99TH CONGRESS
2d Session

HOUSE OF REPRESENTATIVES

REPT. 99-848
Part 1

DESIGNER DRUG ENFORCEMENT ACT OF 1986

SEPTEMBER 19, 1986.—Ordered to be printed

Mr. HUGHES, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 5246 which on July 24, 1986, was referred jointly to the Committee on the Judiciary and the Committee on Energy and Commerce]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 5246) to amend the Controlled Substances Act to prohibit certain conduct with respect to controlled substance analogs, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Designer Drug Enforcement Act of 1986".

SEC. 2. INCLUSION OF DESIGNER DRUGS IN CONTROLLED SUBSTANCES ACT.

(a) DEFINITION.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by adding at the end thereof the following:

"(31)(A) Except as provided in subparagraph (B), the term 'controlled substance analogue' means a substance—

"(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II; and

"(ii)(I) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system; or

"(II) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance.

"(B) 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".

(b) TREATMENT OF CONTROLLED SUBSTANCE ANALOGUES.—Part B of the Controlled Substances Act is amended by adding at the end the following new section.

"TREATMENT OF CONTROLLED SUBSTANCE ANALOGUES

"SEC. 203. A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of the Controlled Substances Act and the Controlled Substances Import and Export Act as a controlled substance in schedule I.".

(c) CLERICAL AMENDMENT.—The table of contents of the Comprehensive Drug Abuse Prevention and Control Act of 1970 is amended by inserting after the item relating to section 202 the following new item:

"Sec. 203. Treatment of controlled substance analogues.".

PURPOSE OF THE LEGISLATION

This bill will enable the Drug Enforcement Administration to investigate and prosecute clandestine chemists who develop subtle chemical variations of controlled substances (called analogues or "designer drugs") for illicit distribution and abuse.

SUMMARY OF THE LEGISLATION

The legislation is designed both to enable swift investigation and prosecution of illicit drug designers and to fully protect the interests of legitimate scientific investigation into the properties of drugs that may have important therapeutic potential.

The legislation is structured to make available all of the criminal and regulatory systems of control of the Controlled Substances Act and the Controlled Substances Import and Export Act. For criminal enforcement, under current law, those include up to a 15 year prison sentence (up to 30 years for a second offense), doubled penalties for selling to persons under age 21 or in or near schools, doubled penalties for repeat offenders, up to life imprisonment for those operating continuing criminal enterprises, authority to wiretap, and forfeiture of the violators' profits.[1]

The term "controlled substance analogue" is defined to conform as closely as possible to the policy of the Controlled Substances Act by requiring a chemical relationship to a substance which is controlled (i.e. a chemical structure substantially similar to that of any controlled substance) and either the existence of some stimulant, depressant or hallucinogenic effect on the central nervous system, or a representation or intent that the substance have a stimulant, depressant or hallucinogenic effect substantially similar to, or greater than, such effect of any controlled substance.

BACKGROUND

In 1983 the Administration's request to undertake "emergency scheduling" of substances which effect the central nervous when they are found to have created "an imminent danger to the public safety" was included in the Comprehensive Crime Control Act of

[1] On August 13, 1986, the Committee on the Judiciary ordered reported the bill H.R. 5394, the Narcotics Penalties and Enforcement Act of 1986 which will provide special mandatory penalties for manufacturers and traffickers in controlled substance analogues

1983, submitted to the Congress by President Reagan on March 15, 1983 (House Document 98-32 and H.R. 2151).

On January 31, 1984, Representatives William J. Hughes and Harold S. Sawyer introduced that proposal, among other proposed amendments as H.R. 4698 (Congressional Record, January 31, 1984, page E 219).

On February 22, 1984 the Subcommittee on Crime began its investigation into the new chemical substances, "controlled substance analogues," that soon thereafter became popularly known as "designer drugs." At that time the Administration requested the authority to undertake "emergency scheduling" of substances which effect the central nervous when they are found to have created "an imminent danger to the public safety" such as "China white", a synthetic heroin, actually a fentanyl analog that had not yet been controlled.[2] The reason for the proposal was the DEA belief that the lag between the suggestion by the Attorney General (the Drug Enforcement Administration) that a substance ought to be controlled or rescheduled [3] and the required findings by the Secretary of Health and Human Services (the Food and Drug Administration) that a particular drug ought to be controlled or rescheduled [4] was too long. In the case of certain analogs of PCP it took 15 months for the substances to be scheduled. Under the "emergency scheduling" authority, DEA believed that the scheduling could be accomplished in 10 or 12 months less time.[5]

The Subcommittee on Crime marked up and reported H.R. 4698 on April 26, 1984 as a clean bill, H.R. 5656. On May 23, 1984 the Committee on the Judiciary ordered H.R. 5656 reported to the full House (H. Rept. 98-835, Part I). Section 3 of the bill created the procedure for scheduling substances on an expedited and temporary basis, to apply to "designer drugs" such as fentanyl analogues, MPPP and MPTP and PCP analogues.[6] This provision was enacted as section 508 of the Dangerous Drug Diversion Control Act (chapter V, part B of the Comprehensive Crime Control Act of 1984, P.L. 98-473, October 12, 1984).

SUBCOMMITTEE HEARING

On May 1, 1986 the Subcommittee on Crime held a hearing on legislation relating to the problem of designer drugs. Testimony was taken from Representative Charles B. Rangel, 16th Congressional District of New York; Senator Lawton Chiles, Florida; Rich-

[2] Testimony of Gene Haislip, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the Subcommittee on Crime of the House Committee on the Judiciary at hearings on H.R. 4698, Diversion of Prescription Drugs to Illegal Channels and the Dangerous Drug Diversion Control Act, February 22, 1984, Serial No. 139, 98th Cong 2d sess. p. 148; and letter of April 2, 1984 from Chairman William J. Hughes to Gene Haislip and reply by Administrator Francis M. Mullen, Jr. on April 23, 1984 at pp. 156-7. See also "The War on Drugs Is Over, The Government Has Lost," by Jack Shafer, INQUIRY, February 1984, reprinted in the Hearings on H.R. 4698 at pp. 460-468

[3] Under section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a))

[4] Under section 201(b) of the Controlled Substances Act (21 U.S.C. 811(b))

[5] See letter of April 23, 1984 and attachments to Chairman William J. Hughes from DEA Administrator Francis M. Mullen, Jr. in Hearings before the Subcommittee on Crime of the House Committee on the Judiciary on H.R. 4698, Diversion of Prescription Drugs to Illegal Channels and the Dangerous Drug Diversion Control Act, February 22, 1984, Serial No. 139, 98th Cong 2d sess at pp. 157-9.

[6] House Report 98-835, Part I, at pp 9-13

ard Hawks, Ph.D., Chief, Research Technology Branch, Division of Preclinical Research, National Institute on Drug Abuse, Public Health Service, U.S. Department of Health and Human Services, accompanied by Vernon Houk, M.D., Director, Center for Environmental Health, Centers for Disease Control, U.S. Department of Health and Human Services; and Edward C. Tocus, Ph.D., Director, Drug Abuse Staff within the Center for Drugs and Biologics, Food and Drug Administration, U.S. Department of Health and Human Services; James N. Hall, Director, UpFront Drug Information Center, Miami, Florida; Robert T. Angarola, Esquire, Hyman, Phelps and McNamara, Washington, D.C.; Lester Grinspoon, M.D., Associate Professor of Psychiatry, Harvard Medical School, Cambridge, Massachusetts; Everett Ellinwood, M.D., Professor of Psychiatry and Pharmacology, Duke University Medical Center, on behalf of the American Psychiatric Association. The statement of Stephen S. Trott, Assistant Attorney General, Criminal Division, U.S. Department of Justice was received for the record.

Need for the Legislation

Designer drugs such as the fentanyl analogues have resulted in over one hundred drug overdoses because in some cases they are as much as 3000 times more potent than heroin. One designer drug (MPPP, an analogue of meperidine (Demerol)) has been marketed with processing impurities (MPTP) that has caused almost total paralysis in dozens of young people because MPTP is believed to cause parkinsonism. At least another 400 persons have been identified as being at serious risk of developing parkinsonism due to their exposure to the impurities associated with this designer drug.[1]

Each controlled substance has been precisely defined and has been demonstrated through scientific tests as having a potential for abuse, meaning that it has a stimulant, depressant or hallucinogenic effect on the central nervous system, which is the basis for the strict control of such substances (section 201(f) of the Controlled Substances Act (21 U.S.C. 811(f)).

Makers of "designer drugs" chemically alter a controlled substance by making slight alterations but maintaining the basic chemical structure of the drug in order to produce a new, uncontrolled chemical which produces an effect on the central nervous system like that of a controlled substance.

These new substances are not controlled and therefore their manufacture and distribution currently do not violate the Controlled Substances Act. The 98th Congress extended to DEA the power to control such new substances on an emergency basis. DEA has used the authority five times to control 13 new dangerous drugs, including 10 fentanyl analogues; MDMA, an analogue of MDA (a schedule I substance); and MPPP and PEPAP (analgues of meperidine). In the Committee's view, generally this authority has

[1] Testimony of Lawton Chiles, U.S. Senator from Florida at Hearings before the Subcommittee on Crime of the House Committee on the Judiciary on H.R. 2014, H.R. 2977, H.R. 3936, H.R. 5231, H.R. 5246, and S. 1437, Legislation relating to the Problem of Designer Drugs, May 1, 1986, 99th Cong. 2d sess.; and Hearing before the Senate Committee on the Budget, July 18, 1985, 99th Cong., 2d sess. S. Hrg. 99-124 chaired by Senator Chiles.

been used very effectively to address much of the designer drug problem.

However, DEA in the course of its investigations has found a very small number of illicit chemists have been very carefully developing new drugs to stay ahead of DEA's scheduling actions. As a consequence, even with the emergency scheduling authority, the public remains at risk, and dangerous chemists are able to escape prosecution due to the following factors. First, there is an enormous number of drugs which can yet be developed. Second, there is an unavoidable delay in discovering that such drugs are being distributed. Third, there is the unavoidable obstacle of establishing that these drugs are being abused and pose an imminent threat to the public health. Finally, there is the elapse of time needed to undertake and complete action to control the drugs. The only way to effectively protect the public is to investigate and prosecute these chemists for their new discoveries prior to formal control of the drugs.

On April 4, 1985, Representative Charles Rangel, Chairman of the House Select Committee on Narcotics Abuse and Control (joined by Mr. Gilman, the ranking minority member of the select committee), introduced H.R. 2014 to require the National Drug Enforcement Policy Board to provide a comprehensive assessment of the designer drug problem and to report to Congress.

On July 11, 1985, Representative Dan Lungren (joined by Mr. Fish, Mr. McCollum and Mr. Gekas, members of the Committee) introduced H.R. 2977 to create certain crimes with respect to designer drugs.

On December 12, 1985, Representative Larry Smith (joined by Mr. Fascell and Mr. Hyde) introduced H.R. 3936, the Drug Enforcement Amendments of 1985, which included provisions addressing designer drugs.

In December 1985, the Drug Enforcement Administration, Office of Diversion Control issued a report on controlled substance analogs. On March 5, 1986, the National Drug Enforcement Policy Board transmitted to the Congress its report on controlled substance analogs.

Committee Action

On July 24, 1986, Representative William J. Hughes introduced H.R. 5231, the Designer Drug Enforcement Act of 1986.

On July 24, 1986, the Subcommittee on Crime, a quorum being present, marked up H.R. 5231 and ordered it reported as a clean bill, H.R. 5246. On July 29, 1986, the Committee on the Judiciary, a quorum being present, marked up H.R. 5246 and ordered it favorably reported to the full House as a single amendment in the nature of a substitute.

Section-by-Section Analysis

Section 1 is the short title.

Section 2 provides for the inclusion of designer drugs ("controlled substance analogues") in the Controlled Substances Act.

(a) Definition:

The term "controlled substance analogue" means a substance—
(i) the chemical structure of which is substantially similar *to the chemical structure* of a controlled substance in schedule I or II; and
(ii) (I) which was a stimulant, depressant, or hallucinogenic effect on the central nervous system; or
(II) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system caused by a controlled substance.

EXPLANATION

The first branch of this definition, (i), focuses on the chemical structure of the substance. The effects of a drug are generally a function of its chemical structure. Broad classes of related drugs will have substantially similar structures with subtle but important differences caused by relatively minor modification of the basic structure. Consequently, both legitimate and illegitimate chemists focus their research in the development of new psychoactive drugs on making subtle modifications of existing controlled substances.

The first branch of the definition is critically important because it serves to link the unknown drugs which are being controlled by this law to the drugs already controlled by the Controlled Substances Act. The Committee, by a voice vote, rejected an amendment to add an alternative definition of controlled substance analogue that did not include either a requirement of a chemical structure substantially similar to the chemical structure of a controlled substance in schedule I or II or an effect of the central nervous system (second branch of the definition) if the substance had been "specifically designed" to produce an effect "substantially similar" to that of a controlled substance in schedule I or II.

The second branch of the definition, (ii), is in the alternative. As a general rule, to justify the strict controls of this act, a "designer drug" ought to have not only a chemical structure like other controlled drugs but some relationship to the stimulant, depressant or hallucinogenic effect upon the central nervous system which is the justification for controlling drugs in the first place. However in the case in which there is no effect upon the central nervous system, then at least it must be shown that some person (namely, the defendant) intended or represented the substance to have an effect on the central nervous system that is substantially similar to or greater than the effect of a controlled substance.

The American Chemical Society, which strongly supported the legislation, urged that both chemical structure and central nervous system effect be required in the definition of controlled substance analogue in order to protect legitimate research.[8]

[8] See letter of May 1, 1986 to Rep. William J. Hughes from George C. Pimentel, President, American Chemical Society, page 3; and letter of July 23, 1986 to Eric E. Sterling, Assistant Counsel, Subcommittee on Crime from Anna Fotiu, Manager, Department of Governmental Relations and Science Policy, American Chemical Society reprinted in Hearings before the Sub-

Continued

Coffee, for example, has a stimulant effect on the central nervous system, but it is not chemically substantially similar to a controlled substance. To punish someone under the Controlled Substances Act who makes or distributes a new substance that has a chemical structure similar to a controlled substance, there ought to be evidence either of some effect on the central nervous system (such as that of caffeine), or that the person has made a representation or has evidenced an intent that the drug mimic the effect of a controlled substance. If the person were to merely say this substance is as powerful as a cup of coffee, and no stimulant or other central nervous system effect is found, then no harm has been committed that ought to involve the Controlled Substances Act.

A pre-introduction discussion draft of H.R. 5231, circulated to Drug Enforcement Administration and the industry for comment, had proposed that the effect test in the second branch of the definition require that the analogue's effect be "substantially similar" to the effect of a controlled substance. The Drug Enforcement Administration had expressed concern that the conjunctive requirement of chemical structure and a "substantially similar" central nervous system effect might be difficult to prove. Before H.R. 5321 was introduced, Mr. Hughes modified the effect requirement in the bill so that the evidence of central nervous system effect is minimal compared to the research burden that Drug Enforcement Administration has to sustain in order to bring a drug under control.[9] Indeed, as defined in the bill, a person could be convicted of felony offenses regarding a particular controlled substance analogue which as a substance could not be scheduled under the Controlled Substances Act. This could result if the analogue's effects did not meet the requirements for scheduling under section 201(c) of the Controlled Substances Act (21 U.S.C. 811(c)), for example, the analogue could lack a potential for abuse or a psychic or physiological dependence liability.

Representative Lungren offered an amendment, adopted by the Committee by a voice vote, to add an alternative representation or intent that the analogue have an effect greater than a controlled substance. A trafficker in controlled substance analogues should not escape sanction because he represents the drug he is selling as, "The greatest high in the world, greater than anything known to DEA."

(B) Exceptions to the definition

One major concerns of the Committee in the development of this legislation was to guarantee that it did not interfere in legitimate pharmaceutical or medical research in any way.

In order to protect the many types of important scientific research involved in developing drugs to relieve pain or to aid in psychiatry and the treatment of emotional disorders, four exceptions to the definition of a controlled substance analogue have been provided by the Committee.

The term "controlled substance analogue" does not include:

committee on Crime of the House Committee on the Judiciary on Legislation relating to the Problem of Designer Drugs, May 1, 1986, 99th Cong. 2d sess.

[9] Controlled Substances Act, section 201(a), (b) and (c); (21 U.S.C. 811(a), (b) and (c))

i) A controlled substance. If a substance has been scheduled as a ıtrolled substance, then it cannot and should not be treated le- lly as a controlled substance analogue, even if its history of use was before it was controlled.

ii) Any substance for which there is an approved new drug appli- tion. These are drugs which have been found by the Food and ug Administration to be safe and effective and have been ap- oved for marketing in interstate commerce. Such drugs, if they ve a stimulant, depressant or hallucinogenic effect upon the cen- al nervous system are brought to the attention of the Attorney ıeral at the time the new drug application is submitted (section 1(f) of the Controlled Substances Act (21 U.S.C. 811(f)) and, if ırranted, scheduled according the regular scheduling procedure section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)).

(iii) With respect to a particular person, any substance for which exemption from the Food and Drug Administration has been anted to permit "investigational use" of the drug by that person, the extent conduct with respect to the substance is pursuant to e exemption. (Such exemptions under the Federal Food, Drug d Cosmetic Act are called "INDs".)

FDA allows drug manufacturers to carry out clinical research on ıman beings in the process of developing new drugs by allowing stribution of the drug in interstate commerce. These exemptions e specific as to substance and manufacturer. This exception is afted to permit prosecution of a person who "diverts" the drug ıalogue from distribution for the purpose of research to illicit ıannels for the purpose of drug abuse.

(iv) Any substance to the extent not intended for human con- ımption before an exemption (that is, an IND) takes effect with spect to that substance. This provision is included in recognition the fact that drug researchers compound new drugs with an tent that ultimately they will be developed to be sold for human ınsumption in the course of medical treatment. This provision has en included to assure that, in a temporal sense, to the extent the ıbstance is not intended to be used or distributed for human con- ımption before the time that an exemption is issued, the sub- ance will not be treated as a controlled substance analog. Similar- , these compounds as manufactured and distributed for research ıat does not involve human consumption are not considered con- olled substance analogs unless they are diverted for human con- ımption.

) Treatment of controlled substance analogues

A new section 203 is added to the Controlled Substances Act to rovide that a controlled substance analogue, to the extent it is in- ınded for human consumption, is to be treated as a controlled sub- ance in schedule I.

Substances in schedule I do not have any currently recognized ıedical use in treatment in the United States, but nonetheless, are ften used in research—either in the area of drug abuse or, as in he case of marihuana, research in the treatment of the nausea re- ıted to cancer chemotherapy or in the treatment of glaucoma.

Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) [illegible] research involves human consump-

tion of schedule I substances to obtain specific registrations for research from DEA upon approval of their research protocols. Those scientific investigators (who are "practitioners" as defined in section 102(21) of the Controlled substances Act (21 U.S.C. 802(21) and are thus eligible for registration under section 303(f) (21 U.S.C. 823(f)) whose research is not undertaken pursuant to an IND or an NDA will be able to undertake research on controlled substance analogues upon obtaining specific registrations for research from the Drug Enforcement Administration upon approval of their research protocols by the Food and Drug Administration and the Drug Enforcement Administration.

It is the Committee's explicit intent that this Act not interfere in any way in legitimate pharmaceutical or medical research or treatment. The Committee debated an amendment offered by Mr. Morrison of Connecticut that would have created an additional exception to the definition of controlled substance analogue with respect to a practitioner who was registered with the Drug Enforcement Administration to conduct research using controlled substances, to the extent permitted under the Federal Food, Drug and Cosmetic Act, only amounts of analogues used in that practitioner's research. The concern was expressed that clinical research involving substances that might be treated as controlled substance analogues is permissible under the Federal Food, Drug and Cosmetic Act outside the exemption for interstate distribution of investigational new drugs. The amendment was withdrawn by unanimous consent to permit examination of the application of the Federal Food, Drug and Cosmetic Act so that the amendment could be perfected and offered on the floor in order to protect such research, if a further exception were found to be necessary.

Committee Approval

On July 29, 1986, the Committee on the Judiciary, a quorum being present, marked up H.R. 5246 and ordered it favorably reported to the full House as a single amendment in the nature of a substitute by a voice vote.

Oversight Findings

The Committee makes no oversight findings with respect to this legislation other than those included in the text of this report.

In regard to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Operations.

New Budget Authority

In regard to clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, H.R. 5246 creates no new budget authority or increased tax expenditures for the Federal Government.

Inflationary Impact Statement

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the bill will have no

foreseeable inflationary impact on prices or costs in the operation of the national economy.

Federal Advisory Committee Act of 1972

The Committee finds that this legislation does not create any new advisory committees within the meaning of the Federal Advisory Committee Act of 1972.

Cost Estimate

In regard to clause 7 of rule XIII of the Rules of the House of Representatives, the Committee agrees with the cost estimate of the Congressional Budget Office.

Statement of the Congressional Budget Office

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, and section 403 of the Congressional Budget Act of 1974, the following is the cost estimate of H.R. 5246.

U.S. Congress,
Congressional Budget Office,
Washington, DC, August 11, 1986.

Hon. Peter W. Rodino, Jr.,
Chairman, Committee on the Judiciary,
Rayburn House Office Building, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has reviewed H.R. 5246, the Designer Drug Enforcement Act of 1986, as ordered reported by the House Committee on the Judiciary, July 29, 1986. We estimate that no significant cost to the federal government and no cost to state or local governments would result from enactment of this bill.

H.R. 5246 would make "controlled substance analogs" subject to the Controlled Substances Act. This would enable the Drug Enforcement Administration to prosecute chemists who develop subtle chemical variations of controlled substances (called "designer drugs").

This bill would aid prosecution in cases brought by the Drug Enforcement Administration involving controlled substance analogs. It would not significantly change investigative efforts or costs as these drugs are currently investigated and tested. It would make possible prosecution and conviction in some cases where it is currently not possible.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes,
Sincerely

Rudolph G. Penner, *Director.*

Changes in Existing Law Made by the Bill, As Reported

In compliance with clause 3 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 italic, existing law in which no change is proposed is shown in roman):

Controlled Substances Act

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TITLE II—CONTROL AND ENFORCEMENT

Part A—Short Title; Findings and Declaration; Definitions

DEFINITIONS

Sec. 102. As used in this title:
(1) * * *

. . . . . .

(31)(A) Except as provided in subparagraph (B), the term "controlled substance analogues" means a substance—
(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II; and
(ii)(I) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system; or
(II) with respect to a particular person, which such person represents or intends to have a * * *

. . . . . .

the central nervous system substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance.
(B) 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.

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PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. (a) * * *

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TREATMENT OF CONTROLLED SUBSTANCE ANALOGUES

SEC. 203. A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of the Controlled Substances Act and the Controlled Substances Import and Export Act as a controlled substance in schedule I.

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