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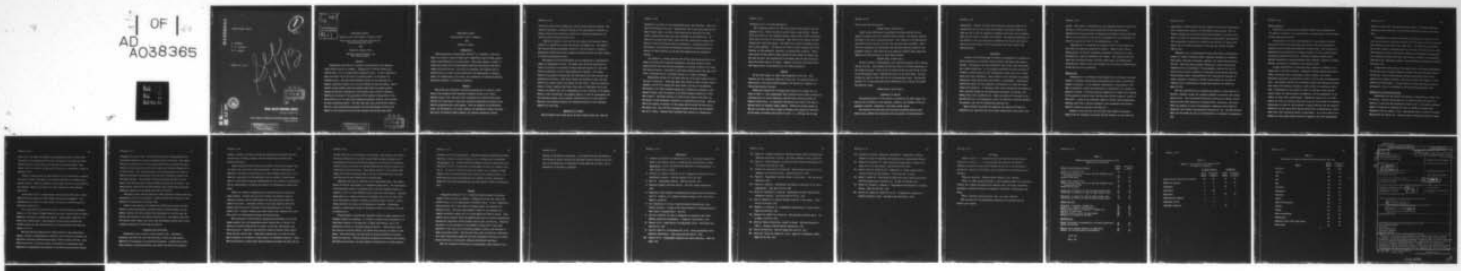

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PROPOXYPHENE ABUSE

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REPORT NO. 74-9

NAVAL HEALTH RESEARCH CENTER

SAN DIEGO, CALIFORNIA 92152

NAVAL MEDICAL RESEARCH AND DEVELOPMENT COMMAND

BETHESDA, MARYLAND

Propoxyphene Abuse*

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Abstract

Propoxyphene (Darvon^{R}) is a centrally acting analgesic with pharmacologic effects similar to morphine. Although one of the most widely prescribed drugs, it is of questionable therapeutic value. It has a significant abuse potential and is the cause of a growing number of accidental and suicidal deaths. The most common method of abuse is oral ingestion of a legally prescribed capsule, but it is also smoked and taken by needle. Abuse entails serious medical risks and repeated high doses can produce psychological and physical dependence of the morphine type as well as tolerance. Physicians can assist in the prevention of the problem by being alert to the abuse potential of the drug and by exercising judgment, caution, and restraint in their prescribing habits. The data from this study revealed that individuals in a young drug-abusing population who take propoxyphene illicitly are likely to have histories of anti-social problems and multiple drug abuse.

Propoxyphene Abuse*

Gerard Herrman, Marc A. Schuckit,

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William M. Harvey

INTRODUCTION

Dextropropoxyphene hydrochloride (Darvon ^{R}), a synthetic, mild analgesic, has become a source of abuse and a significant cause of death, particularly among adolescents and young adults. This study examines a sample of young drug abusers who took propoxyphene illicitly and compares them with a similar group who did not. As an aid to clinicians, the original data is supplemented by a review of the literature on the pharmacology of propoxyphene, the epidemiology of its abuse, and a discussion of preventive measures and issues pertinent to treatment of abusers.

METHODS

This study was conducted on the patient population of a walk-in, storefront, drug information and outpatient treatment service in St. Louis. Between January, 1971, and June, 1972, 48 patients who returned after their initial visit were given a structured, privately administered, personal interview by paraprofessional staff members. Data was gathered in the following areas: (1) demographics, (2) school history, (3) psychiatric history and symptom review of immediate family members, (4) personal psychiatric history

review and mental status examination, and (5) illicit drug use history. The research instrument, a condensed version of the questionnaire utilized in a study of drug use and psychiatric illness in a university population, has been described in detail elsewhere (1).

Psychiatric diagnoses were made for all subjects and immediate family members by a psychiatrist using the criteria of Feighner (2). The subjects who reported taking propoxyphene (Darvon ^{R}) "off the street" or without a prescription (Study Group) were compared with those who did not report taking it illicitly (Comparison Group).

The subjects of this investigation are not necessarily a representative sample of propoxyphene abusers. The agency from which the population was chosen is located on the boundary between urban and suburban St. Louis and serves predominantly lower to upper-middle-class families. The clinic attracts young persons seeking help for drug-related and other personal and interpersonal problems. Only those clients who returned at least one time after their initial contact were chosen for this study. Since the characteristics of clinic repeaters may differ from those of individuals who do not return, the subjects may not be representative of the clientele of the agency. However, these restrictions were applied equally to both the propoxyphene and the comparison groups, and no specific characteristics were used either as the basis for accepting requests for counseling services or for selecting subjects for the study.

DESCRIPTION OF SAMPLE

The 48 subjects had a mean age of 18 years (range 13-28) and, with the

exception of one Negro in the propoxyphene group, were Caucasian. About one-half of both groups were male. Approximately 15% in each group had been set back in grade school, and 60% in each group had not graduated from high school, either because they were still attending or had dropped out. Of those who completed high school, about half had a grade point average (GPA) between 81 and 90 percentage points at graduation. Forty-four percent of the subjects in both groups had previously consulted a professional about nervous or mental problems and 15% had been hospitalized for psychiatric reasons.

In response to a direct question, 62% of the study group and 50% of the others said they had no political preference, and about one-half in each group reported that they had been marginally or actively involved in at least two social movements. One-third in each group expressed doubt that they could find a comfortable place in American society if it remains unchanged.

Propoxyphene abusers (N = 26) had a mean age of 18 years (range 13-27) at the time of interview. Twenty-one (81%) were raised by their biologic parents together, and 20 (77%) stated that their father was head of the household. The fathers of 12 (46%) attended college and 11 (42%) had a graduate or post-graduate degree, while the mothers of 13 (50%) attended college and 8 (31%) had a degree. Excluding retirees, 16 (67%) of the fathers owned their own businesses or held managerial, executive, or professional positions. Although 85% of the mothers of subjects in this group worked outside the home during the school year, only two did so primarily during the hours when the proband was out of school. Sixteen (62%) described their mothers as "domineering,"

"overprotective," or "overly permissive."

The comparison subjects (N = 22) were similar in many ways to the propoxyphene users. Their mean age was also 18 years (range 14-28). Sixteen (73%) were raised by their biologic parents together and 11 (50%) considered their father the head of the household. Nine (41%) of the fathers attended college and 8 (36%) had degrees. Ten (45%) of the mothers attended college and 4 (18%) graduated. The fathers of 11 (52% of those working) owned their business or held managerial, executive, or professional positions. Fifty-nine percent of the mothers worked outside the home during the school year, but only one had a job requiring her to be absent from the home during the hours the subject was not in school. Eighteen (82%) felt that their mother was "domineering," "over-protective," or "overly permissive."

RESULTS

Of the total sample, 26 (54%) took propoxyphene illicitly. They differed from the comparison subjects in four ways: (1) characteristics of their parents, (2) school-related problems, (3) psychiatric diagnosis and (4) non-prescription drug use.

Differences between the two groups were tested by chi square and are shown in Table 1. More propoxyphene users considered their father domineering, over-protective or overly permissive, and had school-related problems and behavior difficulties. No consistent differences were noted in the drug or alcohol habits of immediate family members. Differences between groups on the use of alcohol and illicit drugs by siblings were computed on the basis of the number of brothers and sisters at risk, i.e., siblings over the age

of 13 at the time of interview.

(Insert Table 1 about here.)

Table 2 shows differences in psychiatric diagnoses between the two groups of subjects and their immediate family members. The primary diagnosis was based on the first-appearing syndrome. Four subjects in the propoxyphene group fulfilled the criteria (2) both for drug abuse and sociopathy. There were more sociopaths and individuals with secondary diagnoses among the propoxyphene subjects, while there was more affective disorder among comparison subjects and more alcoholism in their family members.

(Insert Table 2 about here.)

As seen in Table 3, propoxyphene users reported experience with a greater variety of drugs. Only hashish and MDA were taken by a greater percentage of the comparison group. Twelve of the 16 drugs listed were used by 50% or more in the propoxyphene group, compared with seven in the other group. No class of drug was taken by fewer than 30% of the propoxyphene users. The greatest contrast (35 or more percentage points difference) was in the use of "speed" and medicinal drugs.

(Insert Table 3 about here.)

DISCUSSION OF RESULTS

The generalizability of the results is limited by the small sample size and the lack of details on the frequency, quantity, and strength of the propoxyphene consumed. Nonetheless, some basic trends emerge.

The persons who sought help from this drug counseling resource were mostly young, middle-class Caucasians and the majority of them had abused

propoxyphene. Abusers were more likely than the comparison group to be characterized by pervasive anti-social behavior and complex patterns of drug use, but it was not possible to establish the illicit use of propoxyphene as the "cause" of getting into trouble. One possible explanation of the finding is that poly-drug using individuals with chronic anti-social behavior are more likely to take propoxyphene than those without such characteristics.

BACKGROUND

A review of the pharmacology and abuse of propoxyphene is included as a help to physicians, counselors, hotline workers, and other drug resource persons. Propoxyphene was first marketed in 1957 by Eli Lilly and Company as a codeine substitute. It is currently available from Lilly as Darvon ^{R} ("pinks," "red and grays") in six formulations, either alone or in combination with other ingredients. Until recently it was available in capsules containing a white powder and a pink pellet of propoxyphene. Some abusers removed the pellet for oral ingestion or dissolved it in water for intravenous (IV) injection. To counteract this, Lilly reformulated the product in 1972, uniformly dispersing the propoxyphene throughout the mixture, and adding other inert ingredients (3). After expiration of the patent on the hydrochloride salt of propoxyphene in 1972, 10 additional companies marketed the product, most with the encapsulated spherule (4).

Lilly recently introduced the napsylate salt (Darvon-N ^{R}) which is available in an injectable and three tablet formulations, alone and in com-

pounds. This product is advertized as "very slightly soluble in water" (5). The Special Testing and Research Laboratory of the Drug Enforcement Administration (formerly Bureau of Narcotics and Dangerous Drugs) confirmed that it is not soluble in cold water, but asserted that "its solubility in hot water approximates that of the hydrochloride..." (6).

Propoxyphene was introduced for clinical use at a time of great concern about the addictive potential of codeine. Within a short time it became popular in clinical situations and gained a reputation as a safe, non-addicting, effective substitute for codeine. Data collected over the years from controlled studies, clinical observations, and epidemiologic investigations indicate that such confidence in the safety and effectiveness of the drug may not be justified.

Pharmacology

Propoxyphene is a centrally acting analgesic with a chemical structure similar to methadone hydrochloride and pharmacologic effects qualitatively similar to morphine. It is currently classified as a "non-narcotic," but this is primarily a legal term referring to a drug which is not subject to narcotic controls. The Drug Enforcement Administration (DEA) after studying it for possible inclusion under the Drug Abuse Control Amendment, stated in 1973 that "...there is no scientific reason to consider destropropoxyphene anything other than a narcotic analgesic," and recommended that domestic narcotic controls be placed on the drug (6).

Studies on mice and rats (7) have shown that morphine antagonists reduce both the incidence of seizures and the lethality of toxic doses of

propoxyphene, indicating that the toxic effects are due to its interaction with "morphine-type receptors" in the central nervous system. This is further supported by case reports (8,9) that nalorphine, a narcotic antagonist, reverses the respiratory depression of propoxyphene poisoning and that propoxyphene napsylate can be used in the treatment of opiate withdrawal and as an opiate substitute in the long term therapy of heroin addicts (10).

Therapeutic use of propoxyphene involves side effects qualitatively similar to codeine, including nausea, vomiting, constipation, headaches, skin rashes, dizziness, drowsiness, sedation, and severe agitated states (11,12). Taking the drug by needle ("shooting), either intravenously ("mainlining") or intradermally ("skin popping"), involves the risk of severe tissue necrosis secondary to inadvertent intra-arterial injection, acute pulmonary edema, thrombophlebitis with occlusion and sclerosis of veins, cellulitis, abscesses, and other tissue injuries at the site of injection due to extravasation, foreign body material, and infectious agents (8,13).

The toxic manifestations of overdose are similar to those observed in narcotic overdoses, except for a greater incidence of seizures with propoxyphene (12,14). The usual pattern following intoxication is general central nervous system (CNS) depression, including ataxia, drowsiness, and stupor, which may progress to loss of consciousness, respiratory and circulatory depression and collapse, and generalized seizures (9, 11). The DEA estimated that over 200 deaths per year are attributable to an overdose of propoxyphene (6).

Abuse Potential

Assessment of a drug's abuse liability involves four considerations: its addiction liability, its attractiveness, its availability, and the amount of abuse already documented.

Propoxyphene produced physical dependence in post-addiction patients who received 600-825 mg. doses daily for 53 days with abrupt termination yielding minimal morphine-type abstinence symptoms (15). Case reports have documented that propoxyphene can produce tolerance as well as psychological and physical dependence (8,16,17). Withdrawal symptoms include chills, profuse perspiration, cramping abdominal pains, headache, rhinitis, diarrhea, fatigue, nervousness, irritability, and insomnia (8,16).

A major consideration in evaluating abuse potential is whether or not people like to take the substance. Experienced addicts reported pleasurable effects resembling those of marijuana, heroin, morphine, and cocaine following experimental administration of 355 to 650 mg. doses of propoxyphene (15). Case reports indicate that intravenous abusers also experience pleasurable opiate-like feelings including a "rush" similar to intravenous codeine (18). Propoxyphene is also taken for relief of emotional stress and menstrual cramps, for self-treatment of depression, and for enhancement of the effects of drugs taken simultaneously. Amphetamine abusers use it to help reduce the amount of stimulant taken and to prevent the distress of "crashing." Propoxyphene is used for self-treatment of opiate addiction and for temporary maintenance of the opiate habit during incarceration, hospitalization, and at other times when the desired opiate is unavailable. It is not a drug of preference for most opiate addicts because of dysphoria and other disagreeable

effects of high doses, the relatively weak effects, the burning sensation which accompanies injection, and the local damage that occurs to the veins (19).

Propoxyphene is subject to diversion and improper use since it is the most commonly used prescription analgesic (20) and because it ranks among the most frequently prescribed of all drugs (21). Two field surveys conducted by the DEA covering a one-month period in 1969 and a 15-month period in 1971-1972 revealed 593 cases involving the finding of propoxyphene in possession of an individual arrested for some other reason, and thefts of propoxyphene from pharmacies, physicians' offices, and distributors totalling over 124,000 dose units (6).

A legitimate prescription is the normal means of obtaining propoxyphene, but abusers have a variety of methods available for obtaining large amounts of the drug. These include tapping multiple prescription sources (17), raiding family medicine cabinets, soliciting capsules from friends, or purchasing them from dealers. A street dealer is rarely the primary source of propoxyphene, but it is available in the illicit drug subculture (19).

Epidemiology of Propoxyphene Abuse

Propoxyphene has been abused intravenously, subcutaneously, orally, and by smoking. The most common method is to ingest ("drop") the capsule by mouth or to take only the encapsulated pellet (3,19). Oral abusers sometimes enhance the effects by drinking hot water or coffee "to promote rapid absorption from the stomach " (19). Some abusers smoke a mixture of propoxyphene powder and tobacco (6). The most popular intravenous method is prepar-

ation of an "ice shake" by crushing the propoxyphene pellet or dissolving the mixture in a spoonful of cold water, filtering it away from the powder binder through a cotton filter, and injecting the dissolved drug. Some abusers "cook the mixture" by boiling the filtrate to concentrate it prior to injection (18).

Misuse of propoxyphene was found among 10% of 112 middle-class residents of a private girls' high school, and among the majority of 52 middle-class married couples. Eighty-two percent of the couples who had it prescribed for its analgesic effects also used it for self treatment of other physical pains (19).

In the fall of 1970, a questionnaire survey revealed that 15% to 20% of 180,000 American soldiers in West Germany had abused propoxyphene. As a countermeasure in 1971, U.S. Army medical facilities treated the drug as a restricted narcotic (8).

In a survey (22) of over 15,000 sixth to twelfth graders in Anchorage, Alaska, in 1971, Darvon ^{R} ranked among the top seven reported drugs of experimentation, exclusive of alcohol and tobacco. Three percent reported it as their first drug of abuse. The prevalence of abuse among eleventh and twelfth graders was 20%, and the majority of these indicated that they continued to use it.

The Food and Drug Administration (FDA) received 50 drug abuse/injury reports relative to propoxyphene in 1968-1969, and 93 reports of serious complications following overdose between April, 1970 and March, 1973 (6). From 1970 through 1972, 1,672 case reports of accidental and intentional self-poisoning by propoxyphene were reported to the FDA by poison control centers

throughout the U.S.A. (23). The DEA had 946 reports of propoxyphene abuse from medical facilities during a six-month period in 1972-1973. The typical abuser from that data was a 20 to 29-year old female who obtained the drug through a legal prescription and took it orally to alleviate unhappiness or to kill herself. The medical examiners of 34 states reported 257 cases of death by propoxyphene poisoning in 1971 and 1972, including 8 children and 147 known suicides. The mean age of those who died by accident was 28.4 years, while the mean age of those who died by suicide was 38.9 years. Two Darvon Surveys conducted by the DEA revealed 1,916 suicide and non-suicidal ingestions resulting in 323 deaths from 1967 to 1971 (6).

The Dallas County Medical Examiner's office reported 41 deaths involving propoxyphene over a two-year period. Twelve of these were victims of a combination of propoxyphene and alcohol (24).

There is some evidence to indicate that middle-class persons are more likely to misuse propoxyphene, possibly because of their tendency to seek medical services for minor ailments and consequently to have the drug prescribed and available in the medicine cabinet (19). The original data from the present study supports the notion that propoxyphene abusers tend to have a higher socioeconomic status than non-abusers.

DISCUSSION AND CONCLUSIONS

Propoxyphene abuse involves serious medical risks. Dependence, poisoning, and death can occur when the drug is taken in large amounts. Injection of propoxyphene is particularly hazardous. A multitude of infectious problems, including hepatitis, can result from the use of unsterile

needles, syringes, and drugs, and serious complications can ensue from the introduction of foreign material into the blood stream and from intra-arterial injection.

Since propoxyphene abusers who seek treatment tend to have complex drug use habits they risk adverse drug interactions. Because propoxyphene can potentiate the effects of other drugs it is more dangerous when used in combination, especially with CNS depressants such as alcohol or barbiturates. This is a particularly important consideration in the treatment of individuals who use propoxyphene to intensify the effects of simultaneously administered drugs.

There are a number of suggestions for practitioners that emerge from these findings. Current drug use of all clients and patients should be explored carefully, and all prescription and non-prescription substances should be recorded. Intravenous abusers of any drug should be identified because injectors tend to have many of the characteristics of "street" addicts (25). Indirect evidence from other sources (26) indicates that they also tend to be indiscriminate abusers of multiple drugs.

The prevalence of school behavior problems and sociopathy in our study sample suggests that the propoxyphene abuser seeking help is likely to be involved in serious difficulties at school, on the job, with parents, and with the police. Clinicians are advised to explore carefully these problem areas and help resolve them. Individuals seeking help at a time of crisis may be amenable to alteration of their pattern of maladaptive behavior. Those who are unwilling to change their drug and behavior patterns are high risk for

further involvement in difficulties with society. The counselor can outline for these individuals the specific hazards that accompany improper use of propoxyphene and other mood-altering substances and can help in formulating realistic plans to minimize the manifold difficulties which are likely to be encountered if abuse continues. Since nearly one-half of the present study sample had sought professional help in the past, presumably they will again seek help when serious difficulties are encountered.

Physicians can play an important role in preventing abuse. The primary source of misused propoxyphene is a legitimate prescription. The drug appears to be prescribed freely in the belief that it has the analgesic potency of codeine or that it is more effective and no more toxic than aspirin. Actually, propoxyphene has a dubious record as an analgesic and it has not been shown to be consistently superior to placebo in clinical trials (27,28). It has a strong potential for abuse, and is dangerous in overdose. Consequently aspirin or acetaminophen should be the drug of choice for patients with mild to moderate pain.

If propoxyphene is prescribed, physicians should be highly suspicious of frequent requests for renewals. It is best to refrain from prescribing it to individuals unknown to the physician, to known drug abusers, and to the potentially suicidal or seriously depressed patient. Practitioners should not authorize unlimited refills, nor should they prescribe or refill by telephone. When prescribing, the same level of caution demanded for narcotics should be exercised. Patients should be forewarned of the drug's side effects and addiction potential, and they should be instructed not to drink alcoholic

beverages when taking propoxyphene. Directions should be specifically stated and limits should be clearly indicated, i.e., it should not be prescribed for ad libitum use. Patients should be advised to guard the medication carefully and to make it inaccessible to individuals who might be tempted to misuse it. In order to minimize diversion to illicit use, a supply no longer needed should be destroyed rather than stored in the medicine cabinet. To avoid becoming unwitting contributors to a pattern of abuse, pharmacists should fill and refill prescriptions only with specific medical authorization (17).

SUMMARY

Propoxyphene (Darvon ^{R}) is a centrally acting analgesic with pharmacologic effects similar to morphine. Although one of the most widely prescribed drugs, it is of questionable therapeutic value. It has a significant abuse potential and is the cause of a drowing number of accidental and suicidal deaths. The most common method of abuse is oral ingestion of a legally prescribed capsule, but it is also smoked and taken by needle. Abuse entails serious medical risks and repeated high doses can produce psychological and physical dependence of the morphine type as well as tolerance. Physicians can assist in the prevention of the problem by being alert to the abuse potential of the drug and by exercising judgment, caution, and restraint in their prescribing habits. The data from this study revealed that individuals in a young drug-abusing population who take propoxyphene illicitly are likely to have histories of anti-social problems and multiple drug abuse.

With the widespread distribution of propoxyphene, abuse appears to be a

problem of considerable proportions. It is hoped that this investigation will stimulate further interest and encourage research focused on the problem, on identification of individuals who are high risk for abuse, and on formulation of preventive strategies.

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Footnotes

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**An extensive list of propoxyphene references is available from the authors upon request.

Table 1

Differences between Study and Comparison Groups
Expressed in Percentages

Family Use of Alcohol and Drugs	Study Group	Comparison Group
Father took illegal drugs	15	5
Father enjoyed taking, or was in some way dependent upon a prescription drug	15	5
Father drinks daily	31	41
Mother took illegal drugs	12	14
Mother enjoyed taking, or was in some way dependent upon a prescription drug	8	5
Mother drinks daily	19	9
Percentage of brothers at risk who used illegal drugs	37	38
Percentage of brothers at risk who drank alcohol daily	10	8
Percentage of sisters at risk who used illegal drugs	36	38
Percentage of sisters at risk who drank alcohol daily	5	—
School Problems		
Suspended or expelled - Grades 6-12	50	27
Suspended or expelled more than once	15	19
Truant occasionally or frequently - Grades 1-12	73	55
Set back in high school	19	—
Failed a grade or course in high school*	69	28
Dropped out of school at any time	23	5
Miscellaneous		
Father domineering, overprotective, or overly permissive*	81	41
Father domineering*	50	14
Subject began smoking regularly in high school	19	9
Subject has had heterosexual intercourse**	92	64

*$p < .01$

**$p < .05$

Table 2

Subjects and Immediate Family Members with a Psychiatric Diagnosis

	% Family Members		% Subjects	
	Study Group	Comparison Group	Study Group	Comparison Group
Total with any psychiatric disorder	11	16	54	45
Affective disorder	5	3	8	14
Sociopathy	-	-	19	9
Alcoholism	4	10	-	-
Drug abuse	-	3	27	23
Undetermined diagnosis	1	1	-	-
Attempted suicide	-	5	-	-
Secondary diagnosis	-	-	15	-

Table 3

Percentage of Subjects Reporting Non-Prescription Drug Use

Drugs	Study Group	Comparison Group
Marijuana	100	100
Hashish	92	95
THC	65	41
LSD	96	86
MDA	42	45
STP (DOM)	31	27
Psilocybin	54	41
Mescaline	96	77
Peyote	38	32
Other hallucinogens	31	9
Opiates	62	41
"Speed"	85	50
Other amphetamines	81	68
Barbiturates	69	50
Medicinal drugs other than Darvon	77	41
Other drugs	54	27

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Behavior problems

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

Darvon is a centrally acting analgesic with pharmacologic effects similar to morphine. The abuse potential and typical cases of abuse have been well documented. As one of the most frequently prescribed drugs, it is used improperly by a wide variety of individuals. The most common method of abuse is oral ingestion of a legally prescribed capsule, although it is also administered intravenously and by other exotic routes. Abuse entails serious medical risks, including the danger of death from overdose. Repeated high doses can produce psychological and physical dependence of the morphine type, as well as tolerance.

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Individuals in a young drug abusing population who take Darvon illicitly are likely to have histories of anti-social problems and multiple drug abuse. Counselors are alerted to the problem of Darvon abuse and to the importance of identification and treatment. The physician's role in preventing abuse by exercising judgment, caution, and restraint in prescribing the drug is noted.