. H.B. 428, 123rd Gen. A. (1999) (eff. May 17, 2000).

This result is appropriate in light of other provisions of Ohio law and in light of its overall effect. Pursuant to R.C. 3719.43, federal action scheduling controlled substances is automatically effected in the state schedules, "subject to amendment pursuant to [R.C. 3719.44]," which is action by the State Board of Pharmacy. R.C. 3719.43; *see* R.C. 3719.44. R.C. 3719.43 and R.C. 3719.44 do not address the situation in which the General Assembly acts directly to amend the controlled substance schedules appearing in R.C. 3719.41. *See* note 9, *supra*. However, it is clear in the instant case that, because the federal classification of GHB was not yet in effect when the General Assembly enacted Am. H.B. 428, the General Assembly did not adopt in Ohio a classification different from one in effect under federal law. In enacting Am. H.B. 428, the General Assembly intended to include GHB as a controlled substance, but it cannot have intended to modify the GHB classifications prescribed by federal law, for those classifications were not yet in effect. Therefore, it is appropriate that the federal classifications prevail under Ohio law, in accordance with the provisions of R.C. 3719.43.[12]

Therefore, it is my opinion, and you are advised, that pursuant to R.C. 3719.43 and 65 Fed. Reg. 13,235 (Mar. 13, 2000) (amending, *inter alia*, 21 C.F.R. §§ 1308.11(e) and 1308.13(c)), for purposes of Ohio law gammahydroxybutyrate (GHB) is a Schedule I controlled substance and FDA-approved drugs containing GHB are Schedule III controlled substances, notwithstanding the provisions of Am. H.B. 428, 123rd Gen. A. (1999) (eff. May 17, 2000).

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[12]It should be noted, further, that the result of this analysis would be the same if Am. H.B. 428, 123rd Gen. A. (1999) (eff. May 17, 2000) had been adopted as an emergency measure, thereby making the amendments to R.C. 3719.41 effective immediately. *See* Ohio Const. art. II, § 1d. Had the Ohio legislation been effective immediately as an emergency measure, subsequent federal scheduling of GHB would have automatically taken effect to modify the Ohio law pursuant to R.C. 3719.43.