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 analogues, 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) any 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
TREATMENT OF CONTROLLED SUBSTANCE ANALOGUES

"But 201. 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 year prison sentence (up to 80 years for a second offense), doubled penalties for selling to persons under age 21 or in or near schools, double 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 system when they are found to have created "an imminent danger to the public safety" was included in the Comprehensive Crime Control Act of 1983, submitted to the Congress by President Reagan on March 15, 1983 (House Document 98-32 and H.R. 2151).


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 system 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 belief that the lag between the suggestion by the Attorney General (the Drug Enforcement Administration) that a substance ought to be controlled or rescheduled 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 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.

The Committee on Crime marked up and reported H.R. 4698 on April 26, 1984 as a clean bill, H.R. 5666. On May 23, 1984 the Committee on the Judiciary ordered H.R. 6666 reported to the full House (H.Rept. 98-935, 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. This provision was enacted as section 606 of the Dangerous Drug Diversions Control Act (Chapter V, Part B of the Comprehensive Crime Control Act of 1984, P.L. 98-475, October 17, 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-
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 400 people have been identified as being at serious risk of developing parkinsonism due to their exposure to the impurities associated with this designer drug.

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 controlled substances by making slight alterations in 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 15 new dangerous substances: 3-(3,4-methylenedioxyphenyl)propylone (MDMA, commonly referred to as Ecstasy); 3,4-methylenedioxyamphetamine (MDA) (a schedule I substance); and MPPP and PEPA (analogues of meperidine). In the Committee's view, generally this authority has 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 to be 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 in fact being abused and pose an imminent threat to the public health. Finally, there is the lapse 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. Fuccell and Mr. Hyde) introduced H.R. 5936, 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. 5248. On July 29, 1986, the Committee on the Judiciary, a quorum being present, marked up H.R. 5248 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
central nervous system effect of a substance in schedule I or II; and
(ii) (I) which was a stimulant, depressant, or hallucinogenic drug on
the central nervous system; or

(ii) with respect to a particular person, which such person repre-
sents 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 impor-
tant differences caused by relatively minor modification of the
basic structure. Consequently, both legitimate and illegitimate
chemists focus their research in the development of new psychoac-
tive drugs on making subtle modifications of existing controlled
substances.

The first branch of this definition is critically important because
it departs from the unknown drugs which are subject to the
law to the drugs already controlled by the Controlled Substances
Act. The Committee, by a voice vote, rejected an amend-
ment to add an alternative definition of controlled substance ana-
logue that did not include either a requirement of a chemical struc-
ture 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 has 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 con-
trolled drugs but some relationship to the stimulant, depressant,
or hallucinogenic drug. This relationship should be 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 any person (namely, the de-

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.  

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 evi-
dence 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 con-
trolled 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,
has proposed that the effect test in the second branch of the defini-
tion 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 require-
ment of chemical structure and a "substantially similar" central nervous
system effect might be difficult to prove. Before H.R. 5231 was
introduced, Mr. Hughes modified the effect requirement in the bill so
that the evidence of central nervous system effect is minimal com-
pared to the research burden that Drug Enforcement Administra-
tion has to sustain in order to bring a drug under control. 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 re-
quirements for scheduling under section 201(c) of the Controlled
Substances Act (21 U.S.C. 811(c)), for example, the analogue could
lack potential for abuse or a psychic or physiological dependence

Representative Lungren offered an amendment, adopted by the
Committee by a voice vote, to add an alternative representation or
intention 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 re-
search involved in developing drugs to relieve pain or to aid in psy-
chiatry and the treatment of emotional disorders, four exceptions
to the definition of a controlled substance analogue have been pro-
vided by the Committee.

The term "controlled substance analogue" does not include:

---

1 See letter of May 3, 1966 to Rep. William J. Hughes from George C. Plimpton, President,
American Chemical Society, page 3, and letter of July 23, 1966 to Eric L. Sterling, Assistant
Chairman, Committee on Appropriations, Subcommittee on Education and Science Policy, American Chemical Society reprinted in Hearings before the Sub-
committee on Crime of the House Committee on the Judiciary on Legislation relating to the
Problem of Designer Drugs, May 1, 1966, 89th Cong. 2nd sess., 142-143.

2 Controlled Substances Act, section 201(c), 811(c) (21 U.S.C. 811(c), 811(c)).
A controlled substance, if a substance has been scheduled as a controlled substance, then it cannot and should not be treated legally as a controlled substance analogue, even if its history of use was before it was controlled.

Any substance for which there is an approved drug application, these are drugs which have been found by the Food and Drug Administration to be safe and effective and have been approved for marketing in interstate commerce. Such drugs, if they have a sedative, depressant or hallucinogenic effect upon the central nervous system are brought to the attention of the Attorney General at the time the new drug application is submitted (section 101 of the Controlled Substances Act (21 U.S.C. 801(1)), and, upon approval of a new drug application, under section 401(a) of the Controlled Substances Act (21 U.S.C. 811(a))

With respect to a particular person, any substance for which an exemption from the Food and Drug Administration has been granted to permit 'investigational use' of the drug by that person, the extent to which with respect to the person is pursuant to or for a exempted. Such exemptions may be granted under the Federal Food, Drug, and Cosmetic Act as called 'INDs'.

FDA allows drug manufacturers to carry out clinical research on human beings in the process of developing new drugs by allowing distribution of the drug in interstate commerce. These exemptions are specific to such substances and manufacturers. This exception is often used to permit patients who have diverted the drug from the distribution for the purpose of research to receive supplies of the drug by the manufacturer only. The extent to which is permitted by the Drug Enforcement Administration to conduct research using controlled substances, to the extent permitted by the Federal Food, Drug, and Cosmetic Act, only a limited number of substances used in that practitioner's research. The concern was expressed that clinical research involving substances that might be included 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 considered 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 203(a) 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 203(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 204(a) 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 XII 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(c)(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,

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

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 a 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 analogues” 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 analogues. 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 XII 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 omit-
ted 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

Table of Contents

Part II—Control and Enforcement

Part A—Short Title, Findings and Declaration; Definitions

Sec. 102. Short title.
Sec. 101. Findings and declarations.
Sec. 102. Definitions.
Sec. 103. Increased numbers of enforcement personnel.

Part B—Authority To Control; Standards and Schedules

Sec. 201. Authority and criteria for classification of substances.
Sec. 203. Treatment of controlled substance analogues.

Part II—Control and Enforcement

Part A—Short Title, Findings and Declaration; Definitions

Sec. 102. As used in this title:

(i) * * *

(SXA) 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) 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.

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. (b) * * *

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.