106TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPT. 106–340
Part 1

HILLORY J. FARIAS DATE-RAPE PREVENTION DRUG ACT OF 1999

SEPTEMBER 27, 1999.—Ordered to be printed

Mr. BLILEY, from the Committee on Commerce, submitted the following

R E P O R T

[To accompany H.R. 2130]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 2130) to amend the Controlled Substances Act to add gamma hydroxybutyric acid and ketamine to the schedules of control substances, to provide for a national awareness campaign, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

CONTENTS

AMENDMENT

The amendments are as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Hillory J. Farias Date-Rape Prevention Drug Act of 1999".

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Gamma hydroxybutyric acid (also called G, Liquid X, Liquid Ecstasy, Grievous Bodily Harm, Georgia Home Boy, Scoop) has become a significant and growing problem in law enforcement. At least 20 States have scheduled such drug in their drug laws and law enforcement officials have been experiencing an increased presence of the drug in driving under the influence, sexual assault, and overdose cases, especially at night clubs and parties.

(2) A behavioral depressant and a hypnotic, gamma hydroxybutyric acid ("GHB") is being used in conjunction with alcohol and other drugs with detrimental effects in an increasing number of cases. It is difficult to isolate the impact of such drug's ingestion since it is so typically taken with an ever-changing array of other drugs and especially alcohol, which potentiates its impact.

(3) GHB takes the same path as alcohol, processes via alcohol dehydrogenase, and its symptoms at high levels of intake and as impact builds are comparable to alcohol ingestion/intoxication. Thus, aggression and violence can be expected in some individuals who use such drug.

(4) If taken for human consumption, common industrial chemicals such as gamma butyrolactone and 1.4-butanediol are swiftly converted by the body into GHB. Illicit use of these and other GHB analogues and precursor chemicals is a significant and growing law enforcement problem.

(5) A human pharmaceutical formulation of gamma hydroxybutyric acid is being developed as a treatment for cataplexy, a serious and debilitating disease. Cataplexy, which causes sudden and total loss of muscle control, affects about 65 percent of the estimated 180,000 Americans with narcolepsy, a sleep disorder. People with cataplexy often are unable to work, drive a car, hold their children or live a normal life.

SEC. 3. ADDITION OF GAMMA HYDROXYBUTYRIC ACID AND KETAMINE TO SCHEDULES OF CONTROLLED SUBSTANCES; GAMMA BUTYROLACTONE AS ADDITIONAL LIST I CHEMICAL.

(a) ADDITION TO SCHEDULE I.—

(1) IN GENERAL.—Section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end of schedule I the following:

"(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following substance having a depressant effect on the central nervous system, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

"(1) Gamma hydroxybutyric acid.".

(2) SECURITY OF FACILITIES.—For purposes of any requirements that relate to the physical security of registered manufacturers and registered distributors, gamma hydroxybutyric acid and its salts, isomers, and salts of isomers manufactured, distributed, or possessed in accordance with an exemption approved under section 505(i) of the Federal Food, Drug, and Cosmetic Act shall be treated as a controlled substance in schedule III under section 202(c) of the Controlled Substances Act.

(b) ADDITION TO SCHEDULE III.—Schedule III under section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended in (b)—

(1) by redesignating (4) through (10) as (6) through (12), respectively;

(2) by redesignating (3) as (4);

(3) by inserting after (2) the following:

"(3) Gamma hydroxybutyric acid and its salts, isomers, and salts of isomers contained in a drug product for which an application has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act."; and

(4) by inserting after (4) (as so redesignated) the following:

"(5) Ketamine and its salts, isomers, and salts of isomers.".

(c) ADDITIONAL LIST I CHEMICAL.—Section 102(34) of the Controlled Substances Act (21 U.S.C. 802(34)) is amended—

(1) by redesignating subparagraph (X) as subparagraph (Y); and

(2) by inserting after subparagraph (W) the following subparagraph:

"(X) Gamma butyrolactone.".

(d) RULE OF CONSTRUCTION REGARDING CONTROLLED SUBSTANCE ANALOGUES.—Section 102(32) of the Controlled Substances Act (21 U.S.C. 802(32)) is amended—

(1) by redesignating subparagraph (B) as subparagraph (C); and

(2) by inserting after subparagraph (A) the following subparagraph:

"(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.".

(e) PENALTIES REGARDING SCHEDULE I.—

(1) IN GENERAL.—Section 401(b)(1)(C) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(C)) is amended in the first sentence by inserting after "schedule I or II," the following: "gamma hydroxybutyric acid in schedule III,".

(2) CONFORMING AMENDMENT.—Section 401(b)(1)(D) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(D)) is amended by inserting "(other than gamma hydroxybutyric acid)" after "schedule III".

(f) DISTRIBUTION WITH INTENT TO COMMIT CRIME OF VIOLENCE.—Section 401(b)(7)(A) of the Controlled Substances Act (21 U.S.C. 841(b)(7)(A)) is amended by inserting "or controlled substance analogue" after "distributing a controlled substance".

SEC. 4. AUTHORITY FOR ADDITIONAL REPORTING REQUIREMENTS FOR GAMMA HYDROXYBUTYRIC PRODUCTS IN SCHEDULE III.

Section 307 of the Controlled Substances Act (21 U.S.C. 827) is amended by adding at the end the following:

"(h) In the case of a drug product containing gamma hydroxybutyric acid for which an application has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act, the Attorney General may, in addition to any other requirements that apply under this section with respect to such a drug product, establish any of the following as reporting requirements:

"(1) That every person who is registered as a manufacturer of bulk or dosage form, as a packager, repackager, labeler, relabeler, or distributor shall report acquisition and distribution transactions quarterly, not later than the 15th day of the month succeeding the quarter for which the report is submitted, and annually report end-of-year inventories.

"(2) That all annual inventory reports shall be filed no later than January 15 of the year following that for which the report is submitted and include data on the stocks of the drug product, drug substance, bulk drug, and dosage forms on hand as of the close of business December 31, indicating whether materials reported are in storage or in process of manufacturing.

"(3) That every person who is registered as a manufacturer of bulk or dosage form shall report all manufacturing transactions both inventory increases, including purchases, transfers, and returns, and reductions from inventory, including sales, transfers, theft, destruction, and seizure, and shall provide data on material manufactured, manufactured from other material, use in manufacturing other material, and use in manufacturing dosage forms.

"(4) That all reports under this section must include the registered person's registration number as well as the registration numbers, names, and other identifying information of vendors, suppliers, and customers, sufficient to allow the Attorney General to track the receipt and distribution of the drug.

"(5) That each dispensing practitioner shall maintain for each prescription the name of the prescribing practitioner, the prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations, verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance, the patient's name and address, the name of the patient's insurance provider and documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug. Such information shall be available for inspection and copying by the Attorney General.

"(6) That section 310(b)(3) (relating to mail order reporting) applies with respect to gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.".

SEC. 5. DEVELOPMENT OF FORENSIC FIELD TESTS FOR GAMMA HYDROXYBUTYRIC ACID.

The Attorney General shall make a grant for the development of forensic field tests to assist law enforcement officials in detecting the presence of gamma hydroxybutyric acid and related substances.

SEC. 6. ANNUAL REPORT REGARDING DATE-RAPE DRUGS; NATIONAL AWARENESS CAMPAIGN.

(a) ANNUAL REPORT.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall periodically submit to the Congress reports each of which provides an estimate of the number of incidents of the abuse of date-rape drugs (as defined in subsection (c)) that occurred during the most recent one-year period for which data are available. The first such report shall be submitted not later than January 15, 2000, and subsequent reports shall be submitted annually thereafter.

(b) NATIONAL AWARENESS CAMPAIGN.—

(1) DEVELOPMENT OF PLAN; RECOMMENDATIONS OF ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Secretary, in consultation with the Attorney General, shall develop a plan for carrying out a national campaign to educate individuals described in subparagraph (B) on the following:

(i) The dangers of date-rape drugs.

(ii) The applicability of the Controlled Substances Act to such drugs, including penalties under such Act.

(iii) Recognizing the symptoms that indicate an individual may be a victim of such drugs, including symptoms with respect to sexual assault.

(iv) Appropriately responding when an individual has such symptoms.

(B) INTENDED POPULATION.—The individuals referred to in subparagraph (A) are young adults, youths, law enforcement personnel, educators, school nurses, counselors of rape victims, and emergency room personnel in hospitals.

(C) ADVISORY COMMITTEE.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall establish an advisory committee to make recommendations to the Secretary regarding the plan under subparagraph (A). The committee shall be composed of individuals who collectively possess expertise on the effects of date-rape drugs and on detecting and controlling the drugs.

(2) IMPLEMENTATION OF PLAN.—Not later than 180 days after the date on which the advisory committee under paragraph (1) is established, the Secretary, in consultation with the Attorney General, shall commence carrying out the national campaign under such paragraph in accordance with the plan developed under such paragraph. The campaign may be carried out directly by the Secretary and through grants and contracts.

(3) EVALUATION BY GENERAL ACCOUNTING OFFICE.—Not later than two years after the date on which the national campaign under paragraph (1) is commenced, the Comptroller General of the United States shall submit to the Congress an evaluation of the effects with respect to date-rape drugs of the national campaign.

(c) DEFINITION.—For purposes of this section, the term "date-rape drugs" means gamma hydroxybutyric acid and its salts, isomers, and salts of isomers and such other drugs or substances as the Secretary, after consultation with the Attorney General, determines to be appropriate.

Amend the title so as to read:

A bill to amend the Controlled Substances Act to add gamma hydroxybutyric acid and ketamine to the schedules of controlled substances, to provide for a national awareness campaign, and for other purposes.

PURPOSE AND SUMMARY

The purpose of H.R. 2130, the Hillory J. Farias Date-Rape Prevention Drug Act of 1999, is to give the nation's law enforcement agencies the tools needed to control the distribution and abuse of Gamma Hydroxybutyric Acid (GHB), Ketamine, and Gamma Butyrolactone (GBL), otherwise known as "date-rape" drugs.

H.R. 2130 amends the Controlled Substances Act (21 U.S.C. §801 et seq.) to make GHB, a central nervous system depressant that is

abused to produce intense highs and to assist in the commission of sexual assaults, a Schedule I drug, the Drug Enforcement Administration's (DEA's) most intensively regulated category of drugs. In addition, H.R. 2130 schedules Ketamine, an animal tranquilizer that has been similarly abused, in Schedule III of the Controlled Substances Act, and lists GBL, the primary precursor used in the production of GHB, as a List I chemical. H.R. 2130 also provides for a limited exemption from Schedule I manufacturing and distributing facility security requirements for facilities manufacturing and distributing GHB for a Food and Drug Administration (FDA)-approved clinical study (in which case Schedule III facility security requirements will apply), and places an FDA-approved GHB drug product into Schedule III of the Controlled Substances Act. However, the amendment adds additional reporting and accountability requirements for the approved GHB drug product similar to the requirements for Schedule I substances, Schedule II drugs, and Schedule III narcotics (notwithstanding that GHB is not a narcotic drug), and adds Schedule I penalties for the unlawful use of an approved drug product that contains GHB.

H.R. 2130 requires the Department of Health and Human Services (HHS) to establish a national awareness campaign to educate junior high, high school, and college students on the dangers of date-rape drugs, and to assist law enforcement personnel in battling their abuse. The legislation establishes an expert advisory panel to assist HHS in carrying out the national campaign. Under H.R. 2130, HHS is required to provide periodic reports to Congress on the national status of abuse of date-rape drugs. Additionally, two years after the commencement of the National Awareness Campaign, the General Accounting Office (GAO) is required to conduct an evaluation of the effect of the national campaign on the abuse of date-rape drugs, and, if necessary, to provide specific recommendations to improve its effectiveness. Finally, the legislation directs the Attorney General to make a grant for the development of forensic field tests to assist law enforcement officials in detecting the presence of GHB.

Background and Need for Legislation

On March 11, 1999, the Subcommittee on Oversight and Investigations held a hearing on date-rape drugs. The hearing focused on the abuse of date-rape drugs, the law enforcement challenges in battling their abuse, and the administrative procedures involved in scheduling the drugs under the Controlled Substances Act.

At the hearing, the Subcommittee heard from a wide range of witnesses, including representatives from the Department of Justice, the DEA, the FDA, and a number of witnesses representing law enforcement organizations. The Subcommittee also heard compelling testimony from an eighteen-year-old Virginia woman who was sexually assaulted after being given what police believe was a date-rape drug. Finally, a witness from the Orphan Medical Company, the sponsor of an orphan drug under clinical trials, testified regarding the adverse impact that Federal controls would have on one of the date-rape drugs. All the witnesses concluded that the time had come to place strong controls on date-rape drugs, particularly GHB.

The abuse of date-rape drugs has substantially increased in recent years and continues to grow. The DEA has documented over 4,000 overdoses and law-enforcement encounters with GHB and 32 GHB-related deaths. At least 20 States have scheduled GHB under State drug control statutes, and law enforcement officials continue to experience an increased presence of the drug in sexual assaults, driving under the influence (DUI) offenses, and overdose cases involving teenagers. With respect to Ketamine, the DEA has documented more than 560 incidents of the sale and/or use of Ketamine in the nation's junior highs, high schools, and college campuses from 1992 through 1998. H.R. 2130 is named after a young woman from Texas who died after unknowingly ingesting GHB, and whose mother brought her death to the attention of the legislation's sponsor. Other Members' concerns about date-rape drugs have intensified as a result of several GHB-related injuries, including one death, involving Michigan teenagers. In July of this year, five teenagers in Michigan were hospitalized and lapsed into comas after sharing a drink laced with GHB at a party.

CONTROLLED SUBSTANCES ACT

The Controlled Substances Act (CSA) restricts the use and distribution of certain drugs (e.g., heroin, amphetamines, cocaine) by scheduling these drugs as controlled substances. The scheduling is based on an eight-factor analysis which includes: potential for abuse; scientific evidence of pharmacological effects; current scientific knowledge; history and current pattern of abuse; scope, duration, and significance of abuse; risk to public health; psychic or physiological dependence liability; and immediate precursors.

The CSA authorizes the classification of particular drugs. There are five categories of controlled substances, known as schedules, which determine the public availability of the drug, storage and prescription requirements, and penalties for its misuse. This classification process requires the DEA to submit data to HHS and request that HHS conduct a medical and scientific evaluation of the substance in question. HHS must then make a recommendation as to whether and in what schedule the substance should be controlled. HHS's findings as to scientific and medical matters are binding on DEA. If DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse, the Agency may institute a rulemaking proceeding to add a substance to a schedule or transfer it between schedules.

GAMMA HYDROXYBUTYRATE (GHB)

GHB is a central nervous system depressant that is not approved for medical use in the United States. The FDA has issued advisories declaring GHB unsafe and illicit, except under FDA-approved physician-supervised protocols. Although GHB has not been approved by FDA for marketing, it is under investigation for use in treating a sleeping disorder known as narcolepsy under the FDA's Orphan Drug program. GHB abuse is prevalent primarily in the young nightclub and party subculture, where it is a growing concern due to its increasing popularity. As noted above, the DEA has documented over 4,000 overdoses and law enforcement encounters with GHB, and 32 GHB-related deaths since 1990.

Characteristics of GHB abuse include disruptions of short term memory and the speed with which the body metabolizes the substance, so that it can no longer be detected in tests of the blood or urine. These factors, coupled with the general lack of knowledge about GHB within the health and law enforcement communities, ensure that the actual number of people who have died from GHB (either by consumption or while driving under the influence) could be much higher. Seventeen sexual assaults associated with GHB have been documented, while poison control databases show that there were over 600 GHB cases in 1996 and over 900 in 1997. According to the Drug Abuse Warning Network (DAWN), GHB-related hospital emergency department episodes increased from 20 in 1992 to 629 in 1996.

GHB is not a controlled substance under the Federal CSA. To date, 20 States have controlled GHB. Closely related to GHB is its precursor, GBL, which the body converts into GHB when it is consumed. In States where GHB is a Schedule I or II controlled substance, GBL may be considered a controlled substance "analog" under State law because it is pharmacologically substantially similar (in terms of its pharmacological makeup and potential for abuse) to GHB. Products containing GBL are readily available for sale on the Internet and in gyms and health food stores. In addition, GBL is a chemical commonly used as a paint stripper as well as a base chemical for other solvents used for cleaning engines or wood. On January 21, 1999, the FDA warned consumers not to purchase or consume products that contain GBL. FDA also asked the companies that manufacture products containing GBL which are intended for human consumption to recall them voluntarily. The recall was based on 55 adverse health effects, including unconsciousness, coma, respiratory depression, seizures, vomiting, and slowed heart rate. Four companies agreed to cease manufacturing and distribution of GBL, but only three agreed to recall their products. On February 25, 1999, the Centers for Disease Control and Prevention publicized 41 adverse event reports associated with GBL it had recently received from three States.

On May 19, 1999, HHS recommended a dual scheduling of GHB. First, HHS recommended that GHB be scheduled in Schedule I of the CSA. Secondly, HHS recommended that if GHB is being studied under a FDA authorized Investigational New Drug (IND) exemption, the GHB drug product should be placed in Schedule III of the CSA.

KETAMINE

Ketamine is predominantly used as an animal tranquilizer (veterinary products account for about 90 percent of sales). It is only approved for human consumption for use in minor surgical procedures, to treat burn wounds, dental extractions, and as anesthesia for poor-risk patients with depressed vital functions. Ketamine (known popularly as "Special K") has become a common drug at clubs and large-scale parties called "raves." It produces a dose-related progression of effects from a state of dreamy intoxication to delirium accompanied by the inability to move, feel pain, or remember what has occurred while under the drug's influence. The Ketamine encountered to date by law enforcement authorities has

been diverted from legitimate sources, such as veterinary clinics, which are often burglarized to obtain Ketamine. According to the DEA, since 1993, juveniles were involved in 10 percent of all emergency room episodes involving Ketamine and 25 percent of police encounters with Ketamine. Law enforcement agencies are also encountering Ketamine abuse when stopping drivers who appear to be intoxicated.

Eighteen states have controlled Ketamine, with 15 listing it in Schedule III. In 1979, the DEA requested a recommendation from HHS on scheduling Ketamine under the CSA. In 1981, HHS recommended that Ketamine be controlled as a Schedule III substance based on its scientific and medical evaluation. DEA did not schedule Ketamine at that time as the Agency believed it lacked actual abuse data that would sustain the scheduling in the face of legal challenges. However, DEA recently issued a final rule, effective August 12, 1999, that places Ketamine in Schedule III of the CSA.

HEARINGS

The Subcommittee on Oversight and Investigations held a hearing on March 11, 1999. The Subcommittee received testimony from the following witnesses: The Honorable Sheila Jackson-Lee, U.S. House of Representatives, 18th Congressional District, State of Texas; Ms. Candace Pruett, private citizen; Detective Sergeant Mark Faistenhammer, Grosse Ile Police Department, Michigan State Police, S.E.C.I.D. DRANO Unit; Ms. Trinka D. Porrata, Retired LPD police office and designer drug consultant; Ms. Jo Ellen Dyer, Senior Toxicology Management Specialist, California Poison Control System, San Francisco Division, and Assistant Clinical Professor of Pharmacy, University of California at San Francisco; Lieutenant Paul Bane, Drug Enforcement Command, Maryland State Police; Dr. Felix Adatsi, Toxicologist, Michigan State Police; Ms. Denise Snyder, D.C. Rape Crisis Center, Washington, D.C.; Ms. Patricia L. Maher, Deputy Assistant Attorney General, Civil Division, U.S. Department of Justice; Mr. Terrance W. Woodworth, Deputy Director, Office of Diversion Control, Drug Enforcement Administration; Mr. Nicholas Reuter, Associate Director, Domestic and International Drug Control, Office of Health Affairs, Food and Drug Administration; Dr. Stephen Zukin, Director, Division of Clinical and Services Research, National Institute on Drug Abuse, National Institutes of Health; and Ms. Patti Engel, Vice President, Orphan Medical, Inc.

COMMITTEE CONSIDERATION

On July 27, 1999, the Subcommittee on Health and Environment met in open markup session and approved H.R. 2130 for Full Committee consideration, amended, by a voice vote. On August 5, 1999, the Full Committee met in open markup session and ordered H.R. 2130 reported to the House, amended, by voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of Rule XIII of the Rules of the House requires the Committee to list the record votes on the motion to report legisla-

tion and amendments thereto. There were no record votes taken in connection with ordering H.R. 2130 reported. An amendment offered by Mr. Upton, #1, to make technical changes to conform provisions of the bill to the provisions of the Controlled Substances Act, was agreed to by a voice vote. A motion by Mr. Bliley to order H.R. 2130 reported to the House, amended, was agreed to by a voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of Rule XIII of the Rules of the House of Representatives, the Committee held an oversight hearing and made findings that are reflected in this report.

COMMITTEE ON GOVERNMENT REFORM OVERSIGHT FINDINGS

Pursuant to clause 3(c)(4) of Rule XIII of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of Rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2130, the Hillory J. Farias Date-Rape Drug Prevention Act of 1999, will result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of Rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 13, 1999.

Hon. TOM BLILEY,
Chairman, Committee on Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2130, the Hillory J. Farias Date-Rape Prevention Drug Act of 1999.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowic.

Sincerely,

BARRY B. ANDERSON
(For Dan L. Crippen, Director).

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

H.R. 2130—Hillory J. Farias Date-Rape Prevention Drug Act of 1999

Summary: The Controlled Substances Act of 1970 established five schedules of controlled substances, designated by Roman numerals I (greatest potential for abuse) to V (lowest potential). H.R. 2130 would amend the act to add gamma hydroxybutyric acid (GHB) to schedule I and add ketamine to schedule III; in addition, the bill would designate gamma butyrolactone (GB) as a list I chemical (a chemical needed to manufacture a controlled substance). The bill also would direct the Secretary of Health and Human Services, within one year of enactment, to develop and implement a national awareness campaign relating to date-rape drugs. H.R. 2130 would require the General Accounting Office (GAO) to evaluate the effectiveness of that campaign within two years of its start. Finally, the bill would direct the Attorney General to make a grant for the development of forensic field tests to detect GHB and related substances.

CBO estimates that implementing H.R. 2130 would cost less than $500,000 in fiscal year 2000 and about $7 million over the 2001–2004 period, subject to the availability of appropriated funds. Because the bill could affect direct spending and receipts, pay-as-you-go procedures would apply; however, we estimate that the amounts involved would be less than $500,000 a year.

H.R. 2130 contains both an intergovernmental and a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the bill would results in no costs to state, local, or tribal governments, so the threshold established in UMRA ($50 million in 1996, adjusted annually for inflation) would not be exceeded. CBO also estimates that the costs of the private-sector mandate would fall below the threshold established in UMRA ($100 million in 1996, adjusted for inflation).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 2130 is shown in the following table. The costs of this legislation fall within budget functions 550 (health), 750 (administration of justice), and 800 (general government).

	By fiscal year, in millions of dollars				
	2000	2001	2002	2003	2004
SPENDING SUBJECT TO APPROPRIATION					
Estimated authorization level	(1)	3	4	(1)	0
Estimated outlays	(1)	2	3	2	(1)

[1] Less than $500,000.

BASIS OF ESTIMATE

For purposes of this estimate, CBO assumes the bill will be enacted by or near the beginning of fiscal year 2000, that the necessary amounts will be provided for each year, and that outlays will follow the historical spending rates for similar activities.

Spending subject to appropriation

Based on information from the Department of Health and Human Services about a similar anti-drug program, CBO estimates

that the awareness campaign required by the bill would cost less than $500,000 in fiscal year 2000, $2 million to $3 million annually over the 2001–2003 period, and less than $500,000 in 2004, subject to appropriations of the necessary amounts. CBO expects that the GAO would evaluate the campaign mostly in fiscal year 2002 and that this effort, like similar reviews conducted by the agency, would cost about $400,000. Based on information from the Drug Enforcement Administration (DEA), CBO estimates that the grant for development of forensic field tests would cost less than $500,000 in fiscal year 2000 because a significant amount of related research already has been completed.

The bill's designations for GHB and GB would increase the penalties for unauthorized manufacturing or distribution of these substances and would tighten federal control over their use. As a result, the federal government would be able to pursue cases that it otherwise would not be able to prosecute. CBO expects that any increase in federal costs for law enforcement, court proceedings, or prison operations would not be significant, however, because of the relatively small number of cases likely to be involved. Any such additional costs would be subject to the availability of appropriated funds.

Direct spending and revenues

Because those prosecuted and convicted of offenses established under H.R. 2130 could be subject to criminal fines, the federal government might collect additional fines if the bill is enacted. Such fines are recorded in the budget as governmental receipts (i.e., revenues), which are deposited in the Crime Victims Fund and spent in subsequent years. CBO estimates that any additional collections as a result of this bill would be less than $500,000 a year. Because any increase in direct spending from the Crime Victims Fund would equal the fines collected (with a lag of one year or more), the additional direct spending would be less than $500,000 annually.

Pay-as-you-go considerations: The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. Enacting H.R. 2130 could affect both direct spending and receipts, but CBO estimates that any such effects would be less than $500,000 a year.

Estimated impact on state, local, and tribal governments: H.R. 2130 contains an intergovernmental mandate as defined in UMRA. The bill would amend the Controlled Substances Act to include ketamine as a schedule III controlled substance. Because ketamine is administered for medical purposes by practitioners in state and local public hospitals, the administrative duties that would be required by the bill would be considered a mandate. However, because the DEA recently placed ketamine on the list of controlled substances under its administrative authority, this bill would impose no new costs on practitioners or the hospitals that employ them. The other substances addressed in this bill are not administered by practitioners in state or local hospitals.

Estimated impact on the private sector: H.R. 2130 would create a new private-sector mandate for manufacturers, distributors, and dispensers of GHB. The bill would require most such entities to observe and comply with federal regulations for schedule I controlled

substances. Pharmaceutical companies and individuals engaged in drug testing would be able to use GHB under the less restrictive schedule III regulations, but could face additional monthly reporting requirements. Manufacturers, distributors, and dispensers would all have to follow rules governing storage, labeling, sales, and recordkeeping. Because the only current private user of GHB is a group conducting clinical trials of the drug as a treatment for cataplexy, CBO estimates that the costs of the mandate would be below the threshold established in UMRA ($100 million in 1996, adjusted for inflation).

Estimate prepared by: Federal Costs: Mark Grabowicz; impact on State, Local, and Tribal Governments: Lisa Cash Driskill; impact on the Private Sector: John Harris.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

Section 6 of H.R. 2130 directs the Secretary to establish an Advisory Committee to make recommendations to the Secretary regarding the National Awareness Campaign. Pursuant to the requirements of subsection 5(b) of the Federal Advisory Committee Act, the Committee finds that the functions of the proposed advisory committee are not and cannot be performed by an existing Federal agency or advisory commission or by enlarging the mandate of an existing advisory committee.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of Rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides the short title for the legislation, "Hillory J. Farias Date-Rape Prevention Drug Act of 1999."

Section 2. Findings

Section 2 lists finding made by Congress.

Section 3. Addition of gamma hydroxybutyric acid and ketamine to schedules of controlled substances; gamma butyrolactone as additional list I chemical

Subsection (a) adds GHB, its salts, isomers, the salts of its isomers, and any material containing any of these to Schedule I of the Controlled Substances Act, the schedule reserved for those substances that are highly subject to abuse and that have no accepted medical use.

The Controlled Substances Act and implementing regulations tightly control the manufacture and distribution of Schedule I controlled substances. For example, manufacturers must store raw materials, materials being processed, and final products in a safe, steel cabinet, or vault that meets stringent security requirements (28 C.F.R. § 1301.72(a)). Compliance is costly; indeed so costly as to discourage research into, and development of, GHB's potential as a treatment for cataplexy. On the other hand, GHB's potential for abuse necessitates protection against the risk of diversion during the course of lawful scientific research. Thus, for security purposes, registered manufacturers and registered distributors who come within the exemption for the investigation of new drugs authorized by section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) may treat GHB, its salts, isomers, and salts of its isomers as Schedule III controlled substances. Unless otherwise approved by the Drug Enforcement Administration, the minimum security requirements for storage of Schedule III controlled substances demand that the materials be kept in a secure building with limited and controlled access or in a locked concrete and steel cage enclosed within a building (28 C.F.R. § 1301.72(b)).

Subsection (b) classifies as Schedule III controlled substances any GHB products subsequently approved for medical purposes by the Food and Drug Administration under the new drug provisions of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355). Schedule III is the repository of substances that are less subject to abuse than those in Schedule I or II, that have accepted medical uses, but that may be addictive (21 U.S.C. § 812(b)(3)).

Subsection (b) also confirms the classification of Ketamine as a Schedule III controlled substance. Ketamine has recognized medical uses, primarily for the treatment of animals. It has a hallucinogenic effect on human beings and can produce memory loss. As a consequence, it too may be misused as a date-rape drug, although reported cases more often involve GHB. The Department of Health and Human Services has previously recommended its inclusion in Schedule III, but the Drug Enforcement Administration has only recently concluded that incidents of abuse warranted such classification (64 Fed. Reg. 17299 (April 9, 1999); 64 Fed. Reg. 37673 (July 13, 1999)). More than a third of the States have determined that it should be classified as a controlled substance for purposes of State law.

Section 102 of the Controlled Substances Act defines List I chemicals as chemicals used in the manufacture of a controlled substances (21 U.S.C. § 802(34)). Section 310 of the Controlled Substances Act imposes record keeping and reporting requirements upon manufacturers and distributors of listed chemicals, (21 U.S.C.

§ 830) to prevent diversion of the flow of products from lawful commerce to illicit drug production. Subsection 3(c) of H.R. 2130 adds GBL, a chemical used to manufacture GHB, to the inventory of List 1 chemicals.

Subsection (d) clarifies that GBL's or any other chemical's designation as a listed chemical does not preclude the Attorney General from designating it also as a "controlled substance analogue" as well. Controlled substance analogues are the chemical twins of Schedule I or II controlled substances, structurally similar, often with similar effects, but slightly different in composition (21 U.S.C. § 802(32)). For purposes of prosecuting substance misconduct, the Controlled Substances Act treats analogues as Schedule I controlled substances (21 U.S.C. § 813).

GBL has legitimate commercial uses. It is a commonly employed industrial solvent. The Drug Enforcement Administration testified that since analogues are not subject to regulatory control if GHB was designated a Schedule I or II controlled substance, distribution of GBL could be treated as a controlled substance analogue for purposes of prosecution without encumbering its lawful industrial manufacture, sale, or use. Subsection (d) reiterates the continued availability of that option.

Should any GHB product be approved for medical use under the FDA's investigational new drug procedures it must be classified as a Schedule III controlled substance under subsection (b). Subsection (e) establishes the same criminal penalties for the illicit manufacturing or distribution of Schedule III GHB as apply to Schedule I GHB-related crimes.

GHB, by virtue of its classification as a Schedule I controlled substance, carries with it the criminal penalties for criminal misconduct involving Schedule I or II controlled substances under section 401(b) of the Controlled Substances Act (21 U.S.C. § 841(b)(1)(C)). Thus, anyone who unlawfully manufactures, distributes, dispenses, or possesses GHB with the intent to manufacture, distribute, or dispense it is subject to imprisonment for not more than 20 years, a subsequent period of supervised release of at least 3 years, and a fine of not more than $1 million for an individual defendant and of not more than $5 million for an organization. A violation is punishable by imprisonment for not less than 20 years or more than life, if death or serious bodily injury results from its commission. Offenders with a prior, final felony drug conviction, face imprisonment for not more than 30 years, followed by a term of supervised release of at least 6 years, and a fine of either not more than $2 million or $10 million, depending upon whether the offender is an individual or an organization. If death or serious bodily injury results, the repeat offender must be sentenced to life imprisonment.

Subsection (f) makes it clear that the prohibitions and attendant penalties with respect to the use of controlled substances to commit rape or any other crime of violence apply to controlled substance analogues as well. The existing prohibition in section 401 of the Controlled Substance Act does not mention analogues (21 U.S.C. § 841(b)(7)). The omission may make coverage uncertain in spite of the declaration in section 203 (21 U.S.C. § 813) that analogues are to be treated as Schedule I controlled substances. Clarification is

appropriate since the human body responds to consumption of the commercial solvent GBL in much the same way that it reacts to the ingestion of GHB.

Section 4. Authority for additional reporting requirements for gamma hydroxybutyric products in schedule III

Section 4 gives the Attorney General authority to promulgate additional record-keeping and reporting regulations for the research being conducted with respect to GHB under the investigational new drug procedures of the Federal Food, Drug, and Cosmetic Act. Existing law creates no obligation to report transaction or inventory information to the Attorney General in the case of such Schedule III controlled substances. Existing regulations call upon registrants to provide quarterly acquisition and distribution transaction reports, but only with respect to Schedule I controlled substances, Schedule II controlled substances, narcotic controlled substances, and certain psychotropic controlled substances (21 C.F.R. § 1304.33). Registrants must also maintain inventory, transaction, and other controlled substance-related records and must keep them available for inspection and copying (21 C.F.R. §§ 1304.03 to 1304.25).

The regulations authorized under section 4 may require manufacturers, distributors, and other registrants to file annual inventory reports and quarterly acquisition and distribution transaction reports. The regulations may demand that annual inventory reports be submitted no later than January 15 and reflect material in storage and in process as of the close of business on the previous December 31. Registered manufacturers may be compelled to document fluctuations in their inventories, specifying increases attributable to purchases, transfers, and returns, as well as reductions caused by sales, transfers, theft, destruction, and seizure. The Attorney General may insist that reports include the names, registration numbers, and other identification of vendors, suppliers, and customers with sufficient particularity to permit the Attorney General to trace receipts and distribution of the drug.

Section 4 also authorizes the Attorney General to impose additional record keeping requirements. Physicians, pharmacists, and other registered dispensing practitioners may be compelled to maintain for inspection and copying records indicating for each prescription: (1) the name, Federal and State registration numbers, and verification of controlled substance prescription authority of the prescribing individual; (2) the patient's name, address and the name of the patient's insurance provider; and (3) documentation from a medical practitioner of the patient's medical need for the drug.

Section 310 of the Controlled Substances Act requires the manufacturers of listed chemicals to report mail order transactions involving certain listed chemicals with nonregulated persons to the Attorney General (21 U.S.C. § 310(b)(3)). Section 4 of H.R. 2130 allows the Attorney General to issue regulations making those provisions applicable with respect to GHB.

Section 5. Development of forensic field tests for gamma hydroxybutyric acid

Section 5 instructs the Attorney General to make a grant for the development of forensic tests that will enable law enforcement officials to conduct field tests for the presence of GHB and related substances.

Section 6. Annual report regarding date-rape drugs; national awareness campaign

Section 6 directs the Secretary of Health and Human Services (the Secretary) to submit annual reports on the incidents of abuse of date-rape drugs and to launch a national date-rape educational campaign. The annual report to Congress, first due by January 15, 2000, will provide an estimate of the number of incidents of the abuse of GHB, its salts, isomers, and salts of its isomers, as well as of any other date-rape drug the Secretary, in consultation with the Attorney General, finds appropriate to include.

Section 6 provides for the establishment of an Advisory Council consisting of date-rape drug abuse experts to make recommendations to the Secretary. The Secretary, in consultation with the Attorney General and the Advisory Council, is to plan and execute a date-rape national awareness campaign by contract or grant. The campaign, beginning not later than 6 months after enactment, is to be directed at young adults, youths, law enforcement personnel, teachers, school nurses, rape counselors, and hospital emergency room personnel. It will alert them to the danger of date-rape drugs, of the applicable criminal penalties and other provisions of the Controlled Substances Act, and of symptoms exhibited by a date-drug victim including the symptoms of a sexual assault.

Section 6 also provides that two years after the commencement of the National Awareness Campaign, the General Accounting Office is to submit to Congress an evaluation of the effect of the national campaign on the abuse of date-rape drugs.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

* * * * * * *

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

* * * * * * *

DEFINITIONS

SEC. 102. As used in this title:

(1) * * *

* * * * * * *

(32)(A) * * *

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

[(B)**]** *(C)* Such term does not include—

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

* * * * * * *

(34) The term "list I chemical" means a chemical specified by regulation to the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this title and is important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:

(A) * * *

* * * * * * *

(X) Gamma butyrolactone.

[(X)**]** *(Y)* Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

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PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

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SCHEDULES OF CONTROLLED SUBSTANCES

SEC. 202. (a) * * *

* * * * * * *

(c) Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 201, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

(a) * * *

* * * * * * *

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following substance having a depressant effect on the central nervous system, or which contains any of their

salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Gamma hydroxybutyric acid.

* * * * * * *

SCHEDULE III

(a) * * *

(b) [**Depressants**] Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorexadol.

(3) Gamma hydroxybutyric acid and its salts, isomers, and salts of isomers contained in a drug product for which an application has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

[(3)**]** *(4)* Glutethimide.

(5) Ketamine and its salts, isomers, and salts of isomers.

[(4)**]** *(6)* Lysergic acid.

[(5)**]** *(7)* Lysergic acid amide.

[(6)**]** *(8)* Methyprylon.

[(7)**]** *(9)* Phencyclidine.

[(8)**]** *(10)* Sulfondiethylmethane.

[(9)**]** *(11)* Sulfonethylmethane.

[(10)**]** *(12)* Sulfonmethane.

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PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

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RECORDS AND REPORTS OF REGISTRANTS

SEC. 307. (a) * * *

* * * * * * *

(h) In the case of a drug product containing gamma hydroxybutyric acid for which an application has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act, the Attorney General may, in addition to any other requirements that apply under this section with respect to such a drug product, establish any of the following as reporting requirements:

(1) That every person who is registered as a manufacturer of bulk or dosage form, as a packager, repackager, labeler, relabeler, or distributor shall report acquisition and distribution transactions quarterly, not later than the 15th day of the month succeeding the quarter for which the report is submitted, and annually report end-of-year inventories.

(2) That all annual inventory reports shall be filed no later than January 15 of the year following that for which the report is submitted and include data on the stocks of the drug product, drug substance, bulk drug, and dosage forms on hand as of the close of business December 31, indicating whether materials reported are in storage or in process of manufacturing.

(3) That every person who is registered as a manufacturer of bulk or dosage form shall report all manufacturing transactions both inventory increases, including purchases, transfers, and returns, and reductions from inventory, including sales, transfers, theft, destruction, and seizure, and shall provide data on material manufactured, manufactured from other material, use in manufacturing other material, and use in manufacturing dosage forms.

(4) That all reports under this section must include the registered person's registration number as well as the registration numbers, names, and other identifying information of vendors, suppliers, and customers, sufficient to allow the Attorney General to track the receipt and distribution of the drug.

(5) That each dispensing practitioner shall maintain for each prescription the name of the prescribing practitioner, the prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations, verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance, the patient's name and address, the name of the patient's insurance provider and documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug. Such information shall be available for inspection and copying by the Attorney General.

(6) That section 310(b)(3) (relating to mail order reporting) applies with respect to gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.

* * * * * * *

PART D—OFFENSES AND PENALTIES

PROHIBITED ACTS A—PENALTIES

SEC. 401. (a) * * *

(b) Except as otherwise provided in section 409, 418, 419, or 420 any person who violates subsection (a) of this section shall be sentenced as follows:

(1)(A) * * *

* * * * * * *

(C) In the case of a controlled substance in schedule I or II, *gamma hydroxybutyric acid in schedule III,* or 1 gram of flunitrazepam, except as provided in subparagraphs (A), (B), and (D), such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years or more than life, a fine

not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this subparagraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(D) In the case of less than 50 kilograms of marihuana, except in the case of 50 or more marihuana plants regardless of weight, 10 kilograms of hashish, or one kilogram of hashish oil or in the case of any controlled substance in schedule III *(other than gamma hydroxybutyric acid)*, or 30 milligrams of flunitrazepam, such person shall, except as provided in paragraphs (4) and (5) of this subsection, be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United State Code, or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment.

* * * * * * *

(7) PENALTIES FOR DISTRIBUTION.—

(A) IN GENERAL.—Whoever, with intent to commit a crime of violence, as defined in section 16 of title 18, United States Code (including rape), against an individual, violates subsection (a) by distributing a controlled substance *or controlled substance analogue* to that individual without that individual's

knowledge, shall be imprisoned not more than 20 years and fined in accordance with title 18, United States Code.

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