STS - TR - 16

EVALUATING DRUG CONTROL EFFECTIVENESS

Drug Enforcement Administration - U.S. Department of Justice - Washington, D.C. 20537

EVALUATING DRUG CONTROL EFFECTIVENESS

June, 1975

Special Programs Division
Office of Science and Technology
Drug Enforcement Administration
U. S. Department of Justice
Washington, D.C. 20537

EVALUATING DRUG CONTROL EFFECTIVENESS

Bernard A. Gropper, Ph.D.
Office of Science and Technology
Drug Enforcement Administration
U.S. Department of Justice

ABSTRACT

Effects of drug control on abuse patterns and related indicators were analyzed for nine representative drugs scheduled in mid- and late-1973. The drugs included a group of five anorectic stimulants in CSA Schedules III and IV: Benzphetamine, Chlorphentermine, Diethylpropion, Phendimetrazine, Phentermine, and a group of four depressants in CSA Schedule II: a non-barbiturate sedative - Methaqualone, and three barbiturates - Amobarbital, Pentobarbital and Secobarbital.

Statistical and descriptive analyses showed general post-control decreases in DAWN abuse rates. In addition, the relations of abuse patterns to NPA prescription trends and to DEA arrest records showed these benefits did not tend to produce undesired problems in limiting these drugs' availability for legitimate medical purposes, or in arrest and criminalization of otherwise lawful users.

I. INTRODUCTION

1. Objectives of Drug Control

Even the most beneficial and therapeutic drugs can become mixed blessings when they are misused, especially those drugs with psychoactive impacts and a liability for inducing physical and psychological dependence. The potential benefits that the use of drugs under proper medical guidance can bring for the relief of illness and suffering are highly desirable. But the potentially harmful effects on individuals and society that those same drugs can have when they are abused are not.

Unfortunately, such abuse and non-medical use of drugs are problems which have grown to the point where their impacts now cut across every segment of America; no group or region is unaffected or immune.

Control over the use and availability of drugs is obviously a necessity in the overall picture of combatting these drug problems. The fundamental considerations in drug abuse control reflect two basic areas of concern - one primarily related to drugs with no accepted medical uses, and the other

primarily concerned with those drugs which, while offering potential medical benefits, also have substantial potential for abuse. The Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 (CSA) consolidated and strengthened the nation's efforts to combat drug abuse in both of these areas.

The CSA's control provisions have two corresponding objectives: 1) assuring the greatest possible ratio of overall benefits compared to potential harm for licit drugs, and 2) total prevention of traffic in illicit drugs. In practice, placing a medically useful drug under the legal control of the CSA carries with it many provisions regulating its production, distribution and dispensing. These provisions are collectively designed to obtain the best possible balance between our desires to maintain a drug's availability for satisfying legitimate medical needs, while reducing or preventing its abuse and all the associated harmful side-effects.

This report briefly explores some important basic questions about the effects of drug control, and our efforts to develop methods of assessing those effects. First, are our laws and enforcement practices generally effective in reducing abuse of medically useful controlled drugs? Second, do we obtain the improvements we want without tending to create significant problems in other areas? And lastly, how can we best evaluate the overall effectiveness of our drug control procedures?

Although no one can provide fully comprehensive answers to such questions yet, the results of our initial studies have been encouraging. Based on the best information now available, we have found that overall patterns of drug abuse do tend to decline after the drugs are placed under control. Moreover, these reductions do not appear to carry with them unwanted social costs, such as problems of limited medical availability or criminalization of users, that would tend to negate the gains obtained.

2. Evaluating Drug Control Effectiveness

How can we measure drug abuse and evaluate the effects of our control efforts? Anyone who tries to answer these questions rapidly discovers the fundamental practical problem that, although it is possible to qualitatively describe many aspects of drug abuse and its associated effects, it is not possible to measure most of them simply and directly.

The reasons are that drug abuse is really not just a single type of behavior, but many types. They generally occur in private settings, and involve consensual activities that may range anywhere from those that may be condoned or disapproved of by general community standards, to others of various degrees of illegality and criminality. Attempts to directly monitor all these events and the background conditions related to them would probably be both impossible and incompatible with the constitutional safeguards of a free society. Therefore, the best indicators that we can realistically hope to develop for the different factors related to drug abuse must generally be indirect and represent reasonable samples of the most significant factors, rather than absolutely detailed and comprehensive coverage.

Such indirect indicators, while they cannot always provide ideal answers for all possible questions of interest, do permit us to evaluate the general trends and changes in licit and illicit drug usage and to assess the combined effects of different types of control efforts.

3. Indicators of Effects

An example of such indicators is the recently developed Drug Abuse Warning Network (DAWN), which is a coordinated monitoring system that permits many possible patterns of drug abuse in the general population to be detected and studied. DAWN reports a wide variety of data on abuse incidents detected by its nationwide network of hundreds of representative treatment facilities covering emergency rooms, crisis centers, hospital inpatients and medical examiner reports.

Analytically, of course, such incidents represent the combined and cumulative end-effects of all the variables associated with licit and illicit drug abuse. It is important to recognize that the integrative characteristics of these data may be an asset for some questions, but a potential liability for others. On the positive side, the DAWN data base provides a "truer" overall picture for evaluative purposes, in the sense that it does not constrain the user populations who can appear in its records nearly as much as some other methods; nor does it limit the substances eligible for inclusion to the point where significant real-world shifts in usage and interactive effects are artifically excluded from appearing in the data.

But we must recognize the fact that no system can answer all the questions we might want to ask. If we were to attempt to break the data down into more and more detailed subsets of relatively rare events, there would inevitably be very great possibilities of finding few or no data entries for some

specific cross-combinations of drugs, populations, and time periods. Moreover, since the data can only report directly on the characteristics of known abuse incidents, we must also recognize that there is always likely to be an indeterminate number of hidden incidents which go undetected by the system because they induced few or no adverse reactions and therefore did not prompt the abusers to seek help from any treatment facility. Since omniscience is impossible, we cannot be sure of the extent to which the characteristics of those hidden cases are similar or dissimilar to those cases which were detected; but we can use the information obtainable to reduce these inherent uncertainties.

Overall, DAWN offers the most representative and generally unbiased information base available for questions on current patterns of drug abuse. No other existing data base provides comparable nationwide and regional capabilties for the continual monitoring of all types of drugs and user populations. However, for other related questions, it may be necessary to employ other data sources designed to reflect different facets of licit and illicit drug activity.

The National Prescription Audit (NPA) provides an indicator of nationwide prescription trends as they are reflected in monthly sales patterns from a representative panel of retail outlets dispensing drugs at the potential consumer level. By matching and comparing the patterns it shows us for market trends in legitimate drugs, it offers the possibility of detecting such potential effects of control as - changes in prescribing rates reflecting differences in control status; shifts in physician preferences between similar drugs so that a decrease in one is related to possible increases in others; relative impacts of variations in proportional supplies through licit and illicit sources on changing patterns of abuse; and many other possibilities.

By analyzing the trends within these continuous indicators, combining them, and integrating information from other types of data sources relevant to specific questions, we can at least partially compensate for the imperfections in any single data source and try to provide reasonably sound bases for the decisions we must make while working toward improving all these capabilities for the future.

II. SCOPE OF STUDY

1. Needs and Applications

In late 1974, the Special Programs Division of the Office of

Science and Technology was requested to explore the feasibility of using the data bases now available to DEA to test the overall effects of control schedule decisions on various types of substances. In previous related efforts only individual ad hoc analyses had been made, and no generalizable techniques had been developed for these purposes. Some fundamental propositions, therefore, had not been empirically tested. For example, whether or not placing a drug in a control schedule generally tended to result in decreased levels of abuse had not been verified.

Such information and techniques would be very valuable for improved support of regulatory and policy decisions. Our immediate objectives were to be able to develop these techniques so as to be able to apply them to prior control decisions involving various types of drugs and incorporate the results found with them into the body of information available for evaluation in future regulatory decisions.

2. Rationale and Methods

As a first step, all drugs scheduled since the passage of the 1970 CSA were identified and a representative test set was selected which, to the extent possible within the constraints of these real cases, sampled the control schedules and pharmacological categories, and offered substances which represented reasonably large prior markets.

Since the earliest possible identification and evaluation of potential approaches, and availability of initial results was desired for the support of current planning and evaluation needs, various analytic approaches were identified and accepted as conceptually straightforward. Most were rejected, however, as not statistically feasible with the data available. They would have either required acquisition of new types of data, or necessitated excessive delays for either manual retrieval of relevant data from other sources or for computer reprogramming and analysis.

Accordingly, exploratory analyses were initiated with two groups of nine drugs for which abuse data, market data and other related data were available before and after their change of control status. These drugs were: 1) a group of five anorectic stimulants (Benzphetamine, Chlorphentermine, Diethylpropion, Phendimetrazine, and Phentermine) which were originally controlled in mid-1973, and 2) a group of four depressants (three barbiturate sedatives: Amobarbital,

Pentobarbital and Secobarbital, and one non-barbiturate sedative: Methaqualone) controlled in late-1973.

These choices of test drugs offered several advantages; a) they satisfied all the original criteria, b) they included drugs within Schedules II, III and IV, c) they sampled drugs that had been newly scheduled and re-scheduled from lesser to more stringent levels of control, and d) their time of scheduling permitted comparison for reasonably large base periods over 8 to 10-month pre- and post-control intervals.

The primary data bases used were the DAWN for abuse trends and the NPA for licit availability trends. Additional exploratory investigations of other DEA information sources partially reflecting drug control impacts on criminalization and availability to the medically needy were made to supplement the findings within the primary data bases. Information on these related topics was very sparse, however, and they would require much more extensive study for confident identification of the interrelations among them.

3. Analytic Logic and Procedures

Fundamentally, in order to permit the probable attribution of an observed difference in drug abuse patterns to the variable being tested (i.e., in this case, to the combined effects associated with whether or not a drug has been newly-controlled or shifted to a higher control schedule) the data must provide:

1. measures meaningful at a true-zero ratio-scale level (i.e., so that differences and proportions may be validly compared),

2. base periods long enough to include relevant near-term effects (e.g., lags in reaction time) and long-term effects (e.g., secular trends) both before and after the change dates,

3. reference control group data in which all other factors are reasonably constant with regard to the independent variable (i.e., in these cases, comparisons were made against levels observed for all other drugs within the data base which did not undergo a change in control status at that time).

The general procedure then is to identify pre- and post-control rates of whatever indicator is being studied for both a test group and reference comparison group, in order to determine whether or not:

a) each member of the test population changes in the expected direction (i.e., abuse rates decreased)

b) concurrent conditions affecting both types of populations may have been partially or wholly responsible for any observed changes, as evidenced by similar changes in the comparison group's base rates during the same periods

c) the observed patterns of differential changes are statistically different from chance variations.

Additionally, since we must deal here with real-world data bases which were not necessarily designed and operated so as to support these specific analyses, we must recognize and control for the possible effects of concurrent changes in the data base characteristics. When such changes occur, we may attempt to compensate for them statistically by using various normalizing techniques. We may use raw frequency counts only with caution, since they may reflect changes not only in the phenomena of interest, but also concurrent changes in the numbers or types of facilities from which the data were obtained. Although it is not always possible to statistically balance or operationally prevent all such changes, we must use analytic methods which minimize the probability they may be responsible for the effects observed. When convergent results are obtained with different sets of data, we can be reasonably confident that the effects are probably valid and not likely to be artifacts attributable to the specific characteristics of the particular analytic techniques.

Specifically, for each drug or drug category, let:

$$FR = \text{Total Facility Rate} = \sum_{i}^{} \frac{d_f}{n_f}$$

Where: f = facility type: ER = Emergency Room
ME = Medical Examiners
IP = In-Patient Units
CC = Crisis Centers

n = number of facilities of type f in interval

i = intervals for available data (e.g., monthly)

d = data (e.g., frequency of DAWN mentions)

III. RESULTS AND EVALUATIONS

The primary results can be most readily presented through the patterns in the DAWN abuse rates, in the NPA prescription trends, and in the relations between these indicators.

1. Decrease in DAWN Abuse Rates

For the DAWN abuse data, as summarized in Fig. 1 and Table 1, the effects of new control or increased control level appear to be:

a) Near-term decreases in abuse incidents for every drug in the sample groups. Comparisons of pre-control facility reporting rates to post-control rates for the test drugs all showed much greater changes than the reference population, and they all changed in the negative direction.

b) An overall pattern of generally decreased abuse following control which is probably not attributable to chance (significant at the 0.998 level of confidence, using the binomial test for direction and magnitude of change).

c) Suggestions of possible effects within a therapeutic class which appear related to: 1) level of schedule (III>IV) and 2) to the original relative abuse rates; with more effect found for the more stringent schedules and the more heavily abused drugs.

d) Newly controlled drugs appear to show a greater proportional decrease than when substances already controlled are shifted to a more stringent schedule, although decreases are obtained for both types. There is a suggestion here of diminishing returns so that, whatever causative factors may be involved, most of the effect on observed abuse seems to be obtained in the initial control and relatively little further effect on these indicators is obtained with later schedule shifts.

e) The tentative pattern of greater decrease being generally associated within a therapeutic group with larger prior

Figure 1

Effects of Control Schedule Changes on Abuse Incident Rates

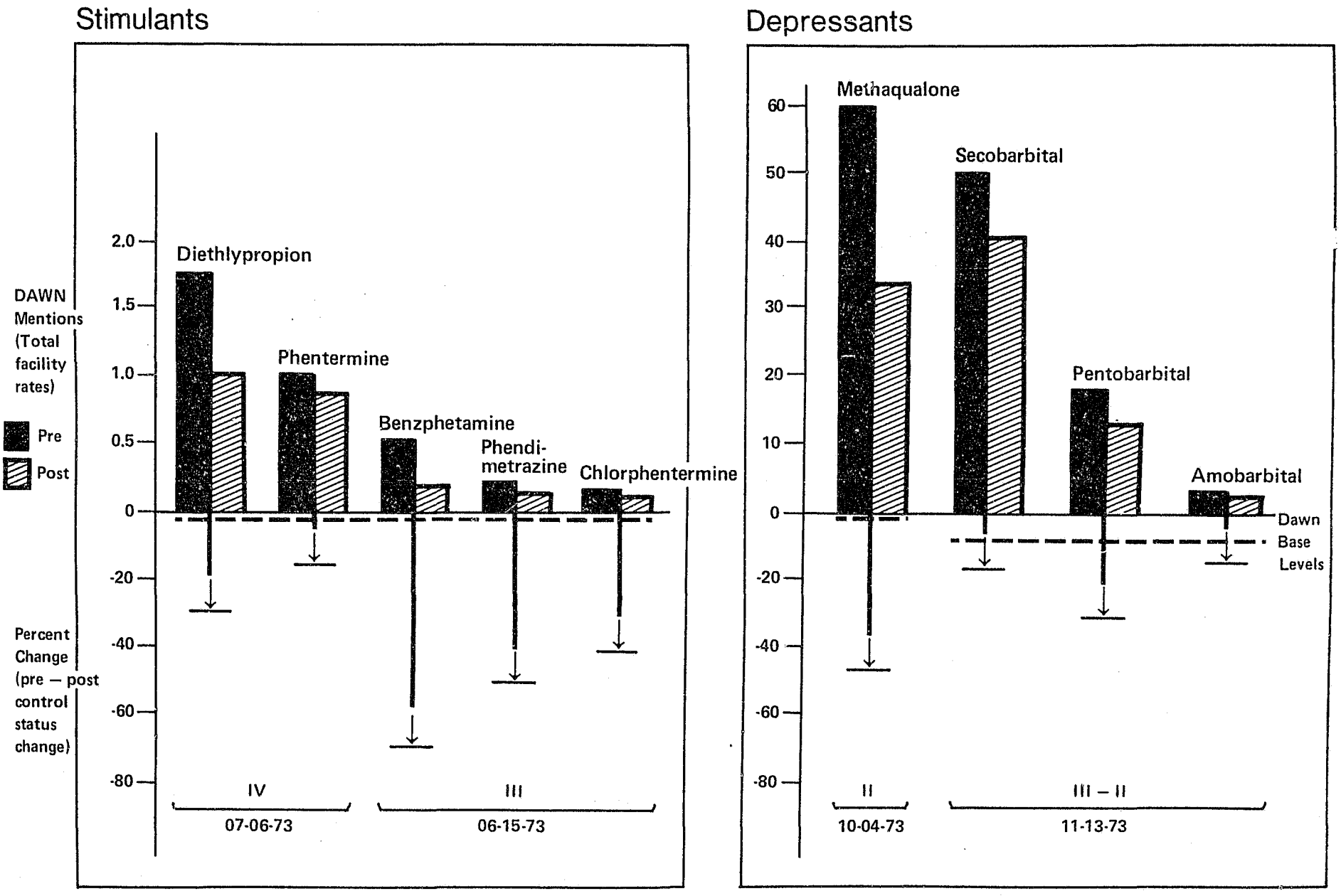


Table 1 Effects of Control Status Changes on Abuse Rates

Categories: Drug/Schedule/Date	Periods (Mos.)	Facility Rates Pre-	Facility Rates Post-	Percent Change
A- Stimulants: Anorectics				
Benzphetamine III 06-15-73	8	0.5035	0.1595	- 68.32
Chlorphentermine III 06-15-73	8	0.2013	0.1184	- 41.18
Phendimetrazine III 06-15-73	8	0.2302	0.1165	- 49.39
Diethylpropion IV 07-06-73	8	1.7133	1.2394	- 27.67
Phentermine IV 07-06-73	8	1.0515	0.8960	- 14.79
B-Depressants				
Methaqualone II 10-04-73	10	60.7366	32.5598	- 46.39
Amobarbital II(RS) 11-13-73	10	2.8133	2.4143	- 14.18
Pentobarbital II(RS) 11-13-73	10	17.7319	12.4696	- 29.68
Secobarbital II(RS) 11-13-73	10	49.7339	41.8301	- 15.89

Comparison Group Rates: All other drugs in DAWN data base which did not undergo a control status change at that time.

A: Total DAWN minus listed stimulants (06-15-73/07-06-73) - 2.39%

B: Total DAWN minus Methaqualone (10-04-73) - 1.06%

Total DAWN minus listed barbiturates (11-13-73) - 8.73%

abuse rates does not hold for those drugs that are shifted from a lower to a higher control level; and other factors appear to be more significant within that sub-group.

f) When groups of related drugs are scheduled at approximately the same time, such class-action scheduling seems to leave the original relative positions intact so that decreases in one drug are not accompanied by increases in other drugs within the controlled set. (See NPA trends below).

Fig. 2 provides a more detailed view of the month-by-month pattern of abuse decreases following control status change for this group of rescheduled barbiturate-sedatives over the period from 1QFY74 through 1QFY75. The 3-month moving average represents a smoothed monthly trend and illustrates how long-term trends may be concealed by short-term fluctuations within the raw frequency data, so that turning points may not be identifiable at the time they occur. Fig. 4 shows the changes for the newly-scheduled non-barbiturate sedative in this group.

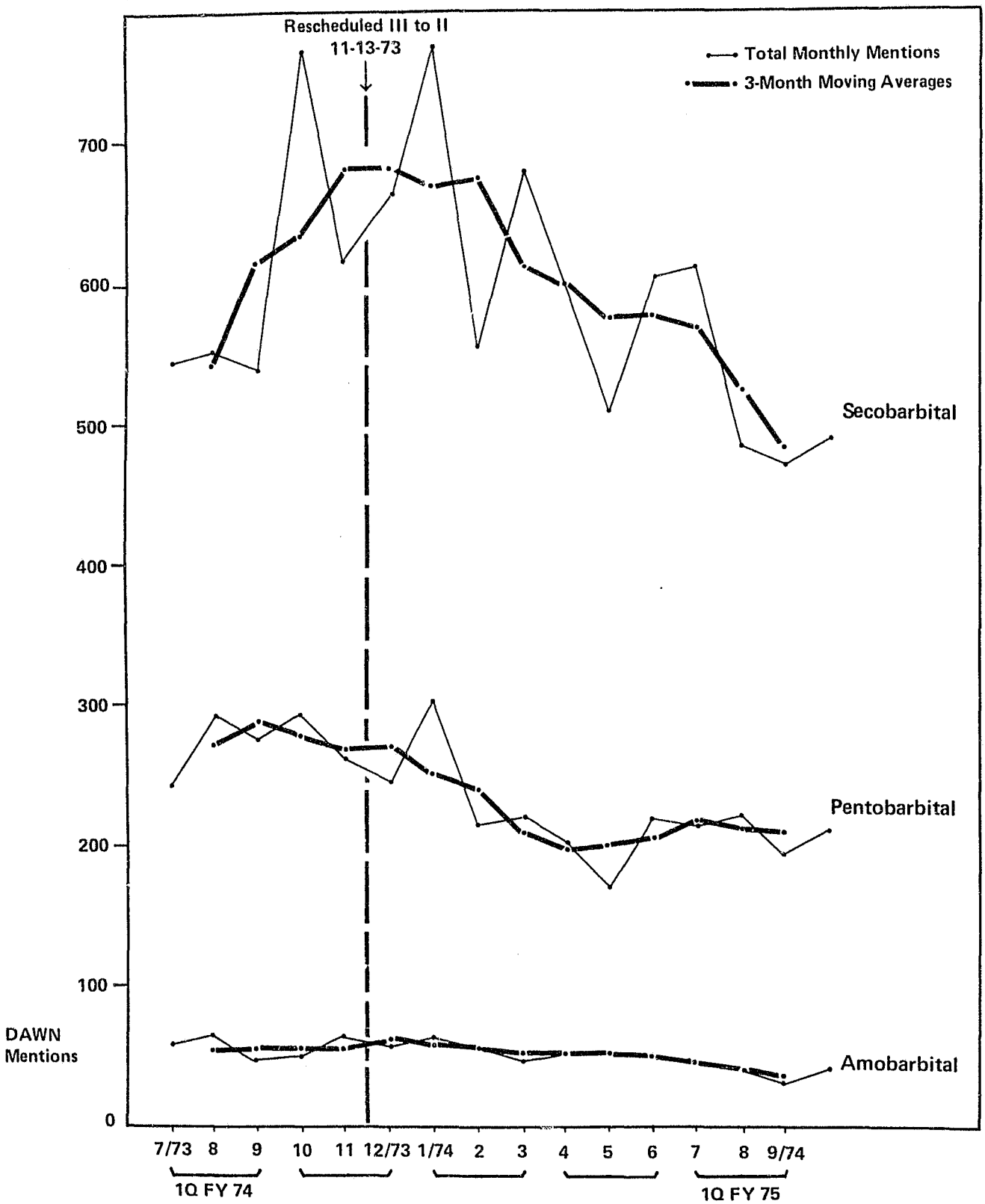
At approximately the same time that the group of anorectics was scheduled, the DAWN data base underwent expansion from DAWN I to II. As a result, the schedule changes and data base changes were confounded across the pre- and post-control periods and it was necessary to statistically control for these differences. As the facility base expanded the raw frequency figures increased, as would be expected even with no change in the basic phenomena being measured. However, when normalized to an abuse rate per reporting facility and summed for all types of facilities, relative stability was shown for the comparison population of all other drugs which did not undergo a control status change across these intervals (per the dotted lines in Fig. 1), while each of the test drugs which did undergo control status changes showed a general pattern of greater decreases. In making this normalization to a facility rate, it was necessary, as a first reasonable approximation, to assume an equal weighting for all facilities of a given type (e.g., emergency rooms) regardless of their individual differences such as size, location, etc.

In addition, both for convenience and comparability with other available data, the present analyses were based on drug "mentions", which indicate the number of reports of a given drug whether used singly or in combination with other substances. But, when the number of abusers is of primary

Figure 2

Trends in Drug Abuse Incidents:

Barbiturates



interest, "episodes" may be used in order to count only a single report for each incident, regardless of the number of substances involved in that particular event. With these cases, the same general results would have been obtained by either method since the frequencies for mentions and episodes were almost identical. For example, the first group of anorectics had equal episodes and mentions for the 8 DAWN II months (245 each) and differed by only one mention during DAWN I (256 episodes and 257 mentions).

It is also possible that the 3-week difference in effective control dates between the anorectic Schedule III and IV subgroups may have contributed to some extent to the relatively smaller decreases for the Schedule IV drugs, which were actually controlled 6 days into the nominal post-control period.

However, for the basic question of whether or not the effects of control are reflected in decreased drug abuse, this possible increase in true difference is irrelevant with these statistical methods. The non-parametric binomial test was used since its evaluation of significance of effect depends only on the direction of the observed differences from the comparison population levels, not on the actual magnitudes of the indicators beyond those threshold levels, and therefore these conclusions are conservative and would not be enhanced by any further decreases.

The basic conclusions, moreover, did not change even when other statistical measures of abuse rates were checked. Equivalent results were obtained when the facility rates were replaced by direct proportions of the raw abuse mentions for the test drugs compared to the total DAWN data base, which tends to verify that the use of facility rates achieved the desired normalizing without altering the basic results for the main questions of interest here.

2. NPA Prescription Trends and Relations to Abuse Rates

Since it is reasonable to expect that observed abuse rates for a given drug may be directly related to the availability of that drug, we may expect that changes in prescription trends might also show scheduling effects. However, those effects may be far from simple since the fact that a drug is scheduled does not prevent the physician from prescribing it whenever he considers it the appropriate form of therapy. On the other hand, the amounts made available through licit sources of supply may change due to other factors which are

not necessarily synchronous with the changes in formal scheduling -- such as increased scientific evidence of a given drug's abuse potential or increased awareness of alternative forms of treatment. When we also consider that licit sources may be supplemented by illicit diversionary sources, we can recognize the need to expand our inquiries to reflect multiple sources and patterns of relations with other alternative drugs.

Overall, our analyses of NPA trends show:

a) Tendencies for long-term decreases in the amphetamine stimulants and barbiturate sedatives to be accompanied by increases in the non-amphetamine stimulants and non-barbiturate sedatives over the six-year interval from 1969 through 1974 (Fig. 3). If we consider the combined overall totals for these sedative groups, we note that maximum total prescriptions were reached in 1971 and over this period an average decrease slope of 2.8% was experienced, with this decreasing trend still evident. For these stimulant categories, however, the maximum prescription level in this period was in 1969 with the overall average decrease of 11.9% tending to bottom-out in 1973.

b) General post-control decreases for both the overall abuse rates and the licit prescription rates, with positive but widely varying correlations with time shown for all drugs tested.

c) Within the sedatives, a much stronger correlation was shown for the previously uncontrolled Methaqualone than for the three previously scheduled barbiturates. Fig. 4 illustrates the strong pattern of synchronous variations between month-by-month abuse rates and NPA prescription levels ($r=0.953$).

Linear regression equations and correlation coefficients were derived for abuse rates and prescription rates with these drugs. Relations were obtained using the linear regression expression $Y_d = mP + b$, with Y_d = the estimated number of DAWN abuse reports per month; m = the slope of the regression line for Y_d as estimated from prescription rates; P = thousands of prescriptions per month; b = the intercept of the regression line with zero prescriptions. For the DAWN II post-control period 7/73 through 9/74 the results showed:

Figure 3

Prescription Trends: Stimulants & Depressants - 1969-74

With Significant CSA Control Actions (↓)

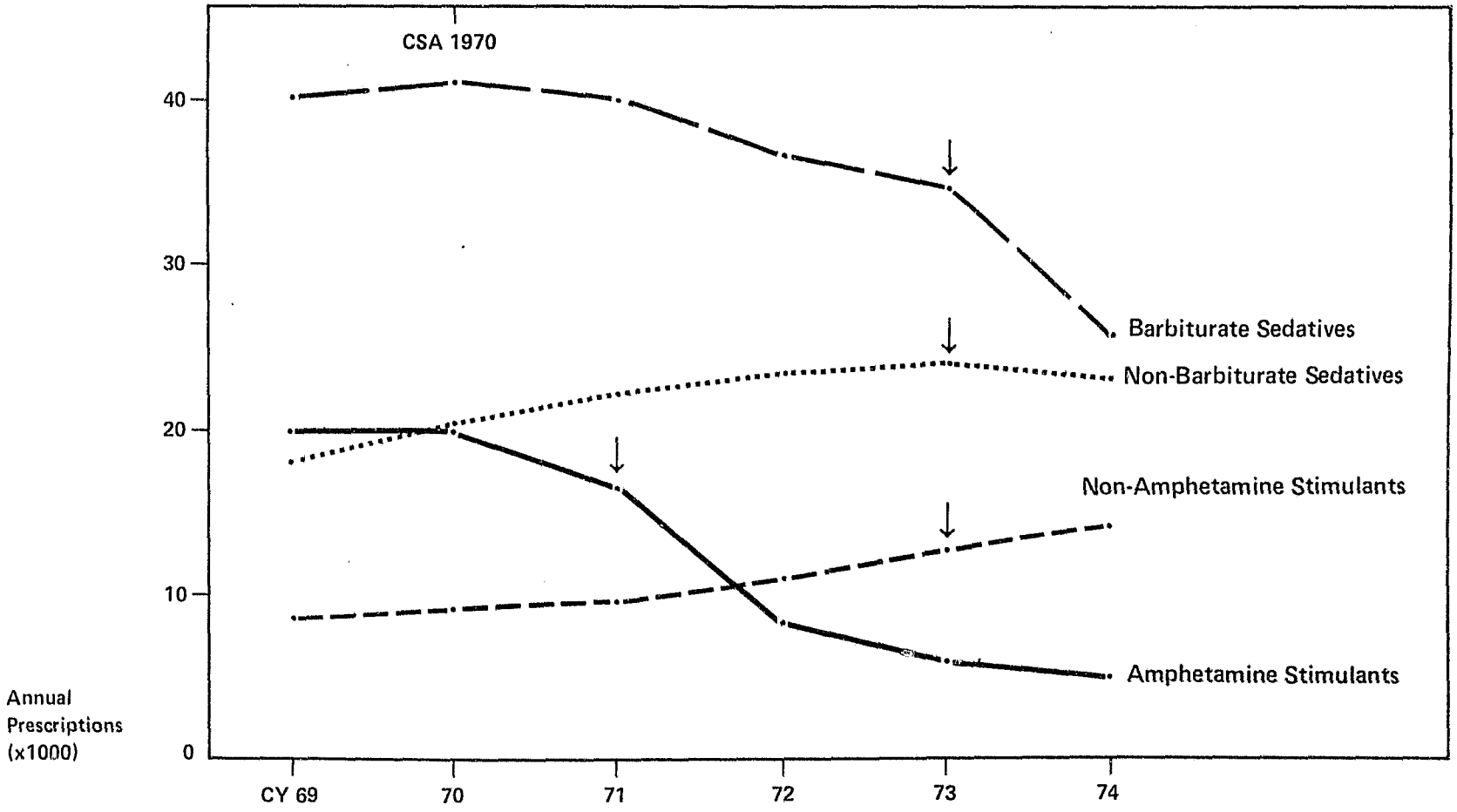
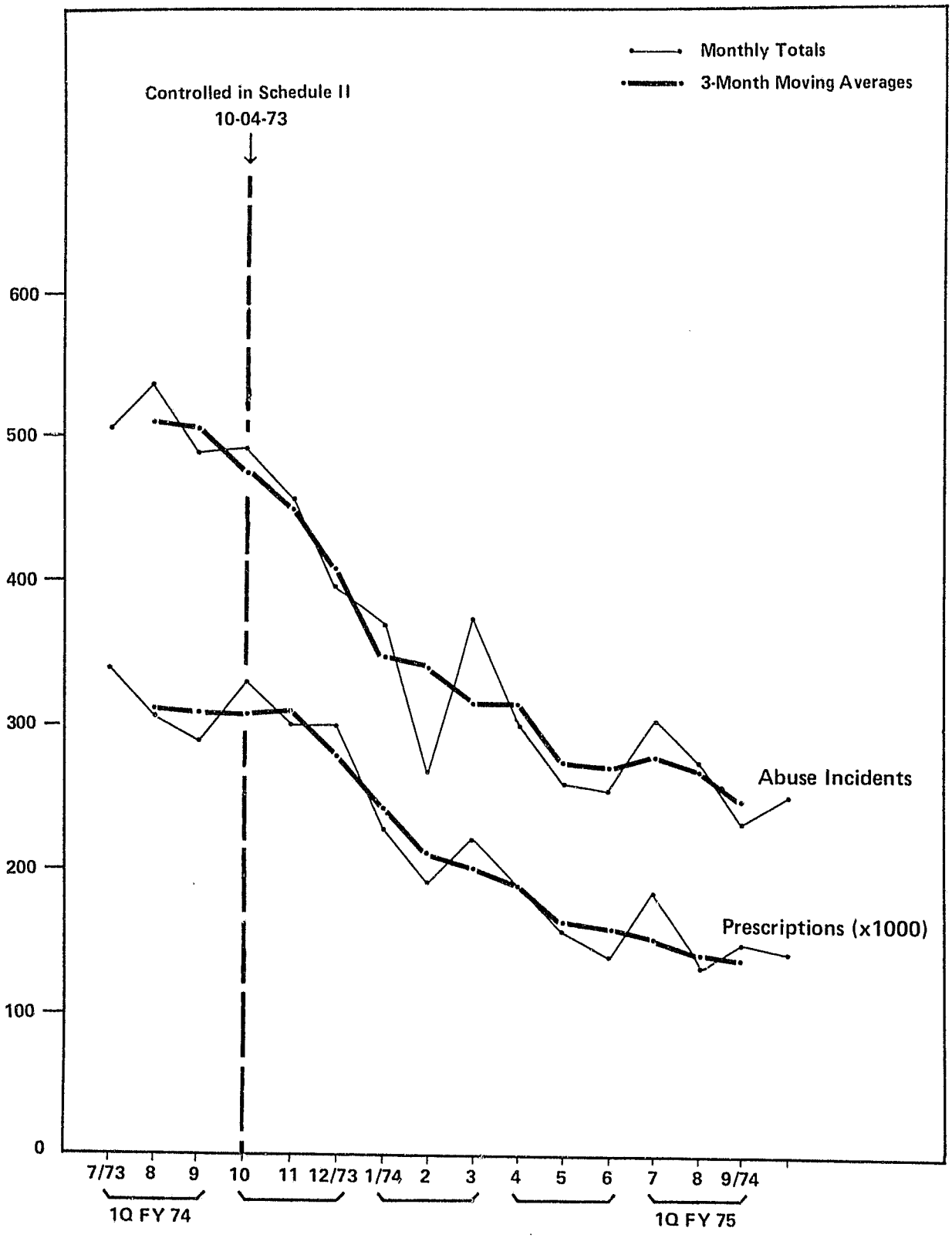


Figure 4

Abuse Incidents & Prescription Trends

Non-Barbiturate Sedative: Methaqualone



- o Methaqualone: $Y_d = 1.35\ P + 56.26$ $r = 0.95307$
- o Amobarbital: $Y_d = 0.12\ P + 40.64$ $r = 0.52887$
- o Pentobarbital: $Y_d = 0.27\ P + 152.94$ $r = 0.26677$
- o Secobarbital: $Y_d = 0.22\ P + 534.42$ $r = 0.22334$

These show several interesting relations that help supplement the direct patterns for the pre- and post-control abuse rates given in Fig 1. For example, we can see that the rate of growth based on licit prescriptions for Methaqualone (1.35 per thousand prescriptions) is about 5 to 10 times as great as the growth rate for any of these barbiturates. Similarly, when the intercept (b) is used as the best estimate for immediate abuse rates if the licit supply were hypothetically suspended, we see that Pentobarbital and Secobarbital would still have approximately 3 times and 10 times as many abuse incidents respectively as Methaqualone. The correlations also suggest that variability in abuse rates for Methaqualone is highly interrelated with variability in prescription rates ($r^2 = .908$, indicating over 90% predictability of the variations in abuse rates). But the barbiturates do not tend to show nearly as much relation to the variations in licit source rates (i.e., Amobarbital = 28%, Pentobarbital = 7% and Secobarbital = 5%). There is a strong implication that secondary and illicit sources play relatively stronger roles in abuse rates for these drugs.

The corresponding curves for the rescheduled barbiturates show far greater variability in the DAWN incidents than in the NPA sales, and there is a clear suggestion that the underlying user-level availability was based largely on illicit diversionary sources of supply, rather than the immediate acquisition-consumption pattern via licit sales that is apparent with Methaqualone. Logically, it appears possible that Methaqualone's pattern may eventually change to be more similar to that shown for the barbiturates, with decreased correlation and increased variability over time.

Overall availability, as inferred from relations within prescriptions and abuse rates, was far greater for this group of sedatives than for the group of newly controlled stimulants (See also Fig. 1).

As a last look at the role played by drug availability in regard to abuse trends, Table 2 summarizes quarterly trends in the sources reported by DAWN cases for these drugs. The dominant qualitative observation suggested by these trends is that the proportions within each drug for the different sources (R_x or non-R_x) appear relatively stable over these periods. Even though the overall total abuse rates may decline sharply (e.g., Methaqualone dropped to approximately half its rate from 1QFY74 to 1QFY75), there is no apparent shift in tendency toward one type of source or another.

Rationales may be made for assuming that increased controls might tend to shift abuse patterns toward either licit or illicit sources after control. For example: a) Physicians might tend to prescribe more conservatively and eliminate marginal cases with abuse potential, but without connections to illicit sources. This would tend to leave only those patients having real medical needs, who could be considered unlikely to abuse the drug, and would thereby decrease both the number and proportion of abuse cases who obtain the drug via such prescription sources; or b) If diversion from overprescribing through licit sources tends to decrease relatively more rapidly than overall prescription levels, thereby affecting some illicit secondary sources for excessively available drugs, a shift toward such increasedly conservative prescribing might tend to result in an apparently greater proportion of licit sources in abuse reports. Such possibilities, of course, can coexist and would require additional data beyond those now available in order to be able to clarify the circumstances influencing each possible pattern.

3. Side-Effects on Medical Availability and Criminalization

Many types of side-effects can be argued as potentially resulting from drug control. Such effects may be considered part of the concommitant costs required to gain the desired benefits of decreased drug abuse and may range from relatively minor inconvenience, to decreased availability to the medically needy, to possible criminalization of users who would not otherwise be considered law violators. Under ideal conditions, any unwanted side effects would be avoided or, if they do occur, would be minimal and fully correctable.

To the extent that they can be qualitatively or quantitatively identified, such side-effects may be used to supplement other indicators of the effectiveness of present drug control procedures and to indicate areas for potential change in existing

Table 2. Sources of Drugs Reported in Abuse Incidents: 1QFY74 Thru 1QFY75

(Prescriptions - vs - All Other Sources)

Drugs:	Sources:	Quarterly Mentions (and Percent of Quarter Total):				
Sedatives		1QFY74 7/73-9/73	10/73-12/73	1/74-3/74	4/74-6/74	1QFY75 7/74-9/74
Methaqualone	Rx	322 (21.7)	276 (20.7)	244 (24.2)	210 (25.5)	176 (22.1)
	Other	1165 (78.3)	1055 (79.3)	764 (75.8)	615 (74.5)	619 (77.9)
	Total	1487 (100.)	1331 (100.)	1008 (100.)	825 (100.)	795 (100.)
Secobarbital	Rx	451 (28.9)	527 (27.3)	509 (27.7)	420 (27.0)	377 (26.1)
	Other	1108 (71.1)	1403 (72.7)	1331 (72.3)	1133 (73.0)	1065 (73.9)
	Total	1559 (100.)	1930 (100.)	1840 (100.)	1553 (100.)	1442 (100.)
Pentobarbital	Rx	328 (44.0)	301 (39.4)	267 (39.7)	211 (40.0)	225 (40.8)
	Other	418 (56.0)	463 (60.6)	406 (60.3)	317 (60.0)	326 (59.2)
	Total	746 (100.)	764 (100.)	673 (100.)	528 (100.)	551 (100.)
Amobarbital	Rx	47 (37.0)	47 (39.8)	48 (41.0)	33 (34.4)	29 (41.4)
	Other	80 (63.0)	71 (60.2)	69 (59.0)	63 (65.6)	41 (58.6)
	Total	127 (100.)	118 (100.)	117 (100.)	96 (100.)	70 (100.)

mechanisms. Unfortunately, existing records do not tend to provide much direct information on such effects and offer very little that is suitable for qualitative or quantitative evaluation.

One of our major areas of concern is to assure that controls do not result in decreased availability of medically useful drugs to those who require them. But, beyond the marketing measures of availability, such as the NPA, no indices exist to chart the physician-patient impacts.

Accordingly, exploratory discussions were held with a panel of the DEA and NIDA medical staffs to review effects on prescribing practices and availability to patients. The panel members attempted to reflect information derived from their knowledge of government records and participation in professional group exchanges. The consensus for the general situation, and for this specific sample of controlled substances, was that:

a. The problems, if any, are very small in terms of the numbers of complaints about decreased availability due to regulatory limitations or changes in prescribing practices.

b. Corrective mechanisms already available within existing procedures appear to be adequate for prompt and complete correction of those few instances which do occur.

c. No clear common denominators appear to characterize known cases, and available anecdotal data are inconclusive. The DEA files were examined for letters of complaint or inquiry. Only three cases were identifed for these stimulants and depressants and they confirm the observations summarized above.

Since the objectives for our initial efforts were to explore the feasibility of using available data resources to evaluate the overall effects of control schedule decisions, we have not attempted extensive surveys of users, physicians, pharmacists, professional organizations or other populations that might provide additional in-depth information on these points.

However, based on the results of our reviews of available information, we believe that although such extensive studies

would probably offer further insights into the detailed aspects of drug availability, they would probably not show conditions to be radically different than the consensus indicated here.

Another area of concern was the possibility that large numbers of arrests would be made for possession of small quantities of these drugs, with resulting criminalization of persons who would not otherwise have been involved with the criminal justice system. To explore the extent to which such criminalization actually occurred with these stimulants and depressants, DEA's Statistical and Data Services Division reviewed the federal files for FY 74, and all cases involving purchases or seizures of any amounts of these drugs were analyzed.

Of the 294 cases for these drugs, 98% were considered to be not newly criminalized by these control and enforcement processes. These cases were considered not criminalized since they involved one or more of the following criteria used to define those arrests involving more than simple personal use:

- Cases also involving narcotics
- Cases involving arrests for sale, distribution or importation
- Cases with more than 500 dosage units of any of these drugs or also having more than 500 dosage units of other dangerous drugs
- Cases involving individuals armed, or with prior criminal records

The total of 7 individuals out of 294 federal FY 74 cases in this initial overview, does not indicate any large criminalization effect. However, since most possession cases for the lesser dangerous drugs are made at the local levels, further reviews of State and local records would be needed to analyze the numbers and proportions of criminalized cases, if any, at those levels.

In terms of the presently available information, however, wholesale arrest and criminalization of otherwise innocent citizens due to their possession of small quantities of these drugs for personal use does not appear to be a significant deleterious effect of changing their control status.

Other areas of related concern, such as drug prices, were also identified. Initial overviews of available data revealed no clear effects attributable to drug control, but all the relevant factors could not be fully explored within the limited data. Indepth economic studies would be needed to clarify the interactive roles of current economic conditions, and normal competitive adjustments within the total pharmacological market, on specific drug prices. But control status changes do not appear to necessarily result in changes in the prices or in the availability of the drugs to those who need them.

SUMMARY

In this report, we have briefly explored some important aspects of the effects of drug control, our efforts to continually develop improved methods for assessing those effects, and their relations to drug control decisions.

Quantitative and qualitative analyses were made of data on drug abuse trends for nine recently controlled drugs, covering five anorectic stimulants and four depressants, including three barbiturates and one non-barbiturate sedative controlled in mid and late 1973. Significant patterns of reductions in drug abuse rates were found for all of these drugs. Moreover, these desired benefits did not tend to be associated with significant levels of undesired side-effects -- medical prescribing practices were not inhibited and ready availability of these drugs for medical needs was maintained, and no large arrest and criminalization of otherwise innocent users was found.

These near-term effects, of course, cannot be expected to be static. Further monitoring and evaluation of long-term trends must be made in order to permit the maintenance of these improved abuse patterns and to develop additional insights into the complex relations affecting the balances between necessary drug availability and undesired drug abuse.

END