SB

371

Senate Health, Education and Social Services Committee

Legislation Checklist

Bill number: SB 371

Sponsor: Rules

Date referred to committee: 1/21/85

Synopsis completed:

Fiscal note:

Further referrals:

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COMMITTEE REPORT

SENATE

FURTHER: JUDICIARY

1/29/86

Date 4-8-86

Mr. President

The Committee on HESS considered SB 371

amending the controlled substance schedules.

and (a majority of the committee) (the committee) reports it back with the following recommendations:

[X] do pass

[ ] do pass with attached amendment(s)

[ ] replace with/or adopt CS for _____
[ ] new title
[ ] same title and recommends _____

[ ] and attached a "LETTER OF INTENT" [ ] NEW FISCAL NOTE

[ ] reports it back without recommendation

[ ] recommends referral to _____ Committee

MEMBERS SIGNING
DO PASS

Ethel De Vries

Joe Joseph Hoon

MEMBERS HAVING
OTHER RECOMMENDATIONS

Billie Jakobsen Yancy Do Pass
Chairman

Chairman recommendation

Current statute allows school boards to dismiss (mid-contract) any teacher for incompetency, immorality, or noncompliance with school laws; to nonretain (at end of contract term) nontenured teachers for any reason; and to nonretain tenured teachers for incompetency, immorality, noncompliance with school laws, or a decrease in school attendance.

A legal opinion addressing the effect of statutory amendments on currently tenured teachers is attached.

SB 371 An Act amending the controlled substance schedules

Current statute requires that if the Federal Drug Enforcement Agency (DEA) adds controlled substances to its schedule, legislation should be introduced to include those substances under Alaska law. SB 371 would add 26 substances that have recently been controlled by the DEA and remove two that have been decontrolled. The list includes several so-called "designer drugs" which are chemical analogs of previously controlled substances.

Including these substances under state law would enable our law enforcement agencies to enforce their use.

HB 472 An Act relating to the interim management of the mental health trust

On April 4, 1986 the committee considered this bill in draft form. Attached are a sectional analysis and amendments proposed by the Department of Natural Resources and the Alaska Alliance for the Mentally Ill.

Sec. 11.71.080. Aggregate weight of live marijuana plants. For purposes of calculating the aggregate weight of a live marijuana plant, the aggregate weight shall be the weight of the marijuana when reduced to its commonly used form. (§ 2 ch 45 SLA 1982)

Article 2. Standards and Schedules.

Section	Section
100. Controlled substances advisory committee	150. Schedule IIA
110. Duties of committee	160. Schedule IIIA
120. Authority to schedule controlled substances	170. Schedule IVA
140. Schedule IA	180. Schedule VA
	190. Schedule VIA
	195. Exempted drugs

Sec. 11.71.100. Controlled substances advisory committee. (a) The Controlled Substances Advisory Committee is established in the Department of Law. The committee consists of

(1) the attorney general or the attorney general's designee;

(2) the commissioner of health and social services or the commissioner's designee;

(3) the commissioner of public safety or the commissioner's designee;

(4) the president of the Board of Pharmacy or the designee of the president who shall also be a member of the Board of Pharmacy;

(5) a peace officer appointed by the governor after consultation with the Alaska Association of Chiefs of Police;

(6) a physician appointed by the governor;

(7) a psychiatrist appointed by the governor; and

(8) two individuals appointed by the governor.

(b) Members of the committee appointed under (a)(5) — (8) of this section serve terms of four years. A member of the committee receives no salary but is entitled to per diem and travel expenses authorized by law for boards and commissions under AS 39.20.180.

(c) The attorney general is the chairman of the committee.

(d) The committee meets at the call of the attorney general.

(e) The committee may not meet less than twice a year.

(f) Five members of the committee constitute a quorum, except that a smaller number may adjourn a meeting in the absence of a quorum. A quorum being present, a majority vote of the total membership is required to take official action. (§ 2 ch 45 SLA 1982)

Cross references. — For terms of initial members, see sec. 25, ch. 45, SLA 1982 in the Temporary and Special Acts.

Sec. 11.71.110. Duties of committee. The committee shall

(1) advise the governor of the need to add, delete or reschedule substances in the schedules in AS 11.71.140 — 11.71.190;

file SB 371

STATE OF ALASKA 1986 LEGISLATIVE SESSION
FISCAL NOTE

FEB 12 1986

Revision Date : _____

REQUEST

Bill/Resolution No. : SB 371
Title : "An Act amending the controlled substance schedules."

Sponsor : Rules Committee
Requestor : Senate HESS
Date of Request : _____

FISCAL DETAIL

Agency Affected : Public Safety
BRU : Alaska State Troopers

Components : _____

EXPENDITURES/REVENUES : (Thousands of Dollars)

OPERATING	FY 86	FY 87	FY 88	FY 89	FY 90	FY 91
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING		0	0	0	0	0
CAPITAL						
REVENUE						

FUNDING : (Thousands of Dollars)

GENERAL FUND						
FEDERAL FUNDS						
OTHER						
TOTAL		0	0	0	0	0

POSITIONS :

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS : Attach a separate page if necessary

Prepared by : Kathy Niles, Admin. Assistant
Division : Commissioner's Office
Phone : 465-4336
Date : 2/05/86

Approved by Commissioner : _____
Agency : Public Safety
Date : 2/5/86

Distribution (by Agency preparing fiscal note) :
- Legislative Finance
- Legislative Sponsor
- Requestor
- Office of Management and Budget
- Impacted Agency(ies)

10/25/85

DEPARTMENT OF PUBLIC SAFETY

POSITION PAPER - SB 371

SUPPORT

February 4, 1986

SB 371 - "An Act amending the controlled substance schedules."

This bill simply updated the chemical nomenclatures of various substances that should be within the "controlled substance" schedules.

Robert J. Sundberg
Commissioner

INDEX TO NEW DRUG BILL

Art. 1 Offenses

Misconduct Involving a Controlled Substance	
in the First Degree	AS 11.71.010
in the Second Degree	AS 11.71.020
in the Third Degree	AS 11.71.030
in the Fourth Degree	AS 11.71.040
in the Fifth Degree	AS 11.71.050
in the Sixth Degree	AS 11.71.060
in the Seventh Degree	AS 11.71.070
Aggregate Weight of Live Marijuana Plants	AS 11.71.080

Art. 2 Standards & Schedules

Controlled Substances Advisory Committee	AS 11.71.100
Duties of Committee	AS 11.71.110
Authority to Schedule Controlled Substances	AS 11.71.120
Criteria for Scheduling Controlled Substances	AS 11.71.120(c)
No Authority over tobacco or alcoholic beverages	AS 11.71.120(e)
Schedule IA	AS 11.71.140
Schedule IIA	AS 11.71.150
Schedule IIIA	AS 11.71.160
Schedule IVA	AS 11.71.170
Schedule VA	AS 11.71.180
Schedule VIA	AS 11.71.190

Art. 3 Miscellaneous Provisions

Penalties Under Other Laws	AS 11.71.300
Rehabilitation	AS 11.71.305
Bar to Prosecution	AS 11.71.310
Defenses Exempted	AS 11.71.320
Liability of Public Servants	AS 11.71.330
Offenses Defined by Amounts	AS 11.71.340
Burden of Proof	AS 11.71.350
Unprivileged Communications	AS 11.71.360

Art. 4 Definitions

Definitions	AS 11.71.900

AMENDMENTS TO AS 17, NEW CHAPTER 30

Art. 1 Regulation of Manufacture, Distribution, Prescription, and Dispensing of Controlled Substances

Regulations	AS 17.30.010
Registration Requirements	AS 17.30.020
Registration	AS 17.30.030
Denial, Revocation & Suspension of Registration	AS 17.30.040
Order to Show Cause	AS 17.30.050
Records of Registrants	AS 17.30.060
Order Forms; Prescriptions	AS 17.30.070
Unlawful Administration, Prescription & Dispensation of Controlled Substances	AS 17.30.080

Index to New Drug Bill

Art. 2 Enforcement and Administrative Provisions

Cooperative Arrangments	AS 17.30.100
Forfeitures	AS 17.30.110
Judicial Review	AS 17.30.130
Education and Research	AS 17.30.140
Confidentiality	AS 17.30.150
Definitions	AS 17.30.160

AMENDMENTS TO AS 17, NEW CHAPTER 35

Alaska Therapeutic Research Act

Legislative Purpose	AS 17.35.010
Therapeutic Research Program	AS 17.35.020
Patient Qualification Review Committee	AS 17.35.030
Sources, Distribution & Possession of Marijuana	AS 17.35.040
Report to the Governor & Legislature	AS 17.35.050
Definitions	AS 17.35.060

AMENDMENTS TO AS 12

Bail Pending Sentencing or Appeal	AS 12.30.040(b)
Laboratory Report of Controlled Substances	AS 12.45.155
Rehabilitation	AS 12.55.015(d)
Fines	AS 12.55.035(b)(1)
Sentences of Imprisonment	AS 12.55.125(b)
Aggravating Factors	AS 12.55.155(c)
Mitigating Factors	AS 12.55.155(d)

MISCELLANEOUS AMENDMENTS

DWI/OMVI	AS 28.35.030(a)(1)
Parole of Drug Abusers	AS 33.15.190(b)
Definitions	AS 11.81.900(b)(4) (6), & (16)
Attempt	AS 11.31.100(d)(1)
Solicitation	AS 11.31.110(c)(1)
Miscellaneous Definitions	AS 08.64.380(3)(B)
	AS 08.80.040(10)
	AS 08.80.470
	AS 08.80.480(20)
PROVISIONS REPEALED	AS 17.10, AS 17.12, AS 17.15

(Attachment #1)

The following is a brief description of the major differences between the Alaska Controlled Substances Act and the federal Controlled Substances Act. For more detailed information please refer to the attachments.

The differences between the Alaska's Controlled Substances law and the federal Controlled Substances Act are outlined below:

A. Criteria used for scheduling controlled substances:

Most of the criteria are basically the same (see Attachment #2a) the two primary differences are:

(i) Alaska does not have the separate criterion, "accepted medical use" for the substance, which the federal CSA does have.

(ii) Alaska's CSA does have a criterion on the relationship between the use of the substance and other criminal activity, which the federal CSA does not have. (See Attachment #2a)

B. The schedule labeling differs. The federal CSA labels the schedules I through V. The Alaska CSA labels the schedules IA through VIA. (The "A" was added to allow for differentiation between the federal schedule and Alaska schedule.)

C. In the Alaska Controlled Substances Act marijuana has been classified schedule VIA, in the federal CSA marijuana is classified a schedule I.

In the Alaska CSA hashish and THC are a schedule IIIA; the federal act has classified marijuana, hashish and THC in Schedule I.

D. Federal Schedules I & II

I Narcotics
I Non-narcotics

II Narcotics
II Non-narcotics

Alaska Schedules IA & IIA

IA Narcotics ONLY

IIA Non-narcotics ONLY

Federal Schedule I & II Narcotics are classified as Schedule IA under the Alaska CSA. Federal Schedule I & II non-narcotics are classified as Schedule IIA under the Alaska CSA. (See Attachment #3)

Designer Drugs: An Enforcement Nightmare

By Jack Shafer

Heroin's surreptitious journey to America has traditionally begun in foreign lands where its raw ingredient Papaver somniferum, opium-poppy, is cultivated. But in 1979, underground chemists in California cracked the foreign connection with "designer drugs," synthetic drugs made in clandestine laboratories for pennies a dose. While not the last shot to be fired in the war on drugs, the designer drugs may be the decisive one. The government has yet to find a way to stamp them out.

These high-tech highs were designed to look like heroin, pack its euphoric punch and stave off withdrawal. But they had another designer wrinkle. By subtly modifying the molecular structure of fentanyl, a commercial synthetic opiate, the chemists created analogs or chemical cousins of fentanyl that were not prohibited by the drug law. These drugs were completely legal to make and use.

Consider the enforcement dilemmas the designer drugs present:

- Their formulas can be found in almost any university chemistry library;
- they can be made in undetectable bathroom-size labs, beyond the reach of customs officers and eradication teams;
- from $500 worth of chemicals one can make $2 million worth of "synthetic heroin";
- one lab can meet the world's demand for heroinlike drugs without harvesting a single opium-poppy;
- because fewer people need to be cut in on the action the profit margin is higher;
- as fast as the government outlaws designer drugs the chemists can synthesize new ones.

Actually, the chemists have been spinning off analogs faster than the government has outlawed them—so far, only one of a half-dozen fentanyls has been banned. They are now so ubiquitous in California that Robert J. Roberton of the state's Division of Drug Programs estimates that up to 20% of California's 100,000 heroin users are now taking one of them. The fentanyl analogs have killed more than 85 people so far, and continue to add to the body count at the rate of two a month.

How many fentanyl analogs are possible? Gary Henderson, a pharmacologist at the University of California at Davis, estimates their number in the tens of thousands. But other synthetics can be re-tailored into legal heroin substitutes, too. In the summer of 1982 an analog of meperidine (the painkiller marketed as Demerol) made the rounds in San Jose, Calif.; an impurity in the concoction gave seven heroin users irreversible brain damage. The drug vanished from the market when the medical warning went out, but we haven't seen the last of this analog. In recent years, independent chemists in Vancouver, British Columbia, and Bethesda, Md., have gone directly to the chemical literature to find the formula for the drug and then poisoned themselves with it. For those who are too lazy to look up the original formula, a simplified 16-step, photocopied recipe for it is now circulating in California drug circles.

The designer market, however, is not limited to heroin substitutes. Nature has provided the chemical patterns for millions of legal drugs of abuse. Nearly every drug, from cocaine to marijuana, LSD to Quaalude (methaqualone) can be mimicked by cheap designer drugs. In fact, a steady stream of designer drugs based on illegal synthetics such as PCP (piperidine), Quaalude, methamphetamine (P2P) and the psychedelics have appeared on the market over the years. If chemists ever dedicate themselves to churning out analogs, the government will find itself playing a permanent game of catch-up. "Eventually the list of illegal drugs is going to be as long as the New York telephone book," said Mr. Henderson.

The federal government is attacking designer drugs with new regulatory powers it won in the crime bill passed by Congress last October. The months—or years—process of banning designer drugs has been shortened so that all the government has to do is identify the new drug, publish its formula in the Federal Register and, *voila*, 30 days later it is as illegal as heroin. But even if the government found a way to ban millions of designer drugs before the fact, clandestine labs would continue to be an unstoppable source of synthetic drugs. The laws already on the books have failed to put so much as a dent in the supply of illicit synthetics. Police close more than 200 clandestine labs annually, but according to the National Narcotics Intelligence Consumers Committee, a federal task force, another 800 labs go undetected each year. Because a single lab can put millions of doses on the market, hundreds of millions of doses of the synthetics still find their way to the market each year.

Synthetic drug profits are so astronomical that many chemists are more than willing to risk up to 40 years in prison and $500,000 in fines. Similarly, chemists have shrugged off recent laws that control the raw ingredients needed to make PCP and methamphetamine by switching to other precursor chemicals or buying what they need on the black market. If the government licensed all lab equipment and chemicals, chemists still would be able to synthesize drugs from earth, air, fire and water using pressure cookers, hot plates and garden hoses.

Since passage of the prohibitionist Harrison Act of 1914, America has been the prime mover in the international system of drug control. By attacking the supply of illicit drugs at their foreign sources, the international system has sought to reduce the supply and price drugs out of the reach of users and potential users.

But controlling the supply is no longer a simple matter of sealing the border drug-tight and uprooting every coca, opium-poppy and marijuana plant on earth. Designer drugs, whether they are banned or not, are impervious to international treaties, eradication schemes and border seizures. Already the fentanyl analogs have spread from their California proving grounds to Arizona, Oregon and New York. As the designer drugs proliferate—and there is no reason to believe they won't—they may well topple the international system of drug control and render the war on drugs permanently unwinnable. There will be just too many inexpensive drugs and too many enterprising druggists to stop.

The drug war will continue with shots being exchanged on both sides. But for now the government is on the run.

Mr. Shafer, a Washington journalist, is writing a book on illicit synthetic drugs. This article is based on a feature story in the March issue of Science 85.

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(65: 101) 8 March 85, p. 24.

'Designer Drugs' Skirt the Law

Phantom Chemist Sought

By Boyce Rensberger
Washington Post Staff Writer

A phantom chemist in California is foiling authorities by tinkering with molecules to create legal "designer drugs" that addicts say are as strong as heroin but that have killed at least 85 people.

"He's clearly a state-of-the-art chemist," said Gary Henderson, a pharmacologist at the University of California at Davis, who coined the term designer drugs. "He'd have to be or he'd kill himself making this stuff. It's that potent."

Drug laws define illegal drugs by their exact molecular structure, so it is possible for the chemist to evade the law by making minor changes in the substance's molecules.

By the time scientists decipher the structure of the chemist's latest product and enforcement agencies take steps to outlaw it—which can consume several months—the chemist simply redesigns the molecule.

Although all of the deaths have occurred in the West, drug officials and chemists say it is only a matter of time before designer drugs spread nationwide.

The mystery chemist is known to have produced 10 variations of the drug fentanyl, widely used as an anesthetic in surgery but otherwise illegal.

Fentanyl has the same effect as heroin or morphine, and addicts can switch freely back and forth, but it is far stronger than heroin and therefore must be cut to a greater degree for street sales.

Only two of the variations of fentanyl have been outlawed. Pharmaceutical indus-

See DESIGNER, A6, Col. 1

3/14/85

THE WASHINGTON POST

Phantom Chemist Makes Legal 'Designer Drugs'

DESIGNER, From A1

try researchers have produced an additional 210 variations, none of which ever reached the market, and hundreds more theoretically are possible.

"Whoever this guy is, he's obviously got some chemical training and he's got a good laboratory," said Donald Cooper, a chemist who has analyzed the phantom chemist's products at the U.S. Drug Enforcement Administration's laboratory near Tysons Corner, Va. "There are good indications he's cognizant of our legal efforts and he's trying to stay one step ahead of us."

Cooper and other chemists who have been tracking the phantom chemist since 1981, when his products first appeared, have developed a grudging admiration for him. They cite a drug he made called 3-methyl fentanyl. It is about 1,000 times stronger than heroin. The amount absorbed through the skin from a smudge on one finger would be "enough to knock you down," said Henderson.

But, Henderson said, "the stuff he makes is clean and the dose is cut just right. Every time I get a sample from the police, I think about this guy. I wonder what he's got in store for us. It's usually pretty interesting."

Henderson and Cooper are among many who believe it is inevitable that designer drugs will spread east. All the deaths so far have been in California except for two in Oregon and one in Arizona.

Although recipes for making fentanyls are not yet in the cookbook form used by clandestine drug labs making LSD, PCP, amphetamines and other older drugs, Henderson and Cooper worry that a chemically sophisticated person could figure it out from chemical literature.

All but one of the fentanyls made by the phantom chemist are forms described in the chemical literature. One, called para-fluoro fentanyl, was his own invention. Investigators say they believe that only one chemist is likely to be at work because the same combination of other substances is used to cut the drug. This would be unlikely if several chemists were working independently.

"If this thing breaks out of the West Coast, we hate to think what could happen," said Ronald Buzzeo, deputy director of the DEA's office of diversion control. "We don't have the legal apparatus to really go after this kind of thing. We're looking at ways to control these drugs as a class but the lawyers and the scientists say it's not clear we can."

The problem is how to write a definition broad enough to include the whole fentanyl family without being so broad that courts consider the law too vague. "Besides," Henderson said, "no matter how many variations you put in the law, I'll bet I can think up another one."

Although several classes of designer drugs are made in other clandestine labs, fentanyls are the major concern now. Another group, for example, also acts like heroin but causes Parkinson's disease.

Because plain fentanyl is about 80 times more powerful than heroin, dealers usually cut it far more than they do heroin. It is often sold as China White, the usual name for a superior grade of Asian heroin. The 3-methyl fentanyl form is sometimes sold as Persian White, the finest grade of heroin.

Plain fentanyl, like all organic compounds, is a molecule made of several kinds of atoms—carbon, hydrogen, oxygen and nitrogen—linked in a specific configuration of rings, strings and other patterns. The shape of the resulting molecule and the nature of the atoms at various positions determine how it will react in the body.

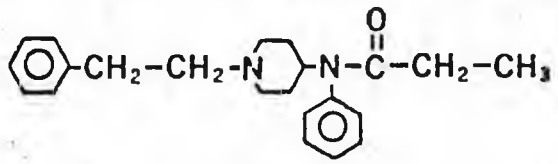
Designer alterations of fentanyl are possible, however, because some points on the molecule can bind to additional atoms or groups of atoms. In the case of 3-methyl fentanyl, the molecule is a plain fentanyl with a methyl group (a carbon surrounded by three hydrogens) stuck on at a position that chemists, by convention, designate as No. 3.

For reasons not understood, this alteration makes the molecule react much more strongly with the nerve cell's opiate receptor sites, multiplying its strength. The alteration also turns the molecule into something other than fentanyl, something legal.

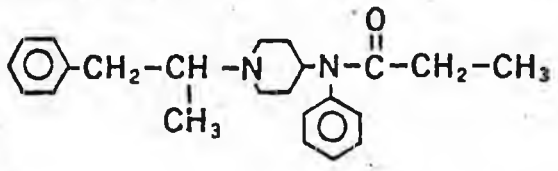
DESIGNER DRUGS

(VARIATIONS IN THE FENTANYL FAMILY)

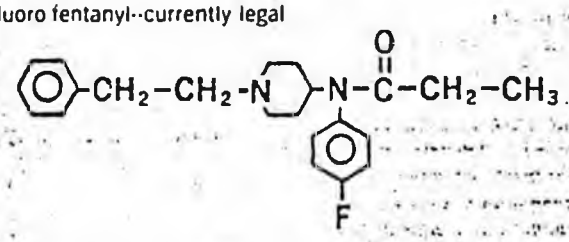
fentanyl--legal only as surgical anesthetic



alpha-methyl fentanyl--illegal



para-fluoro fentanyl--currently legal



Plain fentanyl, top, a synthetic narcotic, made entirely from industrial chemicals. It consists of linked atoms of carbon, hydrogen, oxygen and nitrogen, indicated by initials. Hexagons are chemists' way of representing rings with carbon atoms at each point and hydrogen atoms sticking out from each carbon unless the carbon is linked to something else. To make alpha-methyl fentanyl, middle, chemists follow a slightly different procedure that ends up with a methyl group (CH_3) attached at one point. Para-fluoro fentanyl, bottom, results from a procedure that binds a fluorine atom to one of the rings.

THE WASHINGTON POST

New Variety of Street Drugs Poses Growing Problem

Designer drugs—analogs of compounds with proven pharmacological activity made by underground chemists—present novel challenges to law enforcement officials, legislators, and scientists

Rudy M. Baum, C&EN San Francisco

A breed of underground chemists, most of them in California, are playing a deadly cat-and-mouse game with law enforcement authorities. They are the manufacturers of what have become known as designer drugs. Their customers range from heroin addicts on the streets of Oakland, San Francisco, and Los Angeles to upscale young professionals in Marin County. Until recently, many of their products were perfectly legal. Until laws dealing with drugs of abuse are changed, it is likely that new products from their clandestine laboratories also will, for a time, be legal.

Designer drugs: It's a catchy sobriquet. It's also an imprecise one. Under its broad umbrella have been grouped compounds possessing enormously different pharmacological properties—and enormously different levels of danger to the people who consume them. One class of such drugs has been associated with more than 100 overdose deaths in California. An impurity in another designer drug has caused several cases of irreversible Parkinson's disease among the addicts who used it. Yet another has been condemned by some as a damaging hallucinogen and championed by others as an important new therapeutic agent.

The phenomenon of designer drugs presents law enforcement and drug treatment officials, legislators, and scientists with novel challenges. For example, how does one design a law to make illegal a compound that has not yet been synthesized? Or for another example, is it possible to design a simple, relatively inexpensive analytical procedure to detect a compound present in body fluids at 1 ng per mL? Ironically, the phenomenon also has opened up an exciting new avenue into the study of neurological disease, one that could never have been ethically pursued in the absence of several hundred young heroin addicts who poisoned themselves with a tainted designer drug.

Designer drugs are analogs of compounds with proven pharmacological activity manufactured by underground chemists for sale on the street. For instance, the compound fentanyl is a powerful narcotic marketed under the tradename Sublimaze by Janssen Pharma-

Doonesbury BY GARRY TRUDEAU

Henderson (left): single chemist is responsible. Langston (center): synthetic heroin was behind disaster. Roberton: stepped-up education, prevention efforts

for a scary situation. The way things stand, we have no indication that organized crime is involved. We have no indication that it is a nationwide problem. However, in terms of the potential threat, there are half a million heroin addicts across the country primed to be supplied with these synthetic drugs."

Another feature is that, at least in the case of fentanyl analogs, the level of sophistication required to make even a sloppy batch and not kill oneself is greater than for past analogs. "Making these fentanyl compounds is not the same as making PCP or methamphetamine," Sapienza says. "I don't think that the average bucket chemist would be able to follow a set of instructions to make 3-methyl fentanyl."

The fentanyl and meperidine analogs tend to be linked together in discussions of designer drugs because both classes of compounds are narcotics and are intended for sale to heroin addicts, but they are quite distinct chemically. The evolution of the two as designer drugs also is different, as are the implications of their continued use on the street.

"Fentanyl has been in use medically in Europe since the late 1960s and in the U.S. since the early 1970s, and no one thought it had abuse potential because it is so short-acting. Addicts wouldn't use it if the high lasted only 30 minutes," says Gary L. Henderson, a pharmacologist and toxicologist at the University of California, Davis, who has been studying fentanyl and its analogs since 1972. However, Henderson points out, the fentanyls are unique in that the entire class of compounds is so potent, and analogs can be designed, as they have been by researchers at Janssen, to be either shorter acting or much longer acting than fentanyl itself.

Henderson's involvement with fentanyl began when he was asked to develop an analytical assay for the drug in body fluids for use in clinical monitoring. Because the compound is such a potent narcotic, it is present in very low concentrations in blood and urine of users, and development of such an assay is technically complex. The radioimmunoassay that Henderson and his coworkers fashioned has been improved to the point where it can now detect fentanyl or fentanyl analogs at concentrations as low as 1 ng per mL. Henderson's laboratory is the only one in California, and one of the few in the U.S., that can analyze for fentanyl analogs in body fluids.

Although fentanyl abuse by medical personnel is not uncommon, Henderson says, the first illicit use of the drug his laboratory was called on to investigate was in doping racehorses. "Racehorse underground chemists generally are years ahead of the chemists producing for street abuse," Henderson observes. The effects of narcotics are quite species specific, and in several species, including horses, they act as stimulants. "There is evidence that in ancient times opium extracts were used to stimulate horses. People were using methadone to dope racehorses before anyone in this country knew what methadone was," he says.

In 1981, Roberton contacted Henderson because fentanyl analogs had begun showing up in what were supposedly heroin samples seized by police. That contact has led to an ongoing contract between Henderson's lab and the Division of Drug Programs by which drug and body fluid samples from unexplained overdose deaths and from drug treatment centers can be sent to Henderson for analysis.

Over the past six years, several fentanyl analogs, as well as fentanyl itself, have shown up on the street, Henderson says. The analogs have appeared in a roughly sequential order with some overlap from one to the next. First came α-methyl fentanyl, then *p*-fluoro fentanyl, α-methyl acetyl fentanyl, and, in early 1984, 3-methyl fentanyl. At least two other analogs were found in samples but were probably synthetic byproducts, Henderson says. The α-methyl, *p*-fluoro, and

ance of *p*-fluoro fentanyl. "That had not been described in the literature," Henderson says. "It is a straightforward thing to do, but unlike most underground chemists, he or she went to something that had never been published." A third factor is that "the quality control is really remarkable. These aren't garbage drugs. They are well made, with very few impurities, and the doses are uniform."

Finally, "the real kicker to me was the appearance of 3-methyl fentanyl," Henderson says. "It is hard to synthesize. There is a lot of steric hindrance at the 3-position. Plus, to make this, you stand a good chance of killing yourself. It is so potent in its pure form that you just can't work with it in a normal underground laboratory."

Overall, Henderson concludes, "the thinking behind this is an order of magnitude over your classic amphetamine or PCP chemist who works from a cookbook recipe." However, if the thinking behind the fentanyl analogs is world class, the facilities required to make it are not. "The equipment required is about what you would find in an introductory organic chemistry laboratory," Henderson says.

Henderson's speculation that a single chemist has been behind the fentanyl analogs that have appeared thus far may well be correct. The identity of that chemist likely will never be determined, because, Henderson believes, he or she no longer needs to synthesize product.

"That is one problem with the law enforcement end of this," Henderson says. "The police are oriented toward biker labs. They think they are going to be riding around and see a 50-gal drum of acetone sitting next to a garage. They go inside, and sure enough, some guy has boxes of 3-methyl fentanyl sitting around. That is not going to happen. You make 3-methyl fentanyl once and you have a lifetime supply; 200 g is 200 million doses."

Even if the scenario of a single chemist culprit is correct, it seems likely that other, less sophisticated chemists are being drawn to the synthesis of fentanyl analogs by the potential profits involved. Sapienza says that in June, DEA agents raided two independent clandestine laboratories in the Los Angeles area that were attempting to make some sort of fentanyl analog. Which analog, Sapienza says, is not yet clear. What is clear from the material that was seized is that the chemists involved were not of the caliber of the one who made the material Henderson has analyzed. "What we are seeing from both laboratories are complex mixtures of a number of active ingredients along with many by-product intermediates and impurities," Sapienza says.

The technical sophistication involved in analyzing for fentanyl analogs in blood and urine is causing headaches for drug treatment centers and parole and probation departments. Henderson is working to develop an assay for other laboratories, but he says, "I think it is a quantum jump in technology to make it routine." In addition to the low concentrations involved, different fentanyl analogs may require different immunoreagents.

Roberton outlines the kinds of problems the fentanyl analogs pose. "Say I am a parole officer. I have a man on parole who is required to give a urine sample on demand. He walks into my office one day and I can see that he is high as a kite. I say to him, 'You've been using,' and he responds, 'I haven't used in months.' So we get a urine sample, it goes into the lab, and it tests negative because he has not been using heroin, he has been using 3-methyl fentanyl. There is nothing I can do. It is a perfect drug for people on parole or on probation. People in drug treatment programs can use it, and it will not show up in the routine tests."

One company that does such routine testing is PharmChem Laboratories Inc., Menlo Park, Calif., which specializes in screening for illicit drugs, primarily in urine samples. The company analyzes about 50,000 samples per month from a variety of clients. Among PharmChem's largest clients, in terms of number of samples, are methadone treatment centers and parole and probation departments.

The type of analysis done depends on the client, says Brian Sedgwick, director of research and development of the company. For a typical sample from a drug treatment center, PharmChem carries out a relatively simple, two-plate, thin-layer-chromatography analysis, which can detect seven classes of drugs, including opiates, methadone, amphetamines, barbiturates, and cocaine. The cost of such an analysis is $3.00 to $4.00 per sample.

Samples from another client, the Los Angeles County probation department, undergo a three-test system. The sample is first screened by a two-plate TLC analysis. Samples testing positive are confirmed by an enzyme-linked immunoassay and then by gas chromatography. Only samples testing positive in all three procedures are reported as positive. Some industrial clients require gas chromatography/mass spectroscopy confirmation of positive samples, which adds about $45 to the cost of analysis, Sedgwick points out.

"The fentanyl series of compounds pose major analytical problems," Sedgwick says. For routine screening, the concentrations involved "are well below the range of TLC." That automatically means that immunoassay screening, which can be more expensive, will be required. Currently, an immunoreagent for fentanyl is not yet commercially available, Sedgwick says. And since GC/MS confirmation likely would be required for fentanyl analogs, the cost of analysis probably would be well beyond the budgets of most drug treatment centers and many parole and probation departments.

"If designer drugs do become a major part of the drug abuse scene, and if the trend is toward compounds with increasing potency, the implication for analytical laboratories such as PharmChem is that detection sensitivity will have to increase, and therefore our methodology will have to become more sophisticated, more precise, and possibly more expensive," Sedgwick says. Such trends would require a significant research and development effort.

The designer drugs that are analogs of meperidine

N.M., has published one of the few studies of such MDMA therapy. Greer administered MDMA to 29 subjects, 14 of whom were experiencing relatively minor psychological problems, such as dissatisfaction with themselves and minor depression. Although admitting that the study lacked rigorous scientific controls, Greer found that all 29 subjects reported some benefit from MDMA during the session.

Greer concluded that "the single best use of MDMA is to facilitate more direct communication between people involved in a significant emotional relationship. Not only is communication enhanced during the session, but afterward as well. Once a therapeutically motivated person has experienced the lack of true risk involved in direct and open communication, it can be practiced without the assistance of MDMA." Greer also observed that "MDMA's use as an adjunct to insight-oriented psychotherapy was specifically recommended by six subjects. Many felt that MDMA enhanced self-understanding and was useful in their personal and spiritual growth."

The psychiatrists who have used MDMA in therapy also believe that it has relatively low abuse potential because its beneficial or pleasant effects diminish rapidly with regular use.

By contrast, DEA's Frank Sapienza says that MDMA's abuse potential has been demonstrated by the simple fact that a lot of the drug is being synthesized, sold by dealers on the street, and used by recreational drug users. Based on that evidence and the fact that MDMA is chemically similar to other drugs of abuse, DEA proposed in July 1984 that MDMA be classified as a Schedule I controlled substance. The Schedule I classification was proposed because the Food & Drug Administration had never approved MDMA for medical use. "That is the definition we use," Sapienza says.

DEA was surprised when several psychiatrists and psychologists objected to the proposed scheduling. "We didn't know that it was being used in therapy sessions," Sapienza says.

In hearings on the scheduling, psychiatrists who have used MDMA in therapy argued that the drug should certainly be controlled, but that it should be classified as a Schedule III controlled substance, which is defined as one with moderate abuse potential and accepted medical uses. DEA's emergency scheduling action, coming in the midst of the permanent scheduling procedure, caught those physicians off guard.

Sapienza defends DEA's action on the grounds that research conducted at the University of Chicago demonstrated that MDA is selectively neurotoxic to serotonergic neurons in the brain. Although MDMA's mechanism of action remains unknown, research has shown that its action involves serotonergic neurons. By extrapolation, MDMA also might be neurotoxic to such neurons. DEA's emergency scheduling was based on that possible neurotoxicity and the increasing availability of the drug on the street.

"I think the different views of MDMA are compatible," Sapienza says. In terms of MDMA's abuse potential, he points out that the law does not equate abuse with harmful side effects. It equates abuse with how many people want to use a drug. And there appear to be a significant number of people who want to use MDMA. "They might not call that abuse," he says. "They might call it recreational use." However, the law does not differentiate between the two.

The same sort of dichotomy applies to what is meant by medically accepted uses. The law clearly states that a drug "must go through accepted procedures to prove that it is safe, that it can be produced in pure form, and that it treats some condition," Sapienza says. "MDMA may be able to fit into that category, but the studies have not been done to show that. Therefore, we have to say that it has no accepted medical use, and it has to go into Schedule I."

Such a classification, however, creates a catch-22 situation for the proponents of MDMA as a useful therapeutic drug. The laws applying to Schedule I controlled substances make it quite difficult to obtain approval to conduct clinical trials of a drug. Because it is impossible to obtain patent protection on MDMA, it is unlikely that a pharmaceutical firm will undertake the costly effort to obtain FDA approval for its use.

suffered neurological damage, but I had never seen anything like it before."

Langston and his colleagues found out that the patient's girlfriend, also a heroin addict, was in the same condition. She was admitted to the medical center. Although Langston was convinced that their condition was caused by some environmental source, he was not sure enough that it was the heroin to issue a public alarm. Then through what Langston calls a "remarkable series of coincidences," he learned of two similar cases in Santa Cruz, a town about 30 miles from San Jose on the California coast. Two brothers had used a synthetic heroin and both began to freeze up. They continued to use the drug until both were unable to move. Both probably would have starved had their mother not stopped by their apartment to check on them.

The link to the synthetic heroin had been established in Langston's mind, and he put out a public warning. The publicity surrounding the announcement brought to light three more cases and samples of the synthetic heroin. Ian Irwin, a chemist working with Langston, analyzed the samples by GC/MS, but found no matches against a library of 40,000 mass spectra.

The publicity resulted in yet another clue. Halle Weingarten, a toxicologist with the Santa Clara County Crime Laboratory, called Langston to tell him that she recalled reading about a student who had synthesized his own narcotics and been stricken with symptoms resembling Parkinson's disease. The case had been described by Glenn C. Davis, then an associate professor of psychiatry at the University of Tennessee's Center for the Health Sciences, and several coworkers in a 1979 issue of *Psychiatry Research*. After reading the article, Langston and Irwin concluded

WASHINGTON CRIME NEWS SERVICES'

NARCOTICS CONTROL DIGEST

Vol. 15 No. 7 April 3, 1985

In House, Senate . . .

PROPOSED LEGISLATION WOULD ATTACH "STRINGS" ON U.S. AID TO NARCOTICS SOURCE COUNTRIES

Bi-Partisan Bill Targets Brazil, Peru, Bolivia And Jamaica

A bi-partisan bill that would set narcotics control performance goals for Brazil, Peru, Bolivia and Jamaica as standards for U.S. foreign aid was introduced jointly in the House and Senate March 28.

The International Narcotics Control Act of 1985 is sponsored by Senators Lawton Chiles (D-Fla.), Joe Biden (D-Del.), and Sam Nunn (D-Ga.) and Representatives Dante Fascell (D-Fla.), Dan Mica (D-Fla.), Larry Smith (D-Fla.), Ed Feighan (D-Ohio) and Ben Gilman (R-N.Y.).

The proposed legislation calls for the State Department to pursue a regional Latin American approach to cooperation in the fight against drug smuggling. It would prohibit the use of foreign assistance funds to reimburse for drug crop eradication. And it mandates increased efforts to negotiate extradition treaties regarding drug offenses with major drug producing nations.

"It's time to rethink old approaches and cautions and make it clearly understood that no issue has higher priority in our bilateral relations with narcotics source countries than the elimination of those narcotics," Chiles said.

Rep. Fascell stressed the need to use foreign aid as a lever to encourage foreign cooperation.

(See DRUG BILL, *page eight)*

IN THIS ISSUE

CONGRESS: Wants Strict Controls On U.S. Aid To Source Countries 1

DESIGNER DRUGS: They're Killing People But Police Are Handcuffed 2

INTERPOL: Targets Laundries 6

MARSHALS: Understaffed And Overwhelmed . . 7

DOJ: Will Drug Users Be Prosecuted? 9

REP. HUGHES: Leads Attack On Designer Drugs 9

ARREST/CONVICTION REPORT 10

NARCOTICS INVESTIGATION TRAINING

From May 1-2, the University of Delaware in Wilmington will conduct a seminar on "Drug and Narcotics Investigation: Perspectives on Approaches in the 1980s." Designed for Federal, state and local investigators, the seminar will cover: The current drug scene, establishing and staffing a drug/narcotics unit, supervising undercover officers, how to determine an overdose, PCP, use and debriefing of informants, surveillance, and planning and executing search warrants. The instructor is Det. Sgt. Steve Finkelberg of the Vice Unit, Metropolitan Police Department, Washington, D.C. Tuition is $275. For more information, please contact: Jacob Haber, University of Delaware, 2800 Pennsylvania Ave., Wilmington, DE 19806. Phone: 302-573-4440.

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Problem Spreading . . .

THE ANALOG GAME: DESIGNER DRUGS KILLING, CRIPPLING USERS

Rogue California Chemists Staying One Step Ahead Of The Law

By Robert J. Roberton
Chief, Division of Drug Programs
California Department Of Alcohol/Drug Programs

There is an ominous new phenomenon in the illicit drug market. While techniques and methods of control have been developed for many of the well-known street drugs, ranging from heroin to PCP, we now have the frightening specter of seeing the illicit drug market inundated with new synthetic street drugs which can be developed and manufactured faster than they can be identified and controlled. Before describing this further, let me outline the basis for this frightening new development which has been called the "designer drug" phenomenon.

The term "designer drugs" was originally coined in the laboratory of Dr. Gary Henderson at the University of California, Davis. It was originally meant to refer to the increasing sophistication of chemists in illicit laboratories who are now approaching the ability to produce drugs designed to fit the tastes of individual clients. While that is bad enough, this phenomenon has taken a truly pernicious turn as these drugs are now also being tailored to escape the law. Let me explain precisely how this is possible.

The government is required by law to specify the exact chemical structure and name of an individual compound which it wishes to control. There are a variety of reasons why this specificity is required. Because of the increasing sophistication of these "kitchen" chemists, they are now tailoring these drugs so that they are beyond the reach of the law. It is possible to do this by simply making a minor modification in the chemical structure of a controlled drug, such as adding a fluoride or an extra carbon molecule. The new drug, because the alteration is minor, may be expected to have similar psychoactive effects but, because it is no longer exactly the same chemical, it is no longer controlled. Hence, the chemist making this compound is beyond the reach of the law.

If a new drug becomes widely distributed enough, the Drug Enforcement Administration (DEA) may move to control the compound, but this, until recently, required one to two years. By that time, new variations may already be in circulation. In this way, individuals manufacturing these "designer drugs" can stay ahead of the law almost indefinitely.

Fentanyl

The fentanyls are a class of very potent narcotic-analgesics originally synthesized by the Janssen Pharmaceutical Company of Belgium. Although the chemical structures of these drugs are quite different from the opiates and opioids, the fentanyls, nevertheless, possess all the pharmacological and toxicological actions of the classical narcotics. Fentanyl, the parent drug, is used extensively in clinical medicine as an intravenous analgesic-anesthetic under the trade name Sublimaze. It is a well-respected drug.

Beginning in 1979, illicitly synthesized derivatives of fentanyl began appearing on the streets as drugs of abuse under the name "China White" – the name usually associated with very pure Southeast Asian heroin. Soon thereafter a series of deaths occurred in Southern California which looked like typical heroin overdose deaths – except that toxicological analysis failed to detect any narcotic. To date over 70 such deaths have occurred.

The laboratory at UC Davis, partially supported by the California State Department of Alcohol and Drug Programs, by using very sensitive analytical techniques specific for the fentanyls, has detected various fentanyl derivatives in the body fluids of the overdose victims. In addition, they have detected the fentanyls in the urine of a significant number of individuals enrolling in various methadone and other drug treatment programs throughout California.

To date they have identified five different fentanyl derivatives, in addition to fentanyl itself, in samples being sold illicitly under a variety of names such as "China White," "Synthetic Heroin" and "Fentanyl." The newest derivative, 3-methyl fentanyl, is extremely potent (approximately 3,000 times as potent as morphine) and is thought to be responsible for an alarming number of recent overdose deaths in the San Francisco Bay area.

Fentanyl Derivatives Used Medically

A brief description of the fentanyl derivatives used in human and veterinary medicine is given below:

- Fentanyl: Fentanyl was introduced into the United States in 1968 as an intravenous analgesic-anesthetic under

In summary, the fentanyls appear in all the various forms that heroin does and there is nothing characteristic about the appearance of any sample that will identify it as fentanyl.

Routes Of Administration

Intravenous injection is the most common route of administration for the fentanyls; however, they also may be smoked or snorted. In fact, because of their high lipid solubility, the fentanyls should be excellent drugs for snorting and may become increasingly popular drugs among cocaine users. At least one overdose fatality was identified in which snorting was the only route of administration. We have also been able to detect fentanyl in the urine of individuals who used the drug only by smoking it.

Pharmacological Effects

It should be remembered that although the fentanyls are chemically quite distinct from other narcotics (morphine, heroin, methadone, etc.), they are pharmacologically equivalent; that is, they have all the effects, side effects and toxic effects of the classical narcotic. Therefore, all the actions of the fentanyls can be reversed by naloxone (Narcan(R)), although higher doses of the antagonist may be required.

- Euphoria: The euphoria or "rush" from the fentanyls should be qualitatively similar to that of heroin and the intensity of the effect would depend upon the dose and the particular derivative used.

- Analgesia: Profound analgesia (absence of pain) is a characteristic effect of all the fentanyls. As little as 50 micrograms of fentanyl will produce analgesia while only three micrograms of the 3-methyl derivative would be required.

Side Effects And Toxicity

- Respiratory Depression: Respiratory depression is the most significant acute toxic effect of the fentanyls. The depth and duration of respiratory depression will depend on the dose and the derivative used. However, compared with other narcotics, this effect is relatively short-lived. For example, following 200 micrograms of fentanyl given intravenously, maximum depression occurs within 5-10 minutes, and normal respiration returns within 15-30 minutes.

- Antidote: Naloxone (Narcan(R)) is the antidote of choice for respiratory depression (or any other effect) produced by the fentanyls.

- Bradycardia: Fentanyl produces a dose-dependent decrease in heart rate of up to 25 percent, with a parallel drop in blood pressure of up to 20 percent. This effect is thought to be due to vagal stimulation and can be blocked by atrophine. The role of this response, if any, in overdose deaths is not known.

- Muscle Rigidity: Muscle rigidity, particularly in the chest wall -- sometimes called "wooden chest" -- is a response common to high doses of all narcotics. Individuals using the fentanyls may describe this effect as a muscle tightness or tingling.

- Addiction Liability: The fentanyls produce both tolerance and physiological dependence following repeated administration. Controlled studies have shown that addicts perceive fentanyl subjectives as having heroin-like effects. In California we have found many individuals enrolling in methadone treatment programs who have only fentanyl in their urine upon admission, yet are convinced they use only very high grade heroin. Therefore, when pharmacologically equivalent doses are used, most users probably cannot tell the difference between heroin and the fentanyls.

- Abuse Potential: Fentanyl as a pharmaceutical (Sublimaze(R)) was always thought to have a low abuse potential because of its short duration of action and its restricted availability. Also, Sublimaze(R) is available only in injectable, aqueous formulations containing either 100 micrograms or 500 micrograms per vial (50 microgram/milliliter). These relatively small amounts and low concentrations make it difficult for a tolerant addict to administer a euphoric dose conveniently.

Until now, the only documented illicit use of fentanyl was in "doping" race horses. Narcotics are frequently used to dope horses because they produce excitation in the horse (and other animals such as the cat and mouse). Fentanyl's short duration of action and its very low, difficult to detect, concentrations in blood and urine make it an ideal doping agent. Fentanyl has been used in this manner for nearly a decade.

Now the fentanyls are available throughout most of California and, because they are potent, not detected by routine analytical methods, and, in the case of the newer analogs, quite legal, they may become the drug of choice for many heroin users. It is our opinion that fentanyl use will increase in California, its use will spread to other states, and that new derivatives will appear periodically.

- Overdose Deaths: To date the laboratory has identified 77 overdose deaths caused by the fentanyls. Nearly all of these cases occurred in California; however, two recent deaths occurred in Oregon, which suggests that fentanyl use may be spreading to other states. All cases were similar in that they involved known heroin users, injection sites and accompanying paraphernalia were found, and autopsy showed typical signs of narcotic

overdose, such as pulmonary edema and congestion. Routine toxicological analysis of the body fluids revealed no narcotics, sedative or stimulant drugs present; however, analysis of these fluids in the laboratory using methods specific for the fentanyls revealed very low levels of these drugs. Traces of the fentanyls were also found in the accompanying paraphernalia.

Fentanyl-related deaths have occurred in nearly every urban area in California, in suburban areas, and even in semi-rural areas. Ages of the victims ranged from 20-49 years. Most were male, although nine were female. Most of the victims were white; but there were significant numbers of Hispanics and blacks. In short, fentanyl use is not confined to any geographical area or any social, economic or ethnic group, but is distributed widely throughout the heroin-using population.

• Analysis of Samples for China White: The fentanyls are very difficult to detect either in body fluids or paraphernalia because the amounts present are very small and because they do not react with the reagents routinely used for the analysis of narcotics.

What Are The Hazards?

Why do they represent such a hazard and public health problem? There are several clear-cut reasons. First, these drugs do not require importation and all the costs and expenses thereby incurred. Second, they are much less expensive to make. Third, of course, those making and selling them cannot be prosecuted because they are not illegal.

Let me give some examples. It is estimated that a single chemist working an eight hour day could, using the more potent fentanyl derivatives, supply the entire nation's heroin supply on an ongoing basis. A single six-month supply for the U.S. could be stored in a closet. Hence, one can see the immense attractiveness of this approach in terms of cost and liability to those on the production side of the illicit drug market.

What are the hazards? There are basically three. First, these chemists are obviously not required to carry out safety trials with these new compounds as a legitimate drug company would be. Hence, the first subjects to receive them are not laboratory animals, but human beings using these compounds on the street.

Second, there are no quality controls in these laboratories as there would be in a legitimate drug company. Hence, contaminants or unwanted compounds are not removed, and probably often not even detected.

Third, there is the issue of potency. The fentanyl variants, for instance, must be cut in microgram amounts. To give an example of how small an amount this is, a postage stamp weighs about 60,000 micrograms. Hence, overdoses are common, and the fentanyl series has been held responsible for at least 77 deaths in California so far.

In essence, young drug users who take these new synthetics are playing a form of Russian roulette. Only it is not lead bullets that they are aiming at their brains, but chemical ones.

Given this scenario, one would predict it was only a matter of time before a true poison "hits the streets." This is precisely what happened in Northern California in 1982, when a highly toxic compound known as MPTP was circulated. This compound is neurotoxic to a group of cells in the brain known as the substantia nigra. By pure coincidence, this happens to be the same area that is damaged in Parkinson's disease. We saw a group of young adults two years ago come to the Santa Clara Valley Medical Center who resembled in every way elderly patients with end-stage Parkinson's disease. These young addicts had literally frozen up overnight, and were totally unable to move or talk.

Treatment with anti-Parkinsonian therapy was probably life-saving in three; however, these patients continue to be severely disabled and require medication every one to three hours just to be able to move and eat or drink. Two of them have recently undergone prolonged hospitalizations, and the outlook for their futures must be considered grim indeed.

While there are currently only 20 severely involved young adults who have been permanently crippled by this first "designer drug disaster," we have now identified an additional 500 people who were exposed to MPTP thinking it was a new "synthetic heroin." My estimate is that we have just been scratching the surface so far, and that there are at least one to two hundred more.

Why are these additional individuals important? Because we now have evidence that damage to this area of the brain, even if it is not enough to cause symptoms at first, may act like a time bomb, with changes in the brain slowly ticking away. In other words, sooner or later, these young adults could come down with a Parkinson's disease-like state. Up until now, this concern was just theoretical, but in the last several months, we have started seeing a group of young people at Santa Clara Valley Medical Center who used MPTP two years ago who are now starting to develop a myriad of symptoms, all suggestive of early Parkinson's disease. In short, what we may be facing is an epidemic of Parkinson's disease in young adults in Northern California as a result of this catastrophe. The cost to society, not to mention the human suffering, could be immense.

I bring this entire phenomenon to your attention for a number of reasons. First, I see it as a tremendous potential

scheduled to meet again this spring to draft a model of their proposed legislation for consideration by INTERPOL member countries.

The coordination and cooperative interaction which epitomize the INTERPOL concept are reflected in the makeup of the U.S. delegation to St. Lucia, which consisted of representatives from DEA, FBI, IRS, Customs, Comptroller of the Currency, Postal Inspection Service, and the INTERPOL-USNCB.

The idea of tracing financial assets as a means of identifying high echelon leaders and financiers of narcotics traffickers and other organized criminal groups led to the formation of a new unit at INTERPOL headquarters in Paris. This unit is known as FOPAC.

Editor's Note: For further information, contact: Martin J. White, Assistant Chief, Financial Crimes Unit, INTERPOL-U S National Central Bureau, U.S. Department of Justice, Washington, DC 20530. Phone: 202-272-8383. ■

U.S. MARSHALS SERVICE OFFICERS OVERSTRESSED AS THREATS AGAINST JUDGES ESCALATE

"Service Is Barely Treading Water"

Threats against Federal judges have risen sharply as the government cracks down on terrorists, mobsters and drug runners, the top U.S. Marshal said on March 19, warning that many of his deputies are "on the brink of burnout.

"Threats against the courts, judges, and others have increased alarmingly in recent years," Stanley Morris, director of the U.S. Marshals Service, told a House Judiciary Subcommittee.

Threats against judges alone "have skyrocketed 218 percent" over the past four years, he said.

The Marshals Service has responded "by developing not just sophisticated countermeasures, alarms and armored vehicles, but also by establishing advanced training for deputy marshals in protective services," Morris said.

Working with court security officers, the service now provides perimeter security in 235 major courthouses across the country, he said.

"Despite these countermeasures, threats against judges rise as trials of terrorists, organized crime figures, Colombians and other drug traffickers become more common," Morris said in his prepared testimony.

"Bombs have been found in courthouses. Our offices have taken rocket attacks, and no day has passed since I became director in which some judge has not been under 24-hour-a-day protection."

Deputies About To Burn Out

Morris said the creation of 85 new Federal judgeships by Congress last year greatly increased the Marshals' responsibilities and "has the potential to overwhelm the capabilities" of the service.

"At the close of fiscal year 1984, the service was barely treading water, and many of its deputies were on the brink of burnout," Morris reported.

The Marshals Service is responsible for providing security at 400 court locations, transporting prisoners, tracking down fugitives, retrieving extradited criminals from other countries, protecting witnesses, and managing seized assets.

The Witness Protection Program has come in for criticism in recent years, but Morris said the program now is "one of the most professionally managed" in the government.

There are 4,620 witnesses, both active and inactive, in the program, Morris said. "This, combined with 11,000 family members and the addition of 300-350 new witnesses each year, will continue to challenge the talent and resource of the service," he said.

Morris told the Subcommittee he is proposing legislation overhauling the Marshals Service to enable it to better meet its responsibilities, but the proposal has not yet been cleared by the Justice Department. ■

1. Prohibits U.S. cash payments to reimburse farmers whose drug crops have been eradicated.

2. Permits narcotics control funds to be used to defensively arm host country aircraft used in drug eradication and interdiction.

3. Repeals the current prohibition on U.S. officials being present at drug raids overseas (when the U.S. Ambassador and the host country agree).

4. Requires U.S. agencies to share information to ensure that drug traffickers don't get visas to enter the United States; the State Department must report to the Congress on what steps have been taken.

- Domestic Provisions

1. Imposes a mandatory life sentence for "drug kingpins" (major drug traffickers who run drug rings of at least five people and make substantial amounts of money from drugs).

2. Raises both criminal and civil penalties on banks which facilitate money laundering (civil: raises penalty from $10,000 to $100,000 fine per violation; criminal: raises penalty from $500,000 to 50 percent of the dollar amount of the transactions involved). ■

DOJ CONSIDERING GOING AFTER INDIVIDUAL DRUG USERS

The Federal Government is considering prosecuting and jailing individual drug users because they are part of a "conspiracy chain" that promulgates drug abuse, a Justice Department official says.

Charles Blau, who heads the Organized Crime/Drug Enforcement Task Force (OCDETF) said on April 1 that prosecutions of small-time users of marijuana and other drugs would be aimed at controlling the demand for drugs by sending a message to other users.

Blau said statistics show a large number of major drug distributors were successfully prosecuted in 1984 but large amounts of drugs continued to be produced, imported and sold.

"The other side of this equation basically is the demand side," said Blau. "People are out there using these drugs and we have not broken that curve.

"A person who utilizes a controlled substance which is illegal is as much a part of the conspiracy chain as the person who distributes it," he added.

Until now, the Drug Enforcement Administration and other agencies have concentrated on eliminating major drug networks and their leaders.

Last month the Customs Service, which is part of the Treasury Department, announced it would begin making public the names of people caught smuggling small amounts of drugs for personal use. Blau said that decision is not related to the Justice Department's decision.

Attorney General Edwin Meese will meet April 15-16 in El Paso with 13 Task Force coordinators to "talk about basically where we ought to be going in the next four years within this program and how well we're doing. And that's (going after small users) obviously one of the issues that's going to come up," Blau said.

Meese said March 20 that "there is no such thing as a harmless recreational drug" and that he wants "the individual drug user(s) . . . to understand the moral responsibility that they bear."

Blau said such prosecution would be highly selective.

The news conference was called to announce that the drug program has resulted in 1,152 indictments against 4,624 defendants. ■

GOVERNMENT USES HUGHES ACT TO ATTACK DESIGNER DRUGS

House Crime Subcommittee Chairman Bill Hughes (D-N.J.) on March 28 said that the Drug Enforcement Administration was banning the "designer drug," 3-methyl fentanyl. This drug, sold on the street as "China White," or synthetic heroin, has been responsible for 26 deaths since Aug. 1, 1984.

This is the first use of the emergency scheduling powers authored by Hughes to allow the DEA to temporarily ban dangerous new drugs developed by underground chemists (see related

MDMA: Common Questions

By Alexander T. Shulgin

MDMA has been thrust upon the public awareness as a largely unknown drug which to some is a medical miracle and to others a social devil. Many questions have been asked. It is sad that most of these questions have received answers which have been quite contrdictory, and often untrue. I have had innumerable calls from reporters and magazine staff writers, most of whom have bemoaned the fact that they always seem to encounter one of the two extreme positions. There have been the born-again protagonists who say that once you have tried it you will see the light and will defend it against any attack, and there have been the staunch antagonists who say that this is nothing but LSD revisited and it will certainly destroy our youth.

There are many voices to be heard presenting the modest inventory of facts that are known, but there is no one who will answer questions in a way that can be heard by both camps. Let me distill several reporter interactions into a hypothetical interview which parallels the many telephone inquiries I have had to field in the last few months. The questions are typical. Some questions call for opinions, but many have factual answers which are documented.

What is MDMA?

MDMA is the abbreviation given to a chemical with the full name 3,4-methylenedioxymethamphetamine. It has also been called in recent literature N-methyl-2-(3,4-methylenedioxyphenyl)-isopropylamine and 2-methylamino-1-(3,4-methylenedioxyphenyl)-propane. In Beilstein it is called methyl-¿beta-(3,4-methylenedioxyphenyl)-isopropyl¡-amine; in the early Chemical Abstracts it is called N,alpha-dimethyl-homopiperonylamine, in the pre-1972 Chemical Abstracts it is known as N,alpha-dimethyl-3,4-methylenedioxyphenethylamine; and in the most recent Chemical Abstracts it is N,alpha-dimethyl-1,3-benzodioxole-5-ethaneamine. Although it has many names, to a chemist there is a single chemical structure represented.

What is Ecstasy (or MDM, or Adam, or XTC, or E, or Doctor)?

These are names of street drugs, which have proven to be on many occasions the same as the MDMA as described above. There have been some misrepresentations.

Is MDMA related to MDA?

Yes, it is very closely related to MDA. MDA is the abbreviation for 3,4-methylenedioxyamphetamine, currently listed as a Schedule I drug, under the classification of "hallucinogenic substances." But this is a structural relationship, not a pharmacological relationship. A structural relationship invokes slight rearrangements of atomic features.

MDMA is related to MDA (a hallucinogen) by being its N-methyl analog. It is similarly related to N-methyl-3,4-methylenedioxy-phenethylamine (an antitussive) by being its alpha-methyl homolog. It is similarly related to methamphetamine (a stimulant) by being its 3,4-methylenedioxy-analog. However, pharmacologically, it bears little resemblance to any of these drugs.

Is MDMA a psychedelic drug?

Not in the sense of the popular definition of psychedelic drugs, where one makes immediate associations with drugs such s mescaline or LSD. There is neither the visual distortion nor the interpretive problems that have been reported with most psychedelic drugs.

How is MDMA made?

There are published procedures for its production. The earliest literature describes the use of safrole as an intermediate (1,2). More recently published procedures have employed piperronylacetone as a starting material (3,4). The optical isomers have been prepared by the reduction of the amides prepared by forumlation of the enantiomers of MDA (5). In one analytical report, MDMA was prepared (with byproduct impurities) from MDA by reaction with methyliodide (6).

Where can one get MDMA?

It appears to be readily available on the street. But most of the psychiatrists who have reported on its clinical utility have prepared it themselves, a procedure which in many states meets the legal requirements for drug manufacture. MDMA has recently been offered to researchers by NIDA (National Institute on Drug Abuse), Rockville, MD.

Is MDMA toxic?

There are two interpretations of the word "toxic." In the strict medical sense, toxic means "Is the drug poisonous; i.e., is it lethal?" In the popular language, toxic means "Does the drug have poisonous effects;

i.e., are there unwanted side-effects?"

In answer to the first meaning, yes, MDMA is toxic, as is every chemical known if sufficiently high levels are administered. In an extensive toxicity study (7) the lethality of MDMA was compared with seven other related phenethylamines (including MDA and mescaline) in five animal species. The comparative toxicity is given below for these three compounds, as their LD-50 values in mg/Kg:

	MDMA	MDA	Mescaline
Mouse	97	68	212
Rat	49	27	132
Guinea Pig	98	28	328
Dog	14	7	54
Monkey	22	6	130

The toxcity thus lies as less than that for MDA, and more than that for mescaline.

A second study of toxicity in isolated and aggregated mice (8) has reported the LD-50(i.p.) to be 106 mg/Kg (and 30 mg/Kg in aggregated colonies). The LD-50s for MDA were given (again in mice, i.p.) as 90 mg/Kg and 45 mg/Kg (aggregate). These values are good agreement with the reference (7) data above. A typical human dosage of MDMA (120 mg) is about 1.5 mg/Kg.

As to the second meaning of toxicity (toxic side effects), there are some side-effects that have been frequently reported. See the "side-effects" question below.

Have there been deaths ascribed to the use of MDMA?

Yes. There have been three deaths ascribed to the use of MDMA, but the role that MDMA might have played, or whether MDMA was even involved, is uncertain. Two DAWN reports imply association, one in San Francisco, and one in Seattle. The San Francisco report was mis-entered in the DAWN network, and has been verified as a death involving MDA and alcohol (9). The Seattle report contained evidence that the material present was similar to, but not the same as, MDA. It was assumed to be MDMA, but not verified as such. I have not been able to get any information on the third alleged death.

Is it true that the effective level is close to the toxic level?

As the toxic level in man is not known, this closeness cannot be determined. The term "therapeutic index" has been used as a measure of comparative safety; i.e., how far apart are the effective levels and the lethal levels? The toxicity in mammals following parenteral administration lies between 14 and 100 mg/Kg. Oral toxicity has never been reported. The orally effective dosage in man is about 1.5 mg/Kg so the effective safety factor is greater than ten-fold.

What does MDMA do in animals?

There have been two *in vivo* studies of MDMA in animals. The earlier of these was the toxicology study by Hardman *et al.*(7) wherein several behavioral studies were reported in several animal species. Comparisons of MDMA with seven other structurally-related phenethylamines, in the areas of motor activity, autonomic activity, and CNS activity, showed that it was, in general, similar to the other related compounds. Behavioral effects were observed at levels that approached the toxic levels. No particular effect deserved special mention in the discussion section of this paper.

The latter study (10) has reported both stimulant and analgesic effects of MDMA, in comparison to MDA and several higher homologs and analogs. It proved to be among the most potent of all compounds studied. No extrapolation to human psychotropic response was made.

What does MDMA do in man?

It provides, at least within a therapeutic setting, a brief period of openness and freedom from fear and defensiveness that allows a trust to be established between a therapist and a patient. There is no amnesia and no loss of control. An excellent summing-up can be found in a quote from a recent report by an admitted proponent (11).

"The drug takes away all your neuroses. It takes away the fear response. There is an overwhelming feeling of peace; you're at peace with the world. You feel open, clear, loving. . . can't imagine anyone being angry under its influence, or feeling selfish or mean, or even defensive. You have a lot of insights into yourself, *real* insights, that stay with you after the experience is over. It doesn't give you anything that isn't already there. It's not a trip. You don't lose touch with the world. You could pick up the phone, call your mother, and she'd never know."

Two clinical studies have been reported that emphasize the qualitative aspects of MDMA therapy. A pilot study by Kueny on nine subjects (12) and another by Greer on 29 subjects (13) have both shown therapeutic value.

What is the chronology of effects of MDMA in man?

The usual dosages of MDMA employed in clinical work lie between 100 mg and 150 mg of the amine as the hydrochloride salt. A typical dose would be 120 mg. The onset of transition occurs between 25 and 30 minutes following oral administration. The changes stabilize at or just before the one-hour point and the plateau of effects persists for about 40 additional minutes. If desired, the plateau can be extended for an additional hour with the use of a supplementary 40-50 mg at the 1:30 point of the session. Recovery to the presession baseline psychologically generally requires an additional three hours. The complete dispelling of physical residue (anorexia, for example) may take additional hours.

Can MDMA be abused?

Certainly. When it is used therapeutically, the medical environment precludes much of the abuse potential, but with indiscriminate availability on the "street" it can, and will, be overused and will inevitably be associated with abuse situations.

A related question (of a more legal kind) is, does MDMA have a *high* abuse potential. This is, of course, the crux of the proposed scheduling of MDMA as a high-abuse-potential drug without medical utility. The FDA has explicitly stated that the use of any drug not approved by them constitutes drug abuse. Their implicit stand is that any drug that can be pleasurable has a high abuse potential. The questions posed here lie outside of the pharmacologist's territory.

How would you classify MDMA clinically?

There is no existing clinical classification for MDMA. The research currently exploring the use of

MDMA in psychotherapy more closely resembles a medical procedure such as hypnosis or acupuncture. There is no therapeutics classification for this drug, although efforts have been made to define one (14). The existing classification of "anti-depressant" could be justified, remembering that the effects are relatively abrupt following a single application, rather than being gradual following chronic medication.

Is MDMA illegal?

At the moment, no. (**Editor's note: Dr. Shulgin prepared this article before the DEA's emergency scheduling became effective. As of July 1, MDMA is a Schedule I drug and its possession is potentially a felony).** It was proposed for scheduling in the Controlled Substances Act by notice in the Federal Register in 1984 (15). However, there were several petitions filed requesting hearings to determine the appropriate schedule for listing, and this process was agreed to by the DEA (16). A program for hearings across the country was agreed upon, and arguments and rebuttals were filed. This judicial process was aborted by an evocation of the Emergency Act (S-5656) and May 31, 1985 (17), which proclaimed MDMA as being an "imminent hazard to public safety," thus demanding that it be immediately scheduled as a Schedule I drug, such action to be effective in 30 days.

What will be the eventual fate of MDMA?

This is conjecture into untested legal area. The emergency scheduling will place MDMA into Schedule I for a full year, with an allowed six-month extension. Many states automatically parrot the federal drug laws in the rewriting of their own statutes, and it must be assumed that several states will ammend their narcotics laws to include MDMA as a Schedule I drug. Action in this direction has already been initiated in Texas. Although hearings must be allowed at the end of a year (federal law), the current hearings will have been concluded by then, and some decision will have been made regarding a more modest scheduling. However, there are no legal precedents at hand that permit the re-evaluation of state law to reflect reconsiderations of federal assignment. It must be assumed that MDMA will remain a Schedule I drug in many states regardless of any modification of federal stand.

How does MDMA act?

The current consensus is that MDMA acts through some effect on the serotoninergic nervous system. A number of animal models have been studied to both explain its mechanism of action, and to compare it to structurally-related analogs. A major focus in all of these studies has been the fact that the optically active isomer of all the psychedelic drugs (LSD, MDA, DOM, DOET, and DOB) is the "R" (or levo) isomer, and the optically active isomer of MDMA (and several stimulants such as amphetamine) is the "S" (or dextro) isomer (5). This isomeric difference between MDMA and MDA hs been shown to be true in the release of serotonin from rat-brain synaptosomes (18). In rat discrimination studies (train a rat to respond differently to drug A or no drug, and then challenge with drug B). In rats trained to distinguish DOM from saline, MDMA did not look like DOM (19). However, in rats trained to distinguish MDA from saline, or dextroamphetamne from saline, MDMA in both cases was distinguished from saline (20).

Can MDMA cause brain damage?

The answer is not known. No one has reported any study that addresses this question. One of the major arguments presented supporting the emergency scheduling of MDMA as an imminent hazard (17) was an unpublished study (by Ricaurte et al., ref. 21) on MDA in rats. Here the exposure of rats, acutely, to MDA led to the observation of degeneration of nerve terminals (possibly serotoninergic) in the hippocampus and the striatum. No dopaminergic problems were observed, although these were reported earlier (22) for amphetamine and methamphetamine. From these observations, it has been extrapolated that MDMA (a different drug than MDA or amphetamine) is likely to cause brain damage in man (a different species than rat).

Are there other drugs with actions similar to MDMA?

None are known at the present time. Several drugs are being studied that have some properties in common, but often there is either the absence of the benign "freedom from fear" property, or the presence of some disturbing "psychedelic" side-effects. As of the moment, MDMA remains unique.

What are the side-effects of MDMA?

A number of side-effects have been reported with some regularity as a corollary to MDMA usage. In an extensive clinical study involving some score subjects (23) there was a consistent pressor response resulting in a blood pressure increase of some 15 or so mm/Hg observed at the onset of action, although this disappeared shortly thereafter. There were some complaints of bruxism (teeth clenching) and nystagmus (eye twitching). Some subjects reported a lethargy and headache the following day. These were held by most subjects as being minor problems.

How can one tell if one has valid MDMA?

The record of analytical sophistication relating to the verification of a sample as being MDMA has not been good. Tools such as gas chromatography (GC) or gas chromatography/mass spectrometry (GCMS), and infra-red are excellent, but they have been rarely employed. The earliest report of analysis of seized material (24) showed color tests and U.V. to be inadequate, but reported that infra-red spectroscopy and GC retention times to be satisfactory for identification. TLC properties suggest that MDA can be effectively distinguished from MDMA (6). Some mis-identifications have been reported, both as to compound nomenclature (MDMA vs. MMDA, ref. 25) and as to precursor identification (piperonylacetone vs. piperonylmethyl ketone, ref. 26).

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Dr. Alexander Shulgin is a chemist and pharmacologist who has been active in research in the area of psychotropic drugs for many years. This paper was presented at the summer meeting of the California Association of Toxicologists in Sacramento, CA, Aug. 3, 1985.

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Calendar No. 431

99TH CONGRESS *1st Session*	SENATE	REPORT 99-196

"CONTROLLED SUBSTANCE ANALOGS" ENFORCEMENT ACT OF 1985

REPORT

OF THE

COMMITTEE ON THE JUDICIARY UNITED STATES SENATE

ON

S. 1437

NOVEMBER 21 (legislative day, NOVEMBER 18), 1985.—Ordered to be printed

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CONTENTS

	Page
I. Background and need for legislation	1
II. Section-by-section analysis	4
III. Committee action	6
IV. Regulatory impact statement	7
V. Cost of legislation	7
VI. Changes in existing law	8

Calendar No. 431

99TH CONGRESS
1st Session

SENATE

REPORT
99-196

"CONTROLLED SUBSTANCE ANALOGS" ENFORCEMENT ACT OF 1985

NOVEMBER 21 (legislative day, NOVEMBER 18), 1985.—Ordered to be printed

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

REPORT

[To accompany S. 1437]

The Committee on the Judiciary, to which was referred the bill (S. 1437) to create new penalties for the manufacture, distribution, and possession of controlled substance analogs intended for human consumption, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and an amendment to the title and recommends that the bill as amended do pass.

I. BACKGROUND AND NEED FOR LEGISLATION

A new epidemic of drugs varying in but slight degree from the most dangerous compounds currently proscribed by the Controlled Substances Act has demonstrated that the Act as presently structured is not alone sufficient to regulate the flow of illicit drugs. S. 1437, the Controlled Substance Analogs Enforcement Act, is necessary to close the loopholes that enable underground chemists to evade our Nation's drug laws.

Confined by Federal drug legislation that ties unlawful conduct to precise chemical definitions, law enforcement authorities have long found themselves at least one step behind drug dealers who possess certain rudimentary scientific abilities. Thus in the 1960's, certain mescaline derivatives created great problems until controlled under the Drug Abuse Control Amendments and their successor legislation, the Controlled Substances Act (CSA). In the 1970's, various analogs of PCP and methaqualone flourished until eventually brought within the exact definitions of the Act. Again

in the 1980's the drug laws have been circumvented by profiteers capable of making minor alterations in the molecular structure of a controlled substance. Recent analogs have been based largely on the substances meperidine and fentanyl, from which models an almost infinite number of imitations can be derived. For example, the American Chemical Society notes:

> Fentanyl is not a simple molecule, and it turns out that a vast number of relatively minor modifications of its molecular structure result in compounds that also act as potent narcotics—in some cases, many times as potent as fentanyl. Tinker with a side chain here, add a halogen there, and the result is still probably a chemical that packs a powerful wallop, a chemical that can be sold on the street as heroin, and a chemical that might very well be as legal as sugar. ["Controlled Substance Analogs Enforcement Act," hearings before the Committee on the Judiciary, U.S. Senate, 99th Congress, 1st sess. (1985)].

The Comprehensive Crime Control Act of 1984 partially corrected the structural deficiencies of the Controlled Substances Act. Section 508 of the 1984 measure [21 U.S.C. 811(h)] gives the Attorney General authority to list a substance temporarily under schedule I of the CSA if he finds such action necessary to avoid imminent hazard to the public safety. These emergency scheduling procedures were used for the first time when the fentanyl analog 3-methylfentanyl was temporarily listed in schedule I effective April 25, 1985. Methamphetamine and MDA analog MDMA was similarly scheduled on July 1 of this year; meperidine analogs MPPP and PEPAP were so scheduled effective August 12, 1985.

The emergency scheduling procedure, however, is entirely reactive and can only operate after a controlled substance analog has already been shown to pose a severe risk to the public health. The legal and scientific analysis required to pinpoint first the existence, composition, and circulation of a substance, and then to document its devastating effect, takes time (and, indeed, the emergency scheduling procedures themselves contain an automatic 30-day lag period). Until that usually lengthy process has been completed and the substance is formally proscribed, traffickers in the drug are immune to the penalties of the Controlled Substances Act. Even after the substance has finally been scheduled, of course, another minor alteration in its structure begins the entire process afresh.

The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301, et seq.] is also inadequate to combat the analog problem. 21 U.S.C. 355(a) makes it unlawful to introduce a "new drug" into interstate commerce until certain conditions have been met; this statute, however, is not aimed primarily at the distribution of illicit, addictive drugs patterned after schedule I or schedule II compounds, and therefore carries penalties much lighter than those imposed by the Controlled Substances Act. Concerned more with proper testing and labeling of drugs having arguably beneficial effects than with drugs sold solely for illicit purposes, the Food, Drug, and Cosmetic Act is also inapplicable to the analog problem in that the Food and Drug Administration is not properly equipped to investigate or pursue analog traffickers.

The Senate has studied the nature and scope of the analog problem over the course of three extensive hearings conducted this year. On July 18, 1985, Senator Chiles presided over a hearing of the Committee on the Budget in which the problem was described by scientists, victimized families, and State law enforcement officials. [S. Hrg. 99-124.] As Senator Chiles testified before this Committee, the Budget panel "heard story after story about how these basement chemists could and did stay one step ahead of the law in California; how they could produce a deadly chemical for up to 2 years before the California legislature had the time to declare that *specific* chemical combination illegal." That first hearing convinced him, Senator Chiles continued, that the analog threat could present a "public health disaster" in that a back alley chemist "can spend $2,000 on equipment and chemicals and turn two weeks of time into 200 million doses of drugs (with a), potential street value $70 billion."

The findings of the Budget Committee were reinforced and augmented by a July 25, 1985, hearing of the Subcommittee on Children, Family, Drugs and Alcoholism, of the Committee on Labor and Human Resources, chaired by Senator Paula Hawkins. Mrs. Hawkins' subcommittee heard from State and Federal authorities as well as from an independent scientist and two young drug users. The testimony was unequivocal: as Mrs. Hawkins told this Committee, controlled substance analogs (which she branded "high-tech killers") "bring about the same high, the same addiction and the same net death as natural narcotics, but with much greater potency."

Senate testimony has been unanimous in labeling the controlled substance analog problem a growing danger that demands immediate action. Dr. Patrick Hanna, speaking on behalf of the American Chemical Society, summarized to the Committee why the analogs are neither expensive nor difficult to produce (and why, therefore, they present such an urgent threat):

Equipment cost is low;

Equipment and starting chemicals are readily available;

"Recipes" are in published scientific literature;

Training and scientific knowledge of the producer need not be that of a highly trained scientist/technician; and

Quantities produced from a single synthesis are sufficient to last a lifetime.

The problem is heightened because current law provides such a powerful incentive for profiteers to experiment with conventional chemical structures. Seeking to produce narcotics that do not fall within the exact definitions of the CSA schedules, marginal chemists may manufacture novel compounds of unknown pharmacological properties. The resulting products, whether marketed as counterfeits of the drugs they imitate or as new "synthetic drugs," can have unintended effects: witness the 1982 outbreak of Parkinson's disease in California users of the analogs.

In short, the Committee finds that controlled substance analogs present a clear and present danger to our society. Strong measures are needed to attack this problem.

II. Section-by-Section Analysis

Section 1 designates the statute the "Controlled Substance Analogs Enforcement Act of 1985."

Section 2 amends the Controlled Substances Act by creating new felony and misdemeanor offenses in the controlled substances analog realm. This section makes it a crime punishable by imprisonment for 15 years and a $250,000 fine knowingly or intentionally to manufacture or possess with the intent to distribute, or actually to distribute a controlled substance analog intended for human consumption. Simple possession of a controlled substance analog intended for human consumption, if knowing or intentional, is made a misdemeanor offense punishable by up to 1 year imprisonment and a $25,000 fine. These penalties are consistent with those already enacted for similar offenses involving drugs presently listed in schedules I or II of the Controlled Substances Act.

Several specific intent elements are built into the offenses to ensure that legitimate or unintended actions are not punished. First, to be found guilty, an offender's manufacture, distribution, or possession of an illicit substance must have been knowing or intentional; that is, the offender must have known or intended that he was manufacturing, distributing, or possessing a substance that he knew or intended to have the characteristics of a controlled substance analog as defined in section 3 of this legislation. The Committee contemplates, however, that it will not be a defense to this Act that an offender believed a controlled substance analog actually to be a schedule I or II controlled substance itself.

Further, no felony is committed unless it is the offender's intent to distribute a controlled substance analog to one or more other people, or unless he has already actually distributed the substance. Then, too, for an offense to occur, all or part of the substance involved must have been intended for human consumption. This intent requirement was adopted specifically to protect legitimate scientific research. It ensures, for example, that chemists whose laboratory activity is directed solely toward producing industrial chemicals will not be affected by the Act. The phrase "all or part of which substance is intended for human consumption" makes clear that at least part of the *specific batch* of chemicals involved must have been intended for human consumption. Thus, the legitimate researcher who handles controlled substance analogs while conducting early-stage experiments for a project the ultimate end of which may be to produce an approved drug for human consumption is also unaffected by the Act, so long as he does not intend the specific chemicals on hand to be for human consumption.

Section 2 creates a further protection for legitimate research by exempting actions taken in conformance with the provisions of an approved new drug application or an exemption for investigational use within the meaning of section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355]. While the Federal Food, Drug, and Cosmetic Act applies to interstate commerce, the exemptions created here may be obtained even if the project is intended to remain entirely intrastate. Exemptions for investigational use are presently granted routinely to legitimate scientists in the pharmaceutical industry to make use of controlled substances in the course

of their legitimate research. These exemptions would now be expanded to cover legitimate research using analogs of controlled substances as well as research involving controlled substances themselves. This exemption, once obtained, is meant to be as broad as the offense itself. In the opinion of the American Chemical Society, "this language protects legitimate research and development of new pharmaceuticals."

Section 3 provides a two-pronged definition for the term "controlled substance analog." A chemical compound is a controlled substance analog either if it has a chemical structure "substantially similar" to that of any controlled substance listed in schedules I or II under the Controlled Substances Act, or if it was "specifically designed" to produce an effect "substantially similar" to that produced by any controlled substance defined in schedules I or II.

By encompassing entire classes of drugs rather than listing discrete substances to be controlled, this definition discourages attempts to skirt the law through molecular tinkering. While the Committee realizes that this definition is, of necessity, general, the Committee is also convinced that it adequately describes the sorts of drugs that the legislation seeks to bring under control. It would be impossible to list by their specific chemical structures all potential analogs that unscrupulous chemists might produce. As Senator Biden noted during the Committee's consideration of the bill, "dangerous chemists can create new variations faster than health and enforcement officials can identify and control" those analogs.

The Department of Justice was entirely accurate in summarizing the purpose of this legislation as being "to prohibit persons who specifically set out to manufacture or to distribute drugs which are substantially similar to the most dangerous controlled substances from engaging in this activity." The first prong of the controlled substance analog definition is therefore aimed at those who would traffic in drugs the chemical structure of which is modeled upon that of heroin, cocaine, or other schedule I or II drugs.

All controlled substance analogs of which the Committee is presently aware meet this first, alternative, test. In determining whether a substance does have a chemical structure "substantially similar" to that of a schedule I or II controlled substance, the trier of fact will presumably consider the testimony of expert chemists who have performed laboratory analyses of the drug's molecular makeup. The Committee concurs with the appraisal of the American Chemical Society that the term "substantially similar" chemical structure is meaningful to scientists and capable of reasoned interpretation by the trier of fact. If a drug has been patterned after a controlled substance, its strong chemical similarities to the parent substance can be demonstrated.

Under the second definitional prong, a compound is a "controlled substance analog" if it was "specifically designed to produce an effect substantially similar" to that produced by any schedule I or II controlled substance. This test therefore hinges upon the intent with which the drug was manufactured, although the effect that the substance actually produces may well be relevant in evaluating that intent. The Committee intends that this intent standard, when coupled with the requirement that the effect intended be "substantially" similar to that of a dangerous scheduled substance, exclude

alcohol, tobacco, caffeine and other legitimate consumer products from the controlled substance analog category. Not only do these products operate on the body through different biochemical mechanisms than do schedule I or II drugs, but they are also not specifically designed to produce that degree of effect induced by such scheduled drugs.

As the Department of Justice notes:

> [t]he effect prong of the definition will be most useful [to the prosecution] in situations in which the defendant makes statements to third parties or to law enforcement officials of his or her intent regarding the drug and the effects it has been designed to produce.

Other evidence as to a drug's intended effect might include eyewitness accounts of the reactions experienced by prior users of the drug, or pharmacological evidence relating to the drug's expected abuse potential or the psychological or physiological dependence it is capable of producing.

The definition of "controlled substance analog" contained in this section, therefore, closes the present loopholes in the Controlled Substances Act while still specifying a comprehensible standard of conduct. A substance fitting either of the two prongs of the controlled substance analog definition qualifies as such an analog. The legislation's message to illicit drug traffickers is clear: no longer will you remain immune from punishment when purposefully dealing in drugs that imitate the most dangerous compounds defined by law. When such chemical copies are intended for human consumption and do not fall under the exceptions set out in section 2 of the legislation, simulation is no defense.

Section 3 also specifies that the term "human consumption" is meant broadly and include consumption by application, injection, inhalation, or ingestion.

III. Committee Action

The Senate Committee on the Judiciary conducted a hearing on S. 1437 on September 18, 1985. The Committee heard from Senators Hawkins and Chiles, who described previous Senate study of the controlled substance analog problem. Also testifying were: Stephen S. Trott, Assistant Attorney General, Criminal Division, United States Department of Justice; Gene Haislip, Deputy Assistant Administrator, Drug Enforcement Administration; Ellis K. Fields, President, American Chemical Society; and Patrick E. Hanna, Professor, Medicinal Chemistry and Pharmacology, University of Minnesota.

On October 3, 1985, the Committee ordered S. 1437 reported with an amendment in the nature of a substitute offered by the chairman and ranking member. The amendment made certain technical corrections to the bill as introduced; further, it substituted the phrase "controlled substance analog" for the perhaps too enticing term "designer drug." Moreover, the Committee substitute created a misdemeanor offense for simple possession of a controlled substance analog, and clarified that a crime is committed only if all or part of the specific substance in question was intended for human

consumption. The Committee adopted the substitute by unanimous voice vote.

IV. Regulatory Impact Statement

Pursuant to paragraph 11(b), rule XXVI, of the Standing Rules of the Senate, the Committee has concluded that the bill may impose slight regulatory costs upon a very small number of businesses and individuals that make legitimate use of controlled substance analogs under exceptions provided by the legislation. Because the bill's prohibitions do not apply to experimentation with chemical substances that are not themselves intended for human consumption, most legitimate research in the controlled substance analog area will be unaffected by passage of the Act.

Controlled Substance Analogs that are intended for human consumption may be used in conformance with the provisions of an approved new drug application or an exemption for investigational use within the meaning of section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 355]. Such applications are currently required of those who seek to make legitimate use of schedule I or II controlled substances, and the Committee heard testimony from a representative of the American Chemical Society that, "[m]y colleagues in the pharmaceutical industry do this routinely." The D.E.A. testified that "this is a reasonably simple process . . . not regarded as a difficult or heavy burden for legitimate scientists and research activity." Assistant Attorney General Trott added that the requirement "is easy to comport with if you are an honest person simply pursuing scientific research."

V. Cost of Legislation

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate and section 403 of the Congressional Budget Act of 1974, the Committee provides the following cost estimate, prepared by the Congressional Budget Office:

U.S. Congress,
Congressional Budget Office,
Washington, DC, October 18, 1985.

Hon. Strom Thurmond,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has reviewed S. 1437, the "Controlled Substance Analogs" Enforcement Act of 1985, as ordered reported by the Senate Committee on the Judiciary, October 3, 1985. 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.

S. 1437 adds a section to the Controlled Substances Act which makes it illegal to manufacture, distribute, or possess a controlled substance analog intended for human consumption. The bill specifies maximum fines and jail sentences that may be imposed on offenders.

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, but would make possible 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.*

VI. CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing laws proposed to be made by S. 1437 as reported are shown as follows; new matter is printed in italic, and existing law in which no change is proposed is shown in roman:

COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

For Legislative History of Act, see p. 4566

Public Law 91-513; 84 Stat. 1236

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TABLE OF CONTENTS

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TITLE II—CONTROL AND ENFORCEMENT

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

* * * * * * *

Sec. 102. Definitions.

* * * * * * *

PART D—OFFENSES AND PENALTIES

* * * * * * *

Sec. 403. Prohibited Acts C—penalties.
Sec. 403A. Prohibited acts D.

* * * * * * *

DEFINITIONS

Sec. 102. As used in this title:

* * * * * * *

(31) The term "controlled substance analog" as used in section 403A means a substance other than a controlled substance that has a chemical structure substantially similar to that of a controlled substance in schedules I or II or that was specifically designed to produce an effect substantially similar to that of a controlled substance in schedules I or II. Examples of chemical classes in which controlled substance analogs are found include, but are not limited to, the following: phenethylamines, N-substituted piperidines, morphinans, ecogonines, quinazolinones, substituted indoles, and arylcycloalkylamines.

(32) The term "human consumption" includes application, injection, inhalation, or ingestion.

* * * * * * *

PROHIBITED ACTS C—PENALTIES

SEC. 403. (a) It shall be unlawful for any person knowingly or intentionally—

* * * * * * *

§ 403A. Prohibited acts D

Any person who knowingly or intentionally manufacturers with intent to distribute, possesses with intent to distribute, or distributes a controlled substance analog all or part of which substance is intended for human consumption shall be fined not more than $250,000, or imprisoned not more than fifteen years, or both. Any person who knowingly or intentionally possesses a controlled substance analog all or part of which substance is intended for human consumption shall be fined not more than $25,000 or imprisoned not more than one year, or both. This section does not apply to a person who manufactures, possesses, or distributes a substance in conformance with the provisions of an approved new drug application or an exemption for investigational use within the meaning of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). For purposes of this section, section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be applicable to the introduction or delivery for introduction of any new drug into intrastate, interstate, or foreign commerce.

O

STATE OF ALASKA 1986 LEGISLATIVE SESSION
FISCAL NOTE

Revision Date : _____

REQUEST

Bill/~~Resolution No.~~ : SB 371
Title : "An Act amending the controlled substance schedules."

Sponsor : By Request of the Governor
Requestor : Governor's Office/OMB
Date of Request : 12-16-85

FISCAL DETAIL

Agency Affected : Department of Law
BRU : Prosecutions

Components : _____

EXPENDITURES/REVENUES : (Thousands of Dollars)

OPERATING	FY 86	FY 87	FY 88	FY 89	FY 90	FY 91
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	-0-	-0-	-0-	-0-	-0-	-0-
CAPITAL						
REVENUE						

FUNDING : (Thousands of Dollars)

GENERAL FUND	-0-	-0-	-0-	-0-	-0-	-0-
FEDERAL FUNDS						
OTHER						
TOTAL						

POSITIONS :

FULL-TIME	-0-	-0-	-0-	-0-	-0-	-0-
PART-TIME						
TEMPORARY						

ANALYSIS : Attach a separate page if necessary

- PLEASE SEE PAGE 2 -

Richard L. Pegues
Prepared by : Richard I. Pegues, Director — Phone : 465-3672
Division : Administrative Services Division — Date : 12-20-85

Richard L. Pegues /FAR/
Approved by Commissioner : Harold M. Brown, Attorney General — Date : 12-20-85
Agency : Department of Law

Distribution (by Agency preparing fiscal note) :
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

10/25/85

CONTINUATION of FISCAL NOTE ANALYSIS

For Bill/~~Resolution~~ No. SB371

This bill amends the state's existing controlled substance schedules to conform to the federal schedules, insuring that state law enforcement authorities will have the legal tools necessary to combat illicit trafficking in dangerous drugs. The amended schedule includes several of the so-called designer drugs that have recently emerged outside Alaska in order that we can be prepared should their use spread to the state. The number of new prosecutions that will occur as a result of these schedule changes is expected to be negligible, and any additional cases can be handled with existing prosecution resources, without causing a fiscal impact.

SB 371

BILL SHEFFIELD
GOVERNOR

STATE OF ALASKA
OFFICE OF THE GOVERNOR
JUNEAU

January 29, 1986

The Honorable Don Bennett
President of the Senate
Alaska State Legislature
P. O. Box V
Juneau, AK 99811

Dear Senator Bennett:

Under the authority of art. III, sec. 18, of the Alaska Constitution, and in accordance with AS 11.71.120(b), I am transmitting a bill that amends Alaska's controlled substance schedules to add substances that are controlled under federal law but not under Alaska's law.

This bill would add 26 substances to the Alaska schedules: 16 to schedule IA, three to schedule IIA, one to schedule IIIA, and six to schedule IVA. The bill would also reschedule two substances that have been rescheduled under the federal law, and remove from control two substances that have been removed from the federal schedules. The drug scheduling criteria set out in AS 11.71.120(c) were used to determine the appropriate level of scheduling for each substance.

A section-by-section analysis of the bill, explaining in detail what drugs will be added to the schedules and why, follows:

SECTION-BY-SECTION ANALYSIS OF DRUG BILL

Note: Unless otherwise indicated, the descriptions of the drugs listed below are based upon materials supplied by the federal Drug Enforcement Administration (DEA).

Section 1 removes the substance "nalmefene" from Alaska's Controlled Substances Act by adding it to the list of exclusions in AS 11.71.140(b)(1). Currently, nalmefene is included in schedule IA (AS 11.71.140) because it is a

derivative of the listed opiod "thebaine". Nalmefene is also a derivative of the narcotic antagonist naltrexone, currently excepted from the state Controlled Substances Act. The DEA and the Secretary of the U.S. Department of Health and Human Services have concluded there is insufficient scientific evidence to demonstrate that nalmefene possesses sufficient potential for abuse to justify its continued control in any schedule of the federal Controlled Substances Act.

Section 2 adds five narcotic substances to schedule IA: alfentanil; alpha-methylfentanyl; bulk dextropropoxyphene; sufentanil; and tilidine.

Alfentanil was placed in federal schedule I in accordance with U.S. treaty obligations under the Single Convention on Narcotic Drugs. At the request of the World Health Organization, alfentanil was examined by various groups from the Committee of Problems of Drug Dependence. The results of the study showed that alfentanil is a potent morphine-like compound with two to four times the potency of morphine when used as an analgesic.

Alpha-methylfentanyl, also known as "China White" or "synthetic heroin", is a close structural analog of the Alaska schedule IA substance "fentanyl". It is an analgesic approximately 80 times more potent than morphine. The substance has been placed in federal schedule I because it has a high potential for abuse and currently has no accepted use in medical treatment in the United States.

Bulk dextropropoxyphene (nondosage form) is a federal schedule II opiate. The scheduling criteria used in Alaska require that all federal schedule I and II narcotics be placed in Alaska's schedule IA. This substance, therefore, is placed in schedule IA. It should be noted that dextropoxyphene in dosage form is placed in Alaska's schedule IVA and federal schedule IV. Dextropropoxyphene in dosage form is better known as the drug "Darvon". Nondosage form was placed in federal schedule II in accordance with U.S. treaty obligations under the Single Convention on Narcotic Drugs.

Sufentanil is contained in the federal schedule II; it is a congener of the federal schedule II narcotic substance fentanyl. Sufentanil is indistinguishable in terms of abuse potential from fentanyl, a drug used mainly in operating rooms and abused primarily by operating room personnel.

Tilidine, also known as "tilidate hydrochloride," is a

narcotic analgesic used in the control of moderate to severe pain. Tilidine was placed in federal schedule I in accordance with U.S. treaty obligations under the Single Convention on Narcotic Drugs.

Section 3 adds a new subsection to AS 11.71.140 to list the new "designer drugs" included in the federal schedules by the DEA over the past year. A designer drug is defined as:

> New chemical analogs or variations of existing controlled substances, or other new substances, which have a psychedelic, stimulant, depressant, or narcotic effect and have a high potential for abuse.

The federal 1984 Crime Control Act provided the DEA with emergency scheduling authority, to avoid an imminent hazard to the public safety. Scheduling under this authority is effective for one year and is not applicable to substances for which there is an exemption under the Federal Food, Drug, and Cosmetic Act (e.g., investigational new drugs and new drug applications). To classify a substance under its emergency powers, the DEA must publish a notice of the classification in the Federal Register; the classification becomes effective after 30 days. To date, the DEA has scheduled a total of 12 new substances under its emergency scheduling authority. Eleven of these substances are added, in sec. 3 of this bill, to the state's schedule IA; the 12th is a non-narcotic and is therefore placed in the state's schedule IIA (see sec. 4).

Section 4 would add three new substances to schedule IIA (AS 11.71.150): fenethylline, N-ethylamphetamine, and 3,4-methylenedioxymethamphetamine (MDMA).

Fenethylline is a conjugate of amphetamine and theophyllin (a methylxanthine). The drug produces a delayed, but prolonged, central nervous system stimulatory effect. Fenethylline has a high potential for abuse, has no recognized medical use in the United States, and has not been tested to determine its safety for use under medical supervision. It is a federal schedule I drug, but it has been placed in Alaska's schedule IIA because the drug is non-narcotic.

N-ethylamphetamine's pharmacological and behavioral effects are similar to those of amphetamine and methamphetamine. It is a federal schedule I substance with a high potential for abuse, and no known medical use in the United States.

MDMA, the designer drug known as Ecstasy, is an analog of the substance "methamphetamine." It has a high potential for abuse and no currently accepted medical use in the United States.

Section 5 removes the substance "mazindol" from Alaska's schedule IIIA (AS 11.71.160), and transfers it to schedule IVA (AS 11.71.170) (see sec. 8). This change has been made because mazindol is an anorectic substance which has a lower potential for abuse than other schedule III anorectics; it also presents less danger of psychological dependence relative to other anorectics in schedule III.

Section 6 places the substance "parahexyl" into Alaska's schedule IIIA. Parahexyl is a synthetic analog of delta-9-tetra-hydrocannabinol (THC), and has been placed in federal schedule I. Because Alaska law classifies THC as a schedule IIIA substance, however, it is appropriate to place parahexyl in Alaska's schedule IIIA.

Section 7 adds four benzodiazepines to schedule IVA: alprazolam, halazepam, temazepam, and triazolam. Each substance is an anti-anxiety agent substantially similar to other benzodiazepines currently listed in Alaska's schedule IVA. All four substances have been classified into the federal schedule IV.

Section 8 places the substance "mazindol" in schedule IVA (see sec. 5 description, above). Section 8 also adds two additional substances to schedule IVA: "pipradol" and "SPA". Each of these substances has been classified into the federal schedule IV.

Pipradol is a mild central nervous system stimulant. Its effects resemble those of the amphetamines, but the usual therapeutic dose of pipradol results in less euphoria, anorexia, and insomnia. It is an effective anti-depressant without the extreme central nervous system stimulation found in the amphetamines.

SPA is a substance marketed in Japan, but not in the U.S. It exhibits the same properties as morphine and methamphetamine, but with analgesic effects. Results of a study conducted by the University of Michigan showed that SPA has no physical dependence capacity.

Section 9 classifies the substance "buprenorphine" as a schedule VA (AS 11.71.180) drug. The DEA has placed buprenorphine into federal schedule V. It had previously been

considered a federal schedule II drug because it is a derivative of the substance "thebaine" (a schedule IA narcotic in Alaska). The DEA has found that buprenorphine has a low potential for abuse, has a currently accepted medical use, and has limited potential for physical or psychological dependence.

Section 9 also removes the substance "loperamide" from Alaska's schedule VA. Loperamide, an antidiarrheal, was removed from control by the DEA in 1982. The DEA concluded that loperamide has a currently accepted use in medical treatment in the United States and does not have sufficient potential for abuse to justify its continued control in any schedule of the federal Controlled Substances Act.

To ensure that all dangerous drugs that have a potential for abuse are appropriately covered by Alaska's law, I urge your prompt passage of this bill.

Sincerely,

Bill Sheffield
Governor

SB 371

(2) recommend regulations for adoption by the Board of Pharmacy to prevent excessive prescription of controlled substances and the diversion of prescription drugs into illicit channels;

(3) evaluate the effectiveness of programs in the state providing treatment and counseling for persons who abuse controlled substances;

(4) recommend programs to the Alaska Court System to be instituted as alternatives to the prosecution or imprisonment of offenders who have no prior criminal record involving controlled substance offenses and who are charged with crimes involving controlled substances;

(5) review and evaluate enforcement policies and practices of the Department of Public Safety and the Department of Law with regard to crimes involving controlled substances, and recommend modifications of those policies and practices consistent with the committee's assessment of the probable danger of particular controlled substances; and

(6) review budget requests and recommend amounts for appropriations to the governor and the legislature for departments and agencies responsible for

(A) enforcing criminal laws pertaining to controlled substances;

(B) providing treatment and counseling of persons who abuse controlled substances; and

(C) regulating the legitimate handling of controlled substances. (§ 2 ch 45 SLA 1982)

Sec. 11.71.120. Authority to schedule controlled substances. (a) If, after considering the factors set out in (c) of this section, the committee decides to recommend that a substance should be added to, deleted from, or rescheduled in a schedule of controlled substances under AS 11.71.140 — 11.71.190, the governor shall introduce legislation in accordance with the recommendation of the committee.

(b) If a substance is added as a controlled substance under federal law, the governor shall introduce legislation in accordance with the federal law.

(c) In advising the governor of the need to add, delete, or reschedule a substance under AS 11.71.110(1), the committee shall assess the danger or probable danger of the substance after considering the following:

(1) the actual or probable abuse of the substance including

(A) the history and current pattern of abuse both in this state and in other states;

(B) the scope, duration, and significance of abuse;

(C) the degree of actual or probable detriment which may result from abuse of the substance;

(D) the probable physical and social impact of widespread abuse of the substance;

STATE OF ALASKA
THE LEGISLATURE

POUCH Y - STATE CAPITOL
JUNEAU, ALASKA 99811
907-465-3600

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May, 1986

Copies of minutes listed below were originally included in this file. The minutes are available on the STAIRS date base CM 14. In order to save space copies of minutes have not been left in the files.

Jeanie Henry

Senate Health Education and Social Services Committee 4/8/86, 1:43pm