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United States General Accounting Office Washington, D.C. 20548

Human Resources Division

B-240367

September 12, 1990

The Honorable Charles Rangel Chairman, Select Committee on Narcotics Abuse and Control House of Representatives

Dear Mr. Chairman:

In response to your request, we (1) assessed the current state of knowledge regarding drug abuse treatment, (2) identified what has influenced the state of knowledge regarding drug abuse treatment, and (3) determined current activities at the National Institute on Drug Abuse aimed at developing knowledge regarding drug abuse treatment. Recommendations to the Secretary of Health and Human Services are included in the report.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report for 15 days. At that time, we will send copies to the Secretary and to other interested parties.

Please contact me on 275-6195 if you or your staff have any questions concerning this report. Other major contributors are listed in appendix III.

Sincerely yours,

Mark V. Nadel

Associate Director, National and

Mark V. Hadel

Public Health Issues

Executive Summary

Purpose

Drug abuse is one of our most serious domestic problems, adversely affecting not only the individual user but society as a whole. The Chairman of the House Select Committee on Narcotics Abuse and Control expressed concern over whether investments in research have produced useful knowledge about existing treatments for drug abuse as well as progress in the development of future treatments. The Chairman asked GAO to (1) assess the current state of knowledge regarding drug abuse treatment, (2) identify what has influenced the state of knowledge, and (3) determine current activities at the National Institute on Drug Abuse (NIDA) aimed at developing such knowledge.

Background

Widespread drug abuse is not a new problem. What is new is how drugs are being used and who is using them. Cocaine and its crystalline form, crack, are now more widely used than heroin, which was previously the larger problem. The emergence of new drugs, such as "ice," and the use of combinations of drugs have confounded attempts at treatment. In recent years many women have become addicted. All of these trends further strain the capabilities of the treatment system, which was designed primarily to treat male heroin addicts.

NIDA is the key federal agency responsible for supporting research on drug abuse treatment. It also supports research on the mechanisms through which drugs act in the nervous system, epidemiological studies of the incidence and prevalence of drug abuse, and research aimed at decreasing the spread of AIDS by intravenous drug abusers.

Until 1986, NIDA's research budget was relatively small. Since then its budget has increased dramatically due to the growing drug abuse problem and concerns over the absence of information on the effectiveness of drug abuse treatment. The agency's funding was \$85,392,000 in fiscal year 1986, jumped to \$152,477,000 in 1987, and will grow to \$379,734,000 in 1990.

Results in Brief

During the 1980s, while the nature of the drug abuse problem fundamentally changed, knowledge on how to treat drug abuse advanced slowly. NIDA's relatively low research budget during most of that decade accounts in part for this slow progress. The lack of a strategic plan to direct drug abuse research and the lack of emphasis on the training of drug abuse researchers also slowed progress in understanding how to treat drug abuse.

Executive Summary

Knowledge about drug abuse treatment is limited in significant ways. Knowledge concerning the effectiveness of drug abuse treatments is limited by the lack of recent large-scale evaluations of treatment programs and methodological shortcomings of existing evaluations. Also, little is known about how to match patients with the most appropriate treatment, the effectiveness of certain components of treatment programs, and how best to treat individuals addicted to new drugs.

Despite the recent cocaine and crack epidemic, NDA's treatment research program has given priority to developing therapies for addiction to heroin and other opiates. NIDA has recently begun to place additional emphasis on developing therapies for cocaine abuse, but results from this research are not expected for several years.

Principal Findings

Gaps in Knowledge About Drug Abuse Treatment

Research knowledge applicable to drug abuse treatment has not significantly advanced in the last decade. There are no recently completed national evaluations of treatment programs, and earlier evaluations may have limited applicability to today's population of drug abusers. Treatment effectiveness depends, in part, on matching patient needs to appropriate types of treatment. However, knowledge on patient-treatment matching is limited. Although cocaine abuse became a widespread problem during the 1980s, knowledge on how to treat it is in the early stages of development. (See pp. 15-19.)

NIDA Has Not Implemented a Strategic Plan for Its Research

Gaps in knowledge on drug abuse treatment have not been overcome partly because NIDA has not had a strategic planning process to assure that the research it funds is targeted at the most critical needs. NIDA's treatment research priorities may not adequately address current needs. NIDA's support of research on the development of new treatments places greatest emphasis on opiate abuse, although cocaine/crack abusers now far outnumber opiate abusers. In addition, NIDA has not systematically involved treatment practitioners, who will ultimately use the results of treatment research, in its decision-making regarding treatment research priorities. NIDA has begun to establish a strategic planning process and plans to involve treatment practitioners in this process. (See pp. 20-24.)

Funding for Research Training Has Not Kept Pace With Research Funding

Funding for the training of drug abuse researchers has not kept up with increases in funding for drug abuse research. This limited funding for training has slowed progress in drug abuse treatment research. Training is important to maintain an adequate supply of researchers capable of conducting drug abuse treatment research, particularly in light of the increased availability of research funds. NIDA recognizes this problem and has recently begun to increase funding for training. However, neither NIDA nor the Alcohol, Drug Abuse, and Mental Health Administration, which oversees NIDA, has information on the current supply of and future need for drug abuse treatment researchers. This information is needed in order to plan the appropriate amount of funding to be allocated to research training. (See pp. 29-32.)

Recommendations

GAO recommends that the Secretary of Health and Human Services direct NIDA to implement its strategic planning process and develop a plan that sets forth its long-term overall treatment research objectives and the relative priorities assigned to the different categories of treatment research. This plan should consider (1) current and anticipated trends of drug abuse and (2) the needs of treatment practitioners, who have a key stake in the results of NIDA's research. In addition, the Secretary should direct the Alcohol, Drug Abuse, and Mental Health Administration or NIDA to determine how many researchers are needed to carry out planned research and take appropriate action to ensure their availability.

Agency Comments

GAO did not obtain written comments on this report. GAO discussed the issues in the report with agency officials and included their comments where appropriate.

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Abbreviations

ADAMHA	Alcohol, Drug Abuse, and Mental Health Administrat	ion
AIDS	acquired immunodeficiency syndrome	
GAO	General Accounting Office	
HIV	human immunodeficiency virus	
NIAAA	National Institute on Alcohol and Alcohol Abuse	
NIDA	National Institute on Drug Abuse	
NIMH	National Institute on Mental Health	
PHS	Public Health Service	

Introduction

Fighting the problem of drug abuse in the United States is a leading domestic priority. Drug abuse costs billions every year in expenditures for prevention and treatment programs, costs incurred by the criminal justice system in dealing with drug-related crime, and welfare support for drug abusers and their dependents. It imposes additional costs in the form of health care expenditures for the increasing numbers of intravenous drug abusers developing AIDs each year as well as for care of babies born exposed to drugs or infected with HIV¹ as a result of their mothers' abuse of drugs. In the face of the financial and social toll drug abuse has taken on the nation, it is important for decision makers to know whether existing treatments are effective and what the status is of new treatment approaches.

Concern over how much is known about the effectiveness of existing treatments for drug abuse as well as the status of development of future treatments led the Chairman of the House Select Committee on Narcotics Abuse and Control to ask us to (1) assess the state of knowledge regarding drug abuse treatment, (2) identify what has influenced the state of knowledge regarding drug abuse treatment, and (3) determine the National Institute on Drug Abuse's (NIDA) current activities aimed at developing knowledge regarding drug abuse treatment.

Drug Abuse Patterns Heighten Concern Over Treatment Effectiveness

Research that evaluates the effectiveness of current treatments for drug abuse and leads to the development of new treatments is particularly critical given current patterns of drug use in the United States. The 1990 National Drug Control Strategy calls for using knowledge from such research as a basis for developing treatment strategies.²

Trends in Drug Use

Although the overall number of people who abuse drugs has decreased, drug abuse remains widespread and trends in cocaine use and the emergence of new drugs, such as "ice," raise concerns. The 1988 National

¹The human immunodeficiency virus (HIV) causes acquired immunodeficiency syndrome (AIDS), a fatal disease that severely compromises the human body's ability to fight infections.

²The Anti-Drug Abuse Act of 1988 requires the President to, among other things, submit to the Congress each year a National Drug Control Strategy that sets forth comprehensive, research-based, long-range goals for reducing drug abuse in the United States and includes short-term measurable objectives determined by the Director of the Office of National Drug Control Policy that may be realistically achieved in a 2-year period.

Household Survey³ reported that current illegal drug use has declined significantly throughout the United States among most groups of people and for most illegal drugs. At the same time, however, the number of those making habitual use of cocaine doubled from 1985 to 1988. Much of this increase has been attributed to the use of crack, which is a smokable form of cocaine. Of those surveyed, cocaine use was highest among the unemployed and those aged 18-25. The survey also showed that over 5 million (9 percent) of the nearly 60 million women 15-44 years of age, the childbearing years, used an illicit drug in the month before the survey.

Monitoring of trends in cocaine use shows that generally, there has been a tripling of cocaine-related deaths and a five-fold increase (from 1984 to 1988) in the number admitted to hospital emergency rooms following cocaine use. According to data from the Drug Abuse Warning Network, by 1988, cocaine use exceeded that of heroin and marijuana among emergency room cases and those reported by medical examiners.

In addition, new drugs are emerging, such as "ice," a smokable form of the stimulant methamphetamine. Produced largely in Asian laboratories, "ice" first entered the United States through Hawaii, and it is rapidly becoming a widely used illegal drug. Results of a 1989 survey of drug use⁵ found that the annual prevalence use of this drug in 1989 was about 1.2 percent nationally among high school seniors. In the West, the region expected to be most affected, it was more than twice that (3 percent).

Polydrug use, use of drugs in combination, is another growing trend among those abusing drugs. A 1990 GAO report found that at methadone clinics, besides heroin, patients used other drugs—primarily cocaine,

³The primary data source for determining the incidence and prevalence of drug abuse in the United States among the entire population aged 12 years and older. The results of the 1988 survey are based on personal interviews combined with self-administered answer sheets from respondents randomly selected from the household population.

⁴A large-scale, ongoing drug abuse data collection system sponsored by NIDA. Data from the network are obtained from a nonrandom sample of hospital emergency rooms and medical examiners primarily located in large metropolitan areas. The network collects information about drug abuse related to those seeking hospital emergency room treatment and to deaths reported by medical examiners.

⁵A large-scale epidemiological survey of drug use, the Monitoring the Future Study, was initiated in 1975 through a grant awarded by NIDA to the University of Michigan's Institute for Social Research. This survey measures drug abuse prevalence among high school seniors and graduates, as well as college students from 19 to 30 years old. It is conducted annually to monitor trends in drug abuse and drug-related attitudes in adolescents and young adults at important transitional points in their lives.

but also amphetamines, benzodiazepines (a class of drugs used for treating anxiety and sleep disorders), or alcohol.⁶

Efficacy of Available Treatments for Drug Abuse

Changing patterns in drug use challenge the treatment system. Many programs were designed to treat heroin abuse rather than cocaine/crack addiction or the combined use of drugs. Also, most programs were developed to treat male drug abusers and are not tailored to meet the needs of female addicts, particularly pregnant addicts.

Existing treatment modalities may not be as effective in treating newer patterns of abuse. Current programs to treat drug abuse fall under five broad categories: (1) detoxification programs, usually inpatient, which have the short-range goal of ending users' physical addiction to drugs; (2) mainly private inpatient or residential 3- to 4-week programs, which may provide medical treatment and other services to treat chemical dependency; (3) outpatient clinics, which offer counseling and support for those who want to quit using drugs while they continue to function in the community; (4) methadone maintenance programs, which treat heroin addicts by coupling counseling with the administration of methadone, a medication that "blocks" the craving for heroin while eliminating the usual pain of withdrawal; and (5) residential therapeutic communities, where users spend up to 18 months in a highly structured program to end their drug addiction. In addition, there are support groups such as Narcotics Anonymous, which can serve as a substitute for or an extension of other approaches.

Much of the available data on program effectiveness are based on studies of clients who were enrolled in treatment programs 10 or more years ago. Data from these studies for methadone maintenance programs, therapeutic communities, and outpatient drug-free programs indicate better treatment results for patients who remain in treatment longer. Given changing drug use patterns, however, the results of these studies may not be generalizable to the current population of treatment clients.

⁶Methadone Maintenance: Some Treatment Programs Are Not Effective; Greater Federal Oversight Needed (GAO/HRD-90-104, Mar. 22, 1990).

NIDA Is the Key Agency for Developing Knowledge on Drug Abuse Treatment

Both the Congress and the administration have recently increased support for the development of knowledge on drug abuse treatment. For example, the 1988 Anti-Drug Abuse Act authorized research to evaluate the quality, appropriateness, and costs of various forms of alcohol and drug abuse treatment programs.

In 1989, the President's first National Drug Control Strategy expressed the need for research to evaluate treatment programs to determine "what works." The strategy also stressed the importance of research in the development of new treatments. More recently, the January 1990 National Drug Control Strategy noted that the administration intends to devote \$183 million in new fiscal year 1991 funding to support drug treatment research and development, including \$17 million for data collection and evaluation.

The agency primarily responsible for implementing congressional and administration initiatives on drug abuse treatment research is NIDA. NIDA supports a broad range of research. This includes research on the mechanisms through which drugs act in the nervous system, clinical studies of the effectiveness of new and innovative approaches to the treatment of drug abuse, and epidemiological studies of the incidence and prevalence of drug abuse in the United States. NIDA also supports AIDS-related research aimed at developing better ways to encourage intravenous drug users to enter treatment and to stop the spread of AIDS from intravenous drug users to their sexual partners and children.

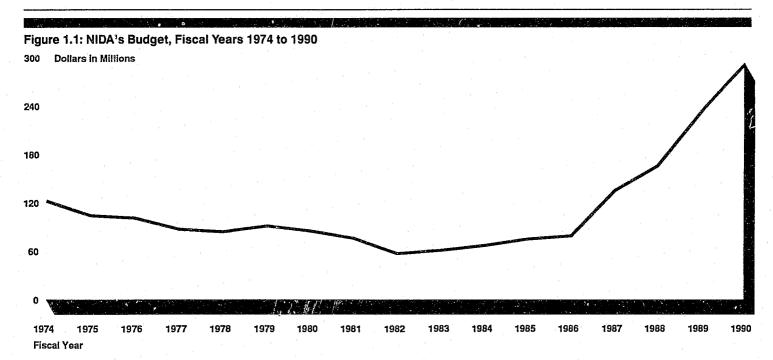
NIDA is one of three institutes within the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), which is an agency within the Department of Health and Human Services' Public Health Service (PHS). Another institute, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), also has funded some research aimed at improving the effectiveness of substance abuse treatment. While a number of other PHS units are also involved in efforts to reduce drug abuse, such as the National Institutes of Health, Centers for Disease Control, Health Resources and Services Administration, and Food and Drug Administration, drug abuse is not central to their missions. In addition, the Department of Veterans Affairs conducts some drug abuse treatment research.

NIDA's role has changed a great deal over time. NIDA was established in 1974 to manage categorical grants for drug abuse prevention and treatment as well as to conduct drug abuse research and disseminate information about drug abuse. During the 1970s, NIDA monitored and supported the development of state and local prevention and treatment

services. NIDA's responsibility for managing the national treatment system ended in the 1980s. The Omnibus Budget Reconciliation Act of 1981 replaced the substance abuse categorical grants with block grants, giving states greater control of prevention and treatment services. As ADAMHA, NIDA's parent organization, took over management of the block grants, NIDA's budget dropped substantially, and the agency shifted its focus to basic and clinical research on drug abuse and decreased its activities aimed at collecting data on and evaluating treatment programs.

However, in recent years, administration and congressional interest in drug abuse has led to a dramatic growth in NIDA's budget (see fig. 1.1). In 1982, NIDA's total budget was cut as a result of the elimination of its responsibilities for managing categorical grants for drug abuse treatment services. NIDA's budget (in current dollars) dropped from \$243.9 million in fiscal year 1981 to \$57.3 million in fiscal year 1982. The community services portion of NIDA's budget, which had supported the management of treatment services as well as research on treatment, was eliminated at that time.

NIDA's budget began to increase gradually in fiscal year 1983 and by fiscal year 1986 the Institute's funding was \$85,392,000. By fiscal year 1989, funding had jumped to \$290,023,000, an increase of 240 percent. In fiscal year 1990, NIDA funding increased to \$379,734,000, about 31 percent above last year's level.



Notes: Amounts include both regular and AIDS funding. Amount for fiscal year 1990 is estimated.

Amounts do not include the community services portion of NIDA's budget, which was eliminated in fiscal year 1982 as a result of the termination of NIDA's responsibilities for managing categorical grants for drug abuse treatment services.

in constant 1982 dollars.

Objectives, Scope, and Methodology

The objectives of our review were to answer the following questions:

- What is the current state of knowledge regarding drug abuse treatment?
- What has influenced the current state of knowledge regarding drug abuse treatment?
- What activities is NIDA currently engaged in to develop knowledge regarding drug abuse treatment?

To accomplish these objectives, we obtained information from NIDA officials regarding NIDA's current and planned research and training activities. As part of our review of NIDA's activities, we reviewed information on NIDA's current research related to drug abuse treatment. Although NIDA produces a yearly estimate of the total amount it allocates to treatment research, it did not have a readily available breakdown of the types of treatment research that it funds. We developed a breakdown of treatment research categories based on meetings with representatives of

NIDA's research divisions. NIDA's divisions then used these categories to give us information on all of their fiscal year 1989 treatment-related research and demonstration projects. NIDA officials reviewed and approved the resulting categorization of NIDA's fiscal year 1989 extramural treatment research.

We also obtained perspectives from eight leading researchers and treatment practitioners regarding the adequacy of NIDA's research and training activities aimed at developing knowledge on drug abuse treatment and the factors that influenced the current state of knowledge. In selecting these individuals, we asked the Director of NIDA, the Deputy Director for Demand Reduction of the Office of National Drug Control Policy, and heads of key drug abuse associations to name experts on drug abuse treatment from a variety of fields. We chose to interview those individuals who were named most often and who represented various fields of drug abuse treatment research and practice. We asked these experts for their views regarding the current state of knowledge on drug abuse treatment, the factors that have influenced this state of knowledge, and the appropriateness and adequacy of NIDA's research and training activities aimed at developing knowledge on drug abuse treatment.

Our work was performed from March 1989 to January 1990 in accordance with generally accepted government auditing standards.

Despite advances in knowledge of the behavioral, biomedical, and neurobiological factors involved in drug abuse, there are significant limitations in knowledge of drug abuse treatment. These limitations have not been overcome, in part because NIDA has not had a strategic planning process. Rather, NIDA has planned its research within the context of the annual budget process, which does not address the long-term future direction of NIDA's research program. Therefore, while much of NIDA's research aims to improve drug abuse treatment, NIDA has not developed an overall strategic plan for its treatment research to assure that research results will address current and anticipated treatment needs. Such a process could assist NIDA in identifying gaps in knowledge and planning long-term strategies for addressing these gaps.

Knowledge Regarding Drug Abuse Treatment Is Limited

NIDA believes that the major achievements of its drug abuse research funding have been the identification of a number of behavioral, biomedical, and neurobiological factors involved in drug abuse. A 1989 Public Health Service Committee Report concluded that funding of biomedical research has resulted in the discovery of sites in the central nervous system where specific drugs act. This discovery and others like it may eventually lead to the development of new treatments for drug abuse.

Despite such advances, research knowledge is limited concerning the relative effectiveness of existing drug abuse treatments and the design of new treatments for cocaine abuse. Knowledge concerning the effectiveness of existing treatment programs is limited by a lack of recent large-scale evaluations and monitoring of treatment programs, methodological shortcomings of existing evaluations, a lack of knowledge on how best to match the type of treatment to the characteristics of the patient, and a lack of knowledge regarding the effectiveness of certain components of treatment programs. Knowledge concerning new treatments for cocaine abuse is also in the early stages of development.

¹State of the Science Report on Current Status of Drug Abuse Research, A Report Prepared for the Assistant Secretary for Health by the Workgroup on Research, PHS Committee to Reduce the Demand for Illicit Drugs, August 1, 1989.

No Current Large-Scale Evaluations and Monitoring of Treatment Programs No large-scale evaluations of drug abuse treatment programs have been completed in recent years. During the 1970s and early 1980s, NIDA funded two broad long-term studies of treatment results: the Drug Abuse Reporting Program, which tracked a sample of clients who were enrolled in treatment from 1969 to 1973, and the Treatment Outcome Prospective Study, which tracked clients who were enrolled in treatment from 1979 to 1981. NIDA also funded a large effort to collect data on the characteristics of treatment programs. The studies were completed in the early 1980s, and because of a lack of funding, no new studies were initiated. The data collection effort was terminated with the advent of block grants. The studies, along with the data collection effort, were key in providing longitudinal information on the effectiveness of drug abuse treatment.

The two long-term studies showed that treatment was effective in reducing drug abuse, reducing criminal activity, and increasing employment, but these conclusions applied to an earlier population of drug abusers. It may be difficult to generalize these findings to the current population of drug abusers and to current treatment programs due to dramatic changes in patterns of drug use and treatment.

In addition, a comprehensive system for collecting data on clients of drug abuse treatment programs, the Client Oriented Data Acquisition Process, begun in 1972, was terminated because states were no longer required to report such data after the Omnibus Reconciliation Act of 1981, which instituted block grants. Under the data acquisition process, treatment facilities that received PHS funds were required to report data on all clients, not just those who were federally funded. Data were used for studying trends at the national, state, or metropolitan area levels.

Treatment Evaluations Compromised by Methodological Problems The methodological shortcomings of treatment evaluations limit the conclusions that can be drawn from them. A major methodological problem that limits comparisons across studies is the lack of a standard measure of treatment effectiveness. Drug use is measured in a number of different ways in drug treatment outcome studies.² Different measures of outcome may yield different results, making comparison across studies difficult. For example, a common outcome of drug use reported in

²Elizabeth Wells, J. David Hawkins, and Richard F. Catalano, Jr. "Choosing Drug Use Measures for Treatment Outcome Studies. I. The Influence of Measurement Approach on Treatment Results." <u>The International Journal of the Addictions</u>, 23(8), 851-873, 1988.

follow-up studies is the abstinence achieved by patients in drug treatment programs. However, measures of abstinence range from the percentage of patients using no illicit drugs during one or more months after treatment to continuous measures, such as the number of drug-free months in a given period.

Methodological difficulties also result from the nature of research on drug abuse treatment. A recent review of the literature on drug abuse treatment effectiveness notes that evaluations in this area are complicated by the difficulty of conducting experimentally controlled studies and of comparing levels of behaviors (such as drug use, crime, and employment) before, during, and after treatment.³ The lack of control groups in these studies makes the conclusions tentative, because factors other than treatment, such as subjects growing older, may account for improvements in outcome.

Criteria Lacking for Matching Individuals to Appropriate Treatment

There is also limited knowledge on how best to match the most appropriate treatment to the individual characteristics of the patient. The September 1989 National Drug Control Strategy states that there needs to be a better understanding of what treatment methods are most effective for different types of addicts and different drug dependencies. Some experts we interviewed cited this as a major gap in knowledge. Such matching is considered important given major differences among patients and treatments and because it could potentially increase effectiveness and efficiency in providing treatment.

Lack of Knowledge on Effectiveness of Treatment Components

Little information exists concerning the effectiveness of certain components of treatment programs. These can consist of pharmacologic and nonpharmacologic therapies that can be used separately or in tandem as components of treatment programs. Pharmacologic therapies consist of the use of treatment medications, such as methadone. Nonpharmacologic therapies consist mainly of a number of psychosocial treatments, such as counseling, psychotherapy, and behavioral therapy. Although the physiological effects of existing pharmacologic therapies are relatively well understood, little is known about the effectiveness of psychosocial components of treatment.

³M. Douglas Anglin and Yih-Ing Hser, "Treatment of Drug Abuse," in forthcoming volume <u>Crime and</u> Justice: An Annual Review of Research.

Psychosocial treatment components can also include relapse prevention techniques. Relapse prevention, the primary goal of "aftercare," is intended to prevent patients from returning to drug abuse by providing them with strategies to ensure that they can maintain a life free of drug dependence. Some researchers we interviewed and the 1989 PHs report pointed out that relapse prevention is an aspect of treatment that has received inadequate attention. The report identified a need to study how to develop and incorporate prevention strategies during treatment, such as helping clients to anticipate and recognize relapse, facilitating reentry to treatment in the event of a relapse, and developing constructive alternative responses to stimuli that can lead to relapse.

Lack of Knowledge on Treating Newer Patterns of Abuse

Not only is there limited knowledge on existing treatments, knowledge on how to treat newer patterns of abuse is also limited. NIDA's extramural treatment research agenda has emphasized funding research to develop therapies for opiate abuse and only more recently has placed added emphasis on developing therapies for cocaine abuse.

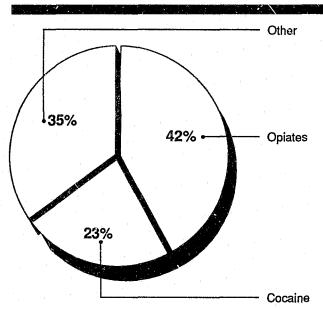
Using data provided by NIDA division directors on extramural research funding, we found that in fiscal year 1989 about 39 percent, or \$103.3 million, of NIDA's \$266.1 million budget for extramural research and demonstrations⁴ was allocated to research aimed at either developing new approaches to treatment or improving and/or evaluating treatment approaches.⁵ Appendix I describes NIDA's allocation of funds to extramural drug abuse treatment research in fiscal year 1989. NIDA's support of research on both pharmacologic and nonpharmacologic therapies emphasizes developing treatments for opiate abuse, even though the number of cocaine/crack abusers far surpasses the number of opiate abusers (see figs. 2.1 and 2.2). NIDA has estimated that in 1988, 2,923,000 Americans aged 12 and older were current users of cocaine. NIDA's latest available estimate of the numbers of heroin addicts is

⁴To examine the impact of NIDA funding on the development of research knowledge on drug abuse treatment, we developed a framework for analyzing NIDA's research budget. We then asked NIDA research directors to categorize their treatment research according to our framework. They were able to do so for extramural treatment research but not for their intramural research program. (The total of \$266.1 million consists of all of NIDA's sources of funding for its extramural research. It includes extramural research and demonstrations funded under NIDA's regular and AIDS budgets.) NIDA's budget director told us that the Institute is currently changing its system to permit easier retrieval of information on its research program. According to NIDA's figures on its intramural as well as extramural research and demonstrations, 48 percent of its budget was allocated to treatment research in fiscal year 1989.

⁵Such research is funded in one of three ways: individual project awards, research centers, or treatment research units. These units are facilities for conducting controlled clinical studies of treatment effectiveness.

500,000. Methadone has been available for many years to treat heroin addiction. At present, no treatment medications of proven effectiveness exist for cocaine abuse.

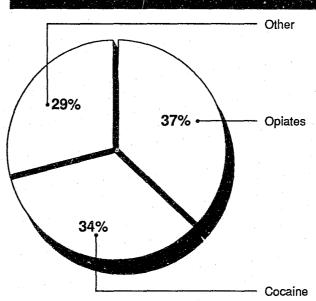
Figure 2.1: NIDA's Funding of Extramural Research on Pharmacologic Therapies in Fiscal Year 1989: Predominant Drug of Abuse Studied



Notes: "Other" refers to other drugs, including methamphetamine, PCP, marijuana, and nicotine; multiple drugs; and nonspecific drugs.

NIDA's own figures indicate that its support of extramural and intramural research as well as demonstrations can be categorized as follows: opiates (48%), cocaine (27%), and other (25%).

Figure 2.2: NIDA's Funding of Extramural Research on Nonpharmacologic Therapies in Fiscal Year 1989: Predominant Drug of Abuse Studied



Notes: "Other" refers to other drugs, including nicotine, multiple drugs, and nonspecific drugs. We could not obtain comparable information for intramural research.

NIDA Is Not Adequately Directing Its Drug Abuse Treatment Research

While NIDA has made some progress in addressing the limitations in knowledge regarding drug abuse treatment, the Institute has not established an overall long-term strategic direction for its research program. NIDA has planned its research within the context of the annual budget process. In contrast, a strategic plan is needed to lay out a long-term future direction for NIDA's research program, taking into consideration the need for developing therapies to treat current and expected future abuses of drugs. Such a plan would provide a justification for the relative priorities assigned to the different categories of treatment research. In addition, NIDA has not provided treatment practitioners, those who will ultimately use the results of treatment research, with a formal ongoing channel through which they can influence NIDA's treatment research priorities. NIDA has begun to establish a strategic planning process and plans to involve treatment practitioners in this process, but has not yet fully implemented these initiatives.

NIDA's Efforts to Address Gaps in Knowledge

NIDA is taking action in several areas to address limitations in knowledge. However, the results of most of these initiatives will not be apparent for several years. The 1988 Anti-Drug Abuse Act requires NIDA to evaluate drug abuse treatment programs to determine the quality and appropriateness of various forms of treatment. NIDA has since resumed

its role in funding large-scale evaluations by initiating a nationwide study of the effectiveness of treatment programs, the Drug Abuse Treatment Outcome Study. The results are expected in 1992.

In another area of limited knowledge, patient-treatment matching, NIDA told us that several projects have been funded and that additional proposals for research have been solicited. The first round of projects, however, will not be completed until 1991.

NIDA defended its emphasis on research related to opiate abuse treatment and noted the dramatic increase in its support of research on cocaine abuse treatment. In fiscal year 1989, NIDA expanded its efforts at developing medications for cocaine as part of its Medications Development Program. NIDA pointed out that its larger funding of opiate abuse research is the result of the Institute's concern with the spread of AIDS by intravenous drug abusers. However, crack cocaine use also contributes to the spread of AIDS through the practice of exchanging sex for crack or for money to buy crack. NIDA also explained that research on opiate abuse has received greater funding because a number of medications for opiate abuse are ready for large-scale clinical testing. Such research projects are more expensive than studies that have not yet reached this stage of testing.

NIDA also pointed out that its investment in cocaine research has dramatically increased in recent years. Currently, the Institute is investigating 18 medications for the treatment of cocaine abuse. Its support of cocaine research between fiscal year 1986 and fiscal year 1989 has increased almost six-fold. However, the results of this research will not be available for a number of years.

NIDA's Strategic Planning Process Has Not Yet Been Fully Implemented

Recognizing a need for overall long-term planning of its research, NIDA began in 1989 to design a strategic planning process. However, the Institute has not yet fully implemented this process and has not yet developed a long-term strategic plan for its research program. Such a plan is particularly important for the drug abuse treatment area, which must address changing patterns of drug abuse, such as the cocaine/crack epidemic. Planning is also critical for ensuring that the large recent increases in NIDA's budget are allocated in a manner that maximizes the development of knowledge in this area.

NIDA's planning of its overall research priorities has been driven by its annual budget process. In this process, the NIDA director receives input

from a variety of sources, such as NIDA's divisions, the Office of National Drug Control Policy, and the Congress. He also relies on information from technical reviews, NIDA's process for reviewing the state of the art in a specific area of research.

NIDA officials told us that much of NIDA's funding is a "continuation base," determined by past priorities. The setting of new priorities tends to occur as a reaction to expected increases in the Institute's funding. Thus, planning usually takes place "on the margins."

NIDA has not engaged in long-term planning to establish overall research priorities. Long-term planning has been at the discretion of the individual research divisions. To date, NIDA has developed plans for specific research areas, such as AIDS and medications development. However, these plans are focused on particular areas of research and do not address NIDA's overall research priorities.

Recognizing that an overall statement of its long-term research priorities is needed, NIDA has taken steps to establish a strategic planning unit and a new Extramural Science Advisory Board in order to help plan the direction of its research for the next 5 years. The unit will work with NIDA divisions, researchers, and the Congress; perform analyses in support of the activities of the Extramural Science Advisory Board; and develop long-range plans that will be considered by the NIDA director in formulating the Institute's long-range plans. The new Advisory Board will be made up of 15 senior scientists from a variety of fields who will be responsible for reviewing NIDA's overall research portfolio and advising NIDA on its research priorities. The board is intended as a "forward thinking group" that would guide NIDA in making long-term planning decisions and conduct in-depth reviews of needs within specific research areas. NIDA officials told us that the new strategic planning initiative is a new step for NIDA and not just a "relabeling of other planning activities."

These new planning initiatives are intended to facilitate what the NIDA director now "does on his own" and are envisioned as the vehicle through which he can decide on priorities more systematically and formally. Also, unlike the current technical review process, the new planning initiatives are intended to take an overall view of research needs and opportunities.

NIDA has been criticized by representatives of the drug abuse community for not considering the needs of treatment practitioners, those who actually deliver different forms of drug abuse treatment, in planning its research. In 1988 the White House Conference for a Drug Free America criticized NIDA about the extent to which its research has been "academically generated within NIDA and by a small group of researchers" rather than being responsive to the needs of practitioners. In addition, members of the treatment community told us that more representation of practitioners is needed. A representative from a national association of state alcohol and drug abuse agencies noted that NIDA's research is limited because NIDA has not interacted in the past with the treatment community in planning its research. Another representative from the same association noted that "there is an absence of available studies applicable to those in the field . . . studies need to be done to improve treatment practices."

NIDA officials acknowledged to us that no formal ongoing mechanism has existed for NIDA to obtain the views of treatment practitioners regarding what treatment research is needed. NIDA officials said that treatment practitioners have provided some input into NIDA's research planning through informal channels, such as interactions of NIDA staff and practitioners at conferences within the drug abuse field and through participation in some technical reviews. In addition, the National Advisory Council on Drug Abuse, composed of researchers, public health officials, and practitioners, has the authority to review NIDA's research priorities. However, NIDA officials told us that most of the council's time is spent on the grant review process.

NIDA officials also told us that their new strategic planning process will include the active participation of members of the treatment practice community. A NIDA official stated that the Extramural Science Advisory Board will include 4 treatment practitioners among its first 15 members. In addition, NIDA is planning to hold a national conference at which it will present its research findings to treatment practitioners and obtain their assistance in identifying topics requiring further research.

Researchers' and Practitioners' Views on Strategic Planning

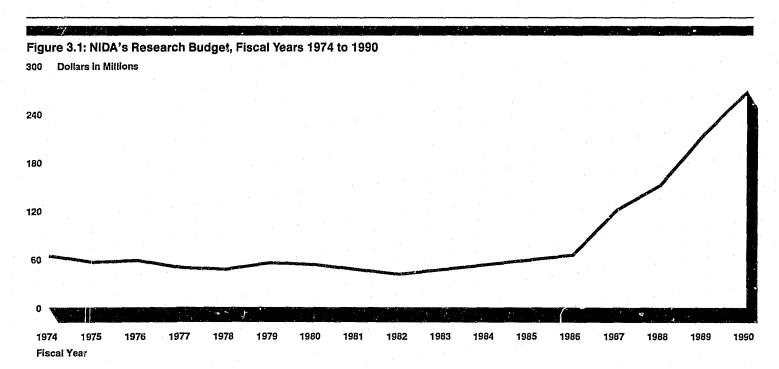
Treatment researchers and practitioners we interviewed also cited the need for strategic planning and described the effects of its absence on NIDA's research program. They noted that such planning is particularly important given changing patterns of drug abuse. According to one researcher, "we are a few years behind what's happening. We are in a position of chasing the phenomena of new drugs." One practitioner told

us that the government needs to design a more dynamic approach to drug abuse treatment research, a standing plan that would account for variation and changes in the abuse profile. A treatment researcher noted "the lack of a master research plan at the Federal level . . . guiding what we need to know." He said that without such a plan lines of inquiry have been pursued erratically.

At present, NIDA's research budget is higher than at any point in its history. NIDA's relatively low budget during most of the 1980s accounts in part for the slow progress made in knowledge on drug abuse treatment during that decade. However, the substantial increases in NIDA's research budget since fiscal year 1987 have presented an opportunity for NIDA to make advances in this area of knowledge. Funding for the training of researchers has also risen, although it has not kept pace with research funding. In addition, planning to address training needs has been inadequate. Given the recent and proposed increases in research and training dollars, the need for planning is particularly important. Planning of both research and research training is essential to ensure that these additional funds are allocated in a manner that will produce the greatest advances in knowledge on drug abuse treatment.

Large Increases in Funding Followed Years of Low Funding Levels

Up to 1987, NIDA's research budget was smaller than the budgets of any of the research institutes within the National Institutes of Health. However, NIDA's funding of research and demonstrations began to pick up dramatically in fiscal year 1987, as shown in figure 3.1. A large part of this increase was for AIDS-related research and demonstrations and increases in spending on drug abuse research. Funding for AIDS-related research and demonstrations rose from 7.5 percent of the NIDA research budget in fiscal year 1986 to 22.7 percent in fiscal year 1987, and to 40.5 percent in fiscal year 1988. It rose to 43.5 percent in fiscal year 1989 and fell to 38.0 percent in fiscal year 1990. Also, the 1986 and 1988 Anti-Drug Abuse Acts authorized major increases in spending on drug abuse research.



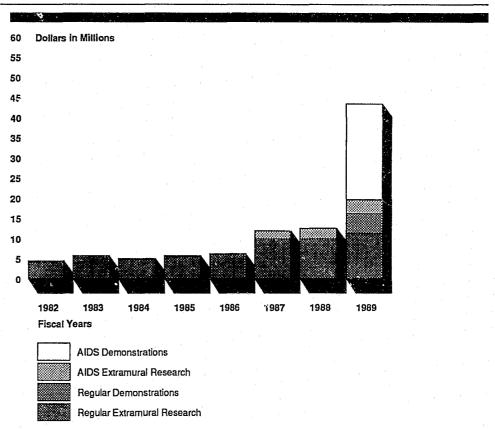
Notes: Amounts include research and demonstrations funded under NIDA's regular and AIDS budgets. Amount for fiscal year 1990 is estimated.

In constant 1982 dollars.

Appropriations made by the 1988 Anti-Drug Abuse Act, for example, substantially increased NIDA's treatment research budget by including \$10 million for the development of new pharmacological therapies for drug abuse. Figure 3.2 shows funding of research and demonstrations by NIDA's Treatment Research Branch, the unit of NIDA that has focused on drug abuse treatment research, from fiscal years 1982 to 1989.

¹Other mandates from the 1988 act include the requirement for NIDA to evaluate drug abuse treatment programs to determine the quality and appropriateness of various forms of treatment. Subsequently, NIDA has resumed its role in funding large-scale evaluations by initiating a nationwide study of the effectiveness of treatment programs, the Drug Abuse Treatment Outcome Study. In response to another mandate of the act, NIDA has begun two large-scale demonstrations programs: demonstrations of drug abuse treatment with vocational training in exchange for public service and demonstrations of treatment for pregnant and postpartum women and their infants. The act also called for the collection of data on drug abuse treatment clients nationwide. Accordingly, NIDA has begun a new treatment client data collection system in cooperation with the states.

Figure 3.2: Research Funding by NIDA's Treatment Research Branch, Fiscal Years 1982 to 1989



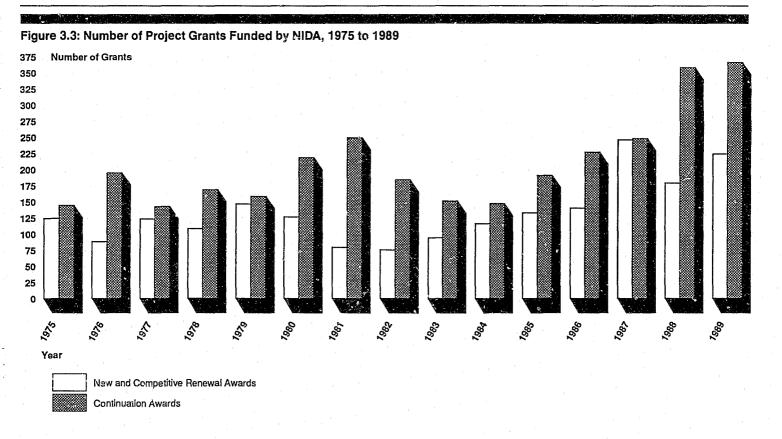
Note: In constant 1982 dollars.

Low funding levels for drug abuse treatment research during most of the 1980s affected the state of knowledge on drug abuse treatment. In 1982, NIDA's budget was cut as a result of the elimination of its responsibilities for managing categorical grants for drug abuse treatment services. The community services portion of NIDA's budget, which had supported the management of treatment services as well as research on treatment, was eliminated at that time.

From 1982 on, treatment research was funded out of NIDA's research budget, which remained relatively low until fiscal year 1987. As a result of these changes, a number of major initiatives in treatment research were discontinued. Large-scale efforts to evaluate treatment programs were terminated. A nationwide system for collecting data on clients of treatment programs was discontinued because states were no longer required to report such data to the federal government.

In addition, investments by NIDA in treatment services research did not grow in the 1980s. In the 1970s and early 1980s, NIDA had funded a number of studies on treatment services, including research to determine the efficacy of vocational rehabilitation and various forms of drug abuse aftercare and to assess different strategies for providing service to special populations. According to the 1989 PHS report, the lack of growth in this area of research during the 1980s caused "current knowledge regarding the relative quality, access, cost, and effectiveness of various drug abuse prevention and treatment modalities" to advance slowly. As a result of low funding levels for drug abuse treatment research during most of the 1980s, little new knowledge on treatment services and clients was generated during that decade, at a time when the nation's system of drug abuse treatment as well as patterns of drug abuse were undergoing fundamental changes.

NIDA's funding of research has also been characterized by a pattern of limited availability of new awards in certain years and dramatic increases in other years. Figure 3.3 shows a history of funding provided for new grants and the continuation of awards from 1975 to 1989. NIDA and ADAMHA officials told us that ideally, the number of new awards in a given year should exceed the number of continuing awards from past years in order to encourage new investigators to enter the field. This has generally not been the case. Also, as shown in figure 3.3, the number of research awards has fluctuated from year to year. Two of the experts we interviewed expressed the opinion that this fluctuation in awards has affected the development of knowledge on drug abuse treatment.



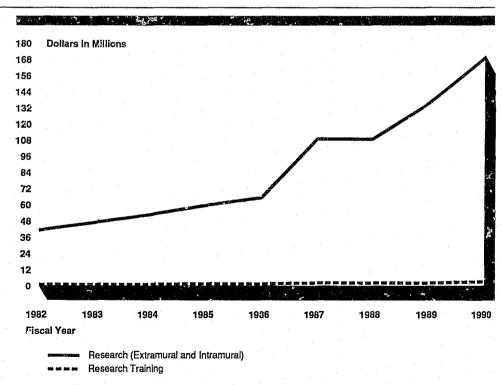
Funding for the Training of Researchers Has Not Kept Pace With Research Funding NIDA had a low level of funding for the training of researchers at the same time that its research funding was characterized by low funding and constraints on the number of new awards. More recently, funding for training has not kept pace with increases in research funding. The training of researchers is essential to maintain a supply of individuals who are capable of conducting drug abuse treatment research. For example, the need for qualified clinical researchers has grown as a result of recent increases in funding for the development of pharmacologic therapies. Although NIDA has recently begun to increase funding for research training, neither NIDA nor ADAMHA has information on the current supply of and future need for drug abuse treatment researchers. This information is needed in order to plan the appropriate amount of funding that should be allocated to research training.

NIDA's role in training researchers in drug abuse treatment is accomplished through (1) training research investigators in drug abuse areas at the predoctoral and postdoctoral levels under the National Research

Service Awards program, (2) career development training, (3) scientific and research mentoring to researchers and others interested in drug abuse research on special populations, and (4) educational programs including the training of physicians in drug abuse issues and the larger AIDS Training Programs.

As figure 3.4 shows, NIDA funding for training has increased very little since fiscal year 1987, when research funding began to rise. As figure 3.5 indicates, NIDA has a ratio of training to research funding that is much lower than those of its sister institutes within ADAMHA. NIDA recognizes that low funding for research training is a problem and has taken steps to remedy the situation. Several of the experts we interviewed expressed the opinion that the lack of funding in past years for the training of researchers has hampered the development of knowledge on drug abuse treatment.

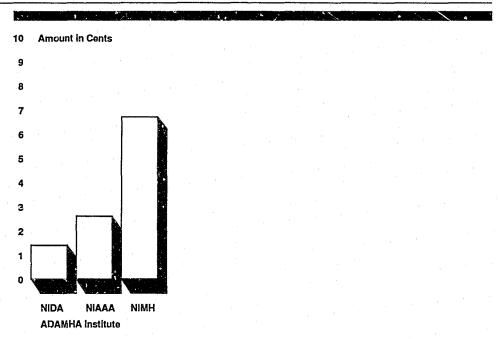
Figure 3.4: NIDA's Funding of Research Training and Research, Fiscal Years 1982 to 1990



Notes: Amounts include both regular and AIDS funding. Amounts for fiscal year 1990 are estimates, Research amounts do not include demonstrations.

In constant 1982 dollars,

Figure 3.5: Amount Spent on Research Training Per Each Dollar Spent on Research at NIDA, NIAAA, and NIMH in Fiscal Year 1989



Note: Includes both regular and AIDS funding. Research amounts include extramural and intramural research. They do not include demonstrations.

NIDA has funded training for relatively few clinical researchers in recent years, in spite of the importance of clinical research to the development of knowledge on drug abuse treatment. Such researchers are needed to conduct clinical trials to study the efficacy of new pharmacological and behavioral therapies to treat drug dependence and also to evaluate the effectiveness of existing therapies. A NIDA official told us that the Institute is concerned about the need to train more clinicians for drug abuse research careers. Two of the experts we interviewed also expressed concern about this issue. Despite these concerns, NIDA's training programs have emphasized training in preclinical or basic research, where much of the research is conducted on a molecular or cellular level, with the focus of developing new knowledge concerning the biological mechanisms underlying drug abuse, its etiology, and its hazards.

NIDA's efforts to increase its training of clinical researchers have been hampered by the slow growth of its training budget and by the difficulty of recruiting physicians into training programs that cannot provide competitive stipend levels. (Physicians are needed in conducting clinical research, particularly research on new medications to treat drug dependence.)

Recently NIDA has taken a number of steps to remedy these problems. First, it has taken advantage of a new opportunity to transfer funds from its research program to its training program. In fiscal year 1990 this will result in a 66-percent increase in its training budget over the fiscal year 1989 level. NIDA's fiscal year 1991 budget request includes a 26-percent increase for training. Second, NIDA has begun to use new funding mechanisms that will allow it to provide higher support levels for physicians receiving training from NIDA.

Despite plans for increased funding for training, however, ADAMHA and NIDA do not have a system for determining the current availability of researchers in the field of drug abuse treatment or for estimating numbers needed in the future. This information is essential for ensuring that the appropriate amount of funds are allocated to drug abuse research training. A NIDA official told us that ADAMHA and NIDA have paid little attention to this issue due to a lack of funding.

Conclusions and Recommendations

Although drug abuse has been identified as one of the nation's leading domestic priorities, there are significant gaps in the understanding of the relative effectiveness of existing treatments and the development of new treatments. Such information is critical for improving treatment of the changing population of drug abusers.

The lack of knowledge concerning the effectiveness of current drug abuse treatment programs and new treatments for changing patterns of drug abuse is due in part to the lack of a strategic planning process at NIDA. However, it also relates to low levels of funding for drug abuse research before fiscal year 1987 and limited funding for training of researchers.

The recent dramatic increase in NIDA's budget resulted from increased concerns by the Congress and the administration regarding knowledge useful in fighting drug abuse and the AIDS epidemic. Over the 5 fiscal years 1986-90, NIDA's budget grew more than four-fold from \$85,392,000 to \$379,734,000. However, NIDA has not had a strategic planning process to direct its allocation of research funds so that changing patterns of drug abuse are addressed. While recent NIDA initiatives have placed added emphasis on cocaine research, long-term strategic planning needs to anticipate further changes in drug user patterns, such as the use of "ice" or other substances, so that treatment research can address problems earlier. Also, NIDA has not systematically involved treatment practitioners, who will use the results of treatment research, in its setting of treatment research priorities. NIDA has taken steps to establish a strategic planning process and plans to involve treatment practitioners in this process, but it has not yet fully implemented these initiatives. In addition, NIDA does not have a system for projecting the number of researchers needed in view of the additional funding available for treatment research. Without a more proactive approach to planning its research and training programs, NIDA has no assurance that recent budget increases will lead to advances in knowledge on drug abuse treatment.

Recommendations to the Secretary of Health and Human Services To help ensure that NIDA-supported treatment research addresses the treatment needs of the drug-abusing population, we recommend that the Secretary direct NIDA to implement its strategic planning process and develop a plan that sets forth its long-term overall treatment research objectives and the relative priorities assigned to the different categories of treatment research. This plan should consider current and anticipated trends of drug abuse and the needs of practitioners from the drug abuse

Chapter 4 Conclusions and Recommendations

treatment community. In addition, the Secretary should direct ADAMHA or NIDA to determine how many researchers are needed to carry out planned research and take appropriate action to ensure their availability.

NIDA's Allocation of Funds to Extramural Drug Abuse Treatment Research in Fiscal Year 1989

Dollars in millions		
Categories ^a	Amount allocated	Number of projects
Individual projects		
Pharmacologic therapies	\$23.4 (23%)	108
Nonpharmacologic therapies	10.6 (10%)	34
Diagnostic strategies	2.5 (2%)	14
Data on treatment services and clients	7.2 (7%)	55
Treatment outcome/effectiveness evaluation	18.3 (18%)	40
Services research	4.1 (4%)	10
Other research	13.9 (13%)	13
Research centers and units	· · · · · · · · · · · · · · · · · · ·	
Research centers	8.1 (8%)	10 ^t
Treatment research units	15.2 (15%)	80
Total	\$103.3 (100%)	

Notes: Figures include research and demonstrations funded under NIDA's regular and AIDS budgets. Figures also include research funded under NIDA's portion of the block grant set-aside and the ADAMHA treatment outcome line item.

Some projects are counted in more than one category. In these cases, the award amounts are split among the relevant categories.

^aDefined in appendix II.

^bCenters.

^cUnits.

Drug Abuse Treatment Research: Description of Categories

Individual Projects

Pharmacologic Therapies

This research is aimed at developing new and improving existing pharmacologic therapies for drug abuse. Research to develop new treatment drugs involves the design of new drugs; assessments of the potential efficacy, toxicology, and abuse liability of new drugs in animal models; and clinical research to test the efficacy and safety of promising new drugs in humans. Research includes preclinical and clinical research on naltrexone and studies to improve the usefulness of methadone as a treatment drug. Starting in fiscal year 1989, NIDA expanded its efforts in this area by establishing a Medications Development Program. In fiscal year 1990, it will establish a formal Medication Development Division.

Nonpharmacologic Therapies

This research is aimed at developing new and improving nonpharmacologic therapies for drug abuse and involves controlled clinical trials to assess the efficacy of a range of psychosocial interventions, including behavioral therapies, psychotherapies, counseling, and relapse prevention techniques. Also includes clinical research on other nonpharmacologic therapies, such as acupuncture.

Diagnostic Strategies

This research involves the diagnosis of disorders in drug abusers. Includes studies of psychiatric disorders, personality characteristics, and social functioning of drug abusers and evaluations of diagnostic instruments. Also includes research on neuro-biological predictors of treatment outcome.

Data on Treatment Services and Clients

Data collection efforts are aimed at gathering information on the characteristics of treatment services and clients admitted to treatment. Efforts include the National Drug Abuse and Alcoholism Treatment Unit Survey, the State Alcohol and Drug Abuse Profile, and the Client Data System Minimum Data Set. The latter project was initiated in fiscal year 1989, as a result of the 1988 Anti-Drug Abuse Act, and includes \$5.5 million in grants to the states to assist them in adopting national client data standards.

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Appendix II Drug Abuse Treatment Research: Description of Categories

Treatment Outcome/ Effectiveness Evaluation

This research is aimed at assessing treatment outcomes and/or evaluating the effectiveness of treatment programs with a focus on clinical outcomes/effectiveness. Included are studies of factors that determine treatment outcomes and evaluations of the effectiveness of common types of programs or of innovative programs. The Drug Abuse Treatment Outcome Study, a new multi-year project that was allocated \$2.4 million in fiscal year 1989, will investigate drug abuse treatment effectiveness based on a nationwide sample of programs. Also included in this category are two new demonstration initiatives that were allocated a total of \$6 million in fiscal year 1989: demonstrations of drug abuse treatment with vocational training in exchange for public service and demonstrations of treatment for pregnant women.

Services Research

This research focuses on the organization, financing, delivery, and performance of drug abuse treatment services. Included are studies of the structure and staffing of drug abuse treatment systems in the United States, utilization of drug abuse treatment services, adequacy of coverage, and methods of financing. Also included are studies of efficiency and effectiveness, focusing on nonclinical outcomes of alternative approaches to drug abuse treatment. The economics of drug abuse and drug abuse treatment, estimates of health and other costs associated with drug abuse, and development of cost-effectiveness and cost-benefit analysis of alternative approaches to drug abuse problems are included.

Other Research

This includes a variety of treatment-related projects, such as small business innovation research projects, support of the Committee on Problems of Drug Dependence conference, and several AIDS outreach demonstration projects. Also included is an \$8.9 million interagency agreement with the Health Resources and Services Administration to demonstrate the incorporation of drug abuse treatment into health care settings.

Research Centers and Units

Research Centers

NIDA funded 18 research centers in fiscal year 1989. Ten of these have been characterized by NIDA as performing research related to drug abuse

Appendix II Drug Abuse Treatment Research: Description of Categories

treatment. Much of the treatment-related research performed in these centers falls under NIDA's Medications Development Program.

Treatment Research Units

Starting in fiscal year 1989, NIDA also funded eight treatment research units. These units are facilities for conducting controlled clinical studies of treatment effectiveness. The research goals of the treatment research units are more flexible than those of centers so that they may respond quickly to new research needs.

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