



Briefing for
Mr. Jose Cerda
Senior Policy Analyst
White House Domestic Policy Council

December 10, 1993

OVERVIEW

HISTORY OF NIDA

- **Research Center in Lexington, Kentucky established in 1935 (Later named Addiction Research Center (ARC))**
- **NIDA established in 1974 by Congress as part of the new Alcohol Drug Abuse and Mental Health Administration (ADAMHA), and, as of October, 1992 became part of the National Institutes of Health.**

NIDA'S MISSION

- **NIDA is charged with the lead role in the Federal research effort to increase knowledge about the incidence, prevalence, causes, and consequences of drug abuse and addiction. Based on this knowledge, NIDA attempts to develop and evaluate improved prevention and treatment interventions, with the ultimate goal of eliminating the demand for illicit drugs in this country.**
- **Research is conducted through the more than 1200 grants, contracts and interagency agreements that NIDA awards to scientists, as well as at the ARC, our intramural research facility and the largest freestanding drug abuse research center in the Nation.**

RESEARCH PORTFOLIO

- **NIDA's current research agenda, intended to effectively address the myriad complexities of drug dependence and addiction, by necessity covers a wide spectrum--from basic biomedical to epidemiologic, prevention, treatment and clinical research.**
- **NIDA is nearly the sole provider of our Nation's drug abuse research--supporting 88% of that conducted in this country.**
- **NIDA is actively engaged in collaborative efforts with many of the other NIH Institutes as well as with numerous other government agencies such as the Substance Abuse and Mental Health Services Administration (SAMHSA).**

NIDA'S PROGRAMS AND ACTIVITIES

- **Organized both by formal organizational structure as well as by overarching program areas that cut across organizational lines (matrix management system).**

PROGRAM DIVISIONS and ARC

- **Division of Basic Research**
 - **supports studies which explore the behavioral and biomedical mechanisms underlying drug abuse, its causes, and its consequences, new methodologies to test the abuse potential of new compounds, and the processes of learning and memory as they relate to addiction.**
- **Division of Epidemiology and Prevention Research**
 - **broad-based program; examines the natural history, incidence and prevalence of drug abuse among selected subpopulations through surveys**
 - **also conducts research on the efficacy of various prevention strategies and the economic, demographic, and psychosocial factors that place individuals at higher risk for becoming drug abusers.**
- **Division of Clinical Research**
 - **supports a broad spectrum of basic, behavioral and applied research on the behavioral pharmacology of abused substances, the effectiveness of existing drug abuse treatment therapies and the assessment of new and promising ones.**
- **Medications Development Division**
 - **develop pharmacotherapies to treat drug addiction; looking for medications that will act as antagonists and block the reinforcing properties of drugs; correct imbalances caused by prolonged exposure to drugs; help make individuals more amenable to other kinds of treatment.**

- **most urgent goal is to begin clinical trials of those medications already available which have shown promise in treating addiction to opiates, cocaine, PCP, and methamphetamine.**
- **Addiction Research Center (ARC)**
 - **research conducted complements that supported by program divisions**
 - **conducts preclinical and clinical research on the causes, treatment and prevention of drug abuse and addiction; the behavioral mechanism underlying the addictive process; and the addictive potential of new drugs.**
 - **allows NIDA to respond rapidly to emerging research issues**
- **Office on AIDS**
 - **conducts research to improve the effectiveness of drug abuse treatment for injecting drug users; to develop alternative HIV control measures; and to expand the knowledge base concerning the link between drug abuse and AIDS.**
- **Women's Health Issues Program**
 - **exploring gender-related differences in drug abuse etiology and impact as well as identification of differences in treatment needs and in optimally effective prevention strategies for women.**
- **Office of Science Policy, Education, and Legislation**
 - **Research Training**
 - **looking for ways to strengthen and foster interest in our training mechanisms for researchers, health professionals, special populations, and HIV and substance abuse researchers and for ways to continue to draw new scientists into the fold.**
 - **NIDA has identified the training of clinical researchers as a top training priority**

- **NIDA is also working on attracting students to research at the early stages of their education program through our science education activities.**
- **Minority Activities**
 - **Special Populations Program: designed to help minorities participate in NIDA's research activities, including implementing training to increase the number of ethnic minority drug abuse researchers, and promoting support of more ethnic minority drug abuse research.**
- **Science Education Program**
 - **designed to expose young students to research, and to encourage them to undertake science careers.**
- **Research Dissemination**
 - **Translate research into practice through:
Technology transfer activities (CRADAS)
Videos for treatment professionals
Conferences**
 - **Publications disseminated through National Clearinghouse for Alcohol and Drug Information (NCADI)**
- **International Program**
 - **Fosters interchange with scientists from foreign countries conducting research on drug abuse, and promotes, facilitates, and supports international research in drug abuse on a broad range of topics through training, technical assistance, and scientific information dissemination.**

PROGRAM AREAS

- **Neurosciences**

- **coordinates NIDA's involvement in "Decade of the Brain" activities including the long-term neurotoxicity of drug use; the neurobiological effects of maternal and fetal drug use; mechanisms underlying biological vulnerability to drug abuse; and the biological basis for the rewarding consequences of drugs.**

- **Medications Development**

- **synthesizing new chemicals and screening them in animals; development of linkages with pharmaceutical firms to further mutual goals; conducting clinical trials to test potential medications in humans.**

- **Nonpharmacologic Treatment**

- **research on the factors that influence drug treatment; improved patient-treatment matching; and improvement of treatment engagement, retention and compliance.**

- **AIDS**

- **33% of AIDS cases reported in U.S. are IV drug-related; 57% of pediatric cases were of mothers who were either injecting drug users themselves or had been in sexual contact with an injecting drug user.**
- **TB and MDR-TB among drug abusers**
- **improvement of drug abuse treatment in IV drug users; development of effective outreach and intervention strategies.**

- **Maternal-Paternal-Fetal Drug Effects**

- **exploring the epidemiology of drug exposed infants; the treatment of drug abusing women of childbearing age, and the teratogenic, mutagenic, and environmental effects of drugs.**

- **Epidemiology and Prevention**

- **nature and extent of drug abuse in several important subpopulations (National High School Senior Survey; National Pregnancy and Health Survey)**
- **development of effective prevention strategies**

- **Health Services Research**

- **assess the capacity of the drug abuse treatment system and the cost effectiveness and efficacy of treatment and/or services.**

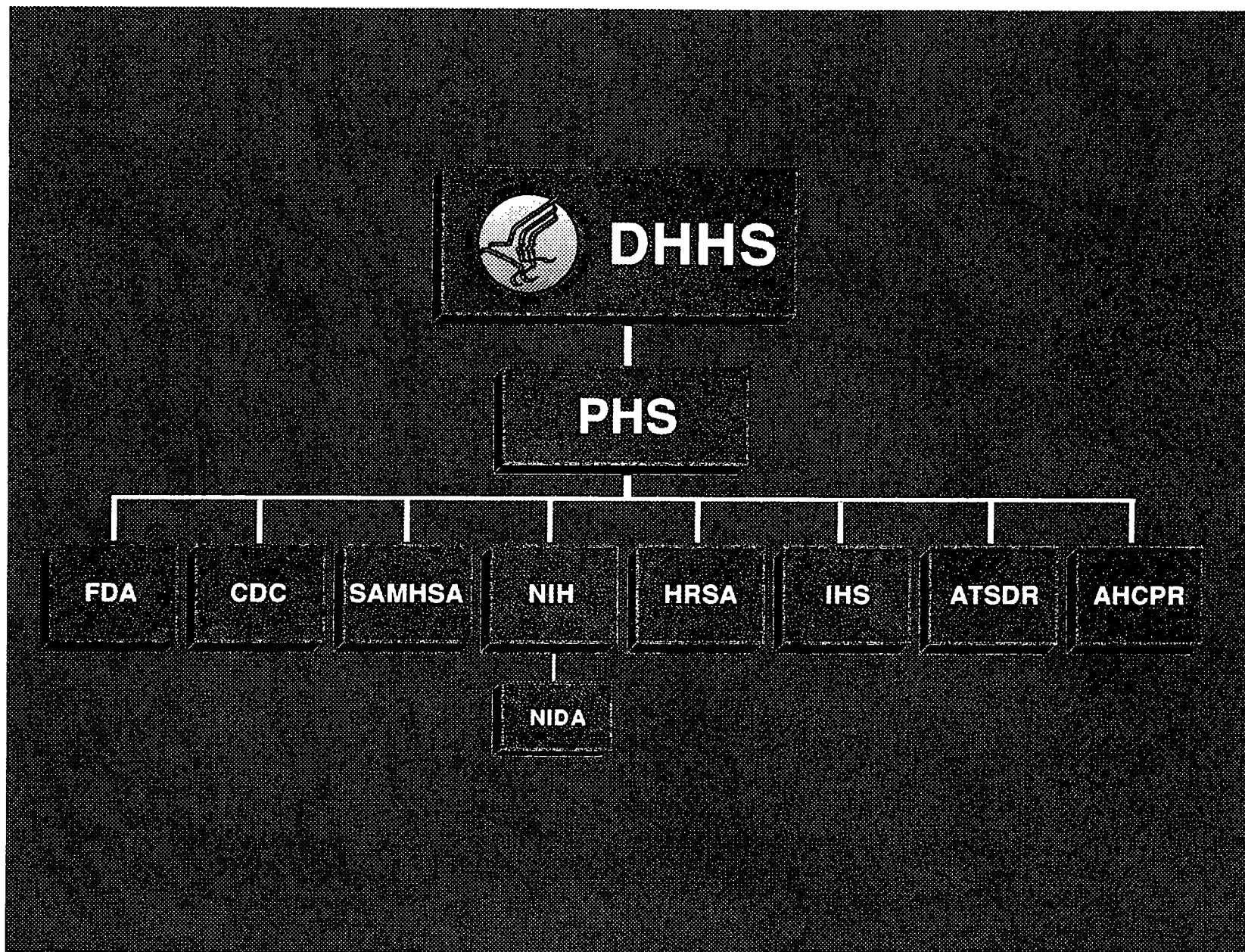


Figure 1

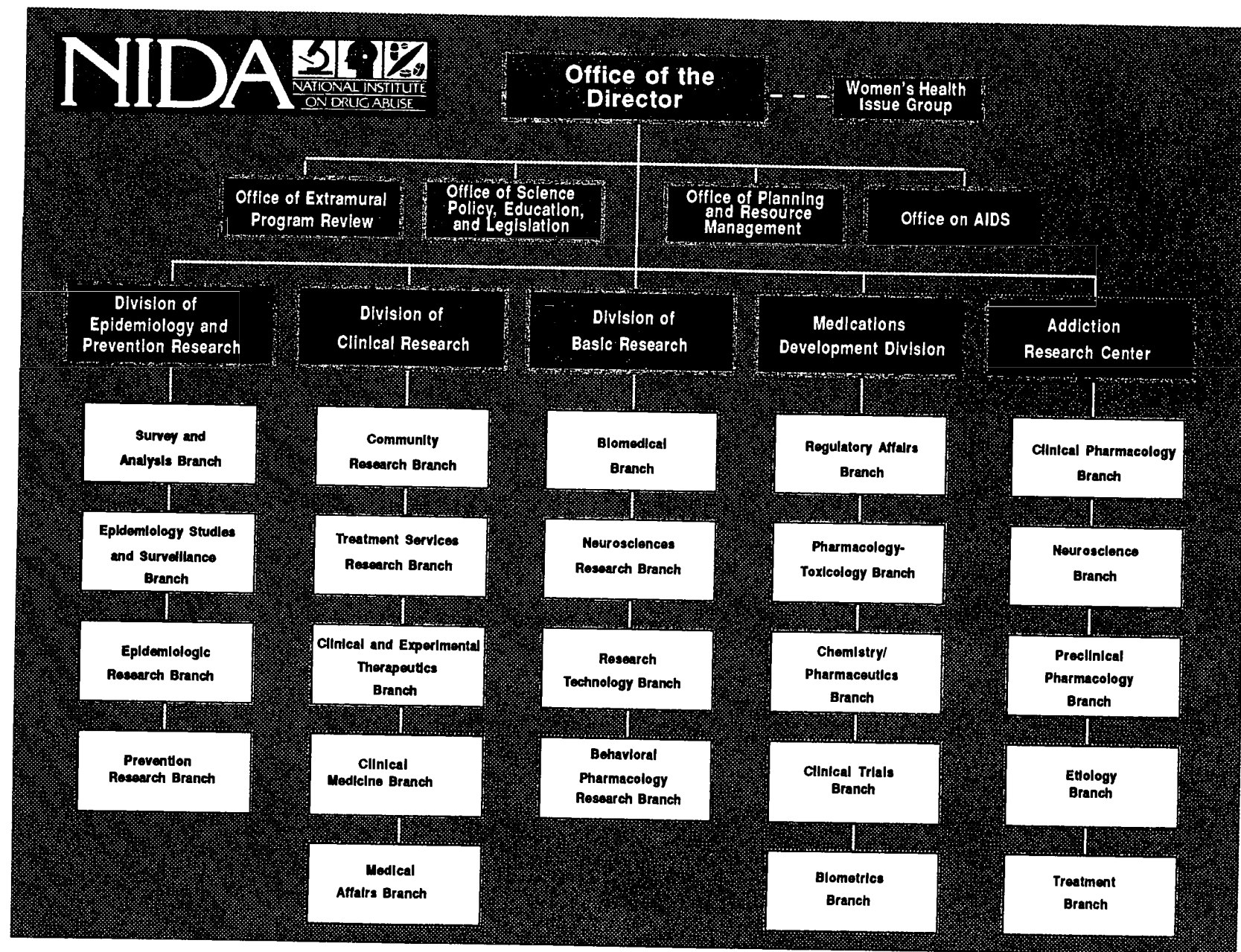
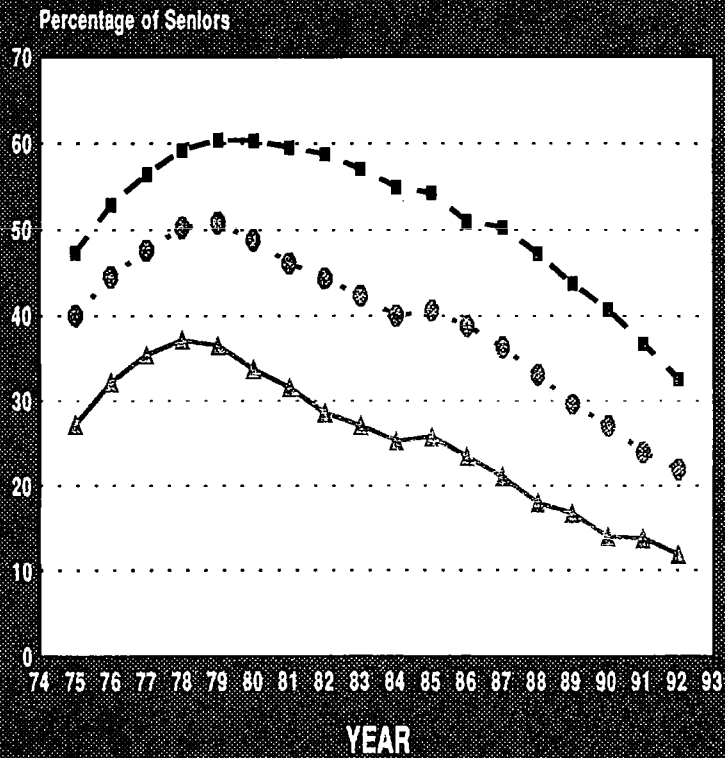


Figure 2

Trends in Marijuana Use

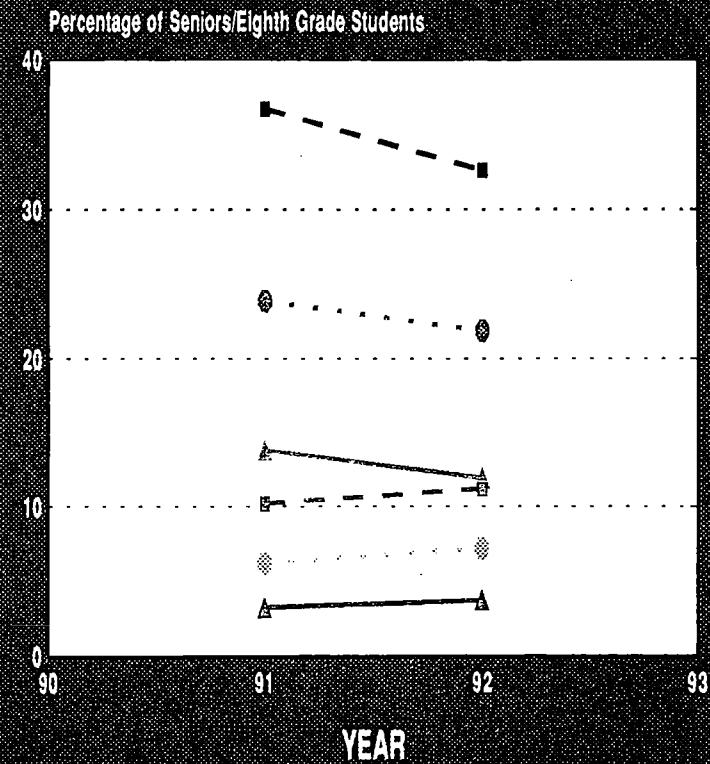
United States, 1975-1992

High School Seniors



■ Lifetime Use ● Past Year Use ▲ Past Month Use

Seniors & 8th Grade Students



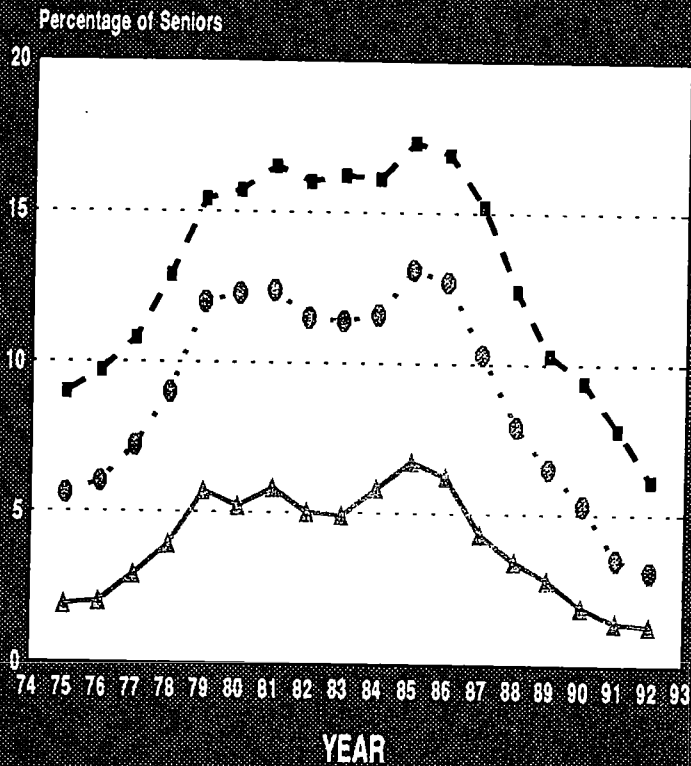
■ Lifetime (8th) ● Past Year (8th) ▲ Past Month (8th)
 ■ Lifetime (Seniors) ● Past Year (Seniors) ▲ Past Month (Seniors)

Source: Monitoring the Future Survey

Trends in Cocaine Use

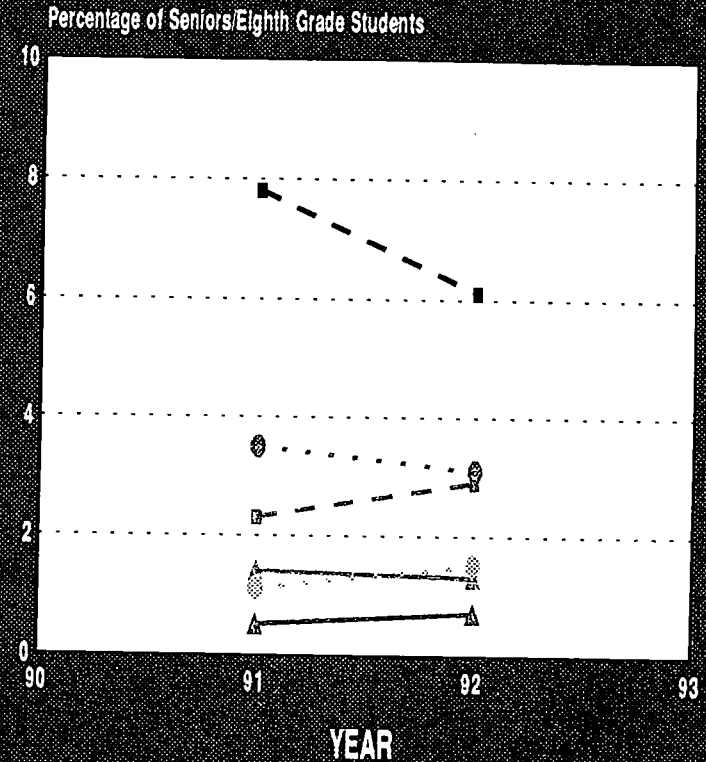
United States, 1975-1992

High School Seniors



■ Lifetime Use ● Past Year Use ▲ Past Month Use

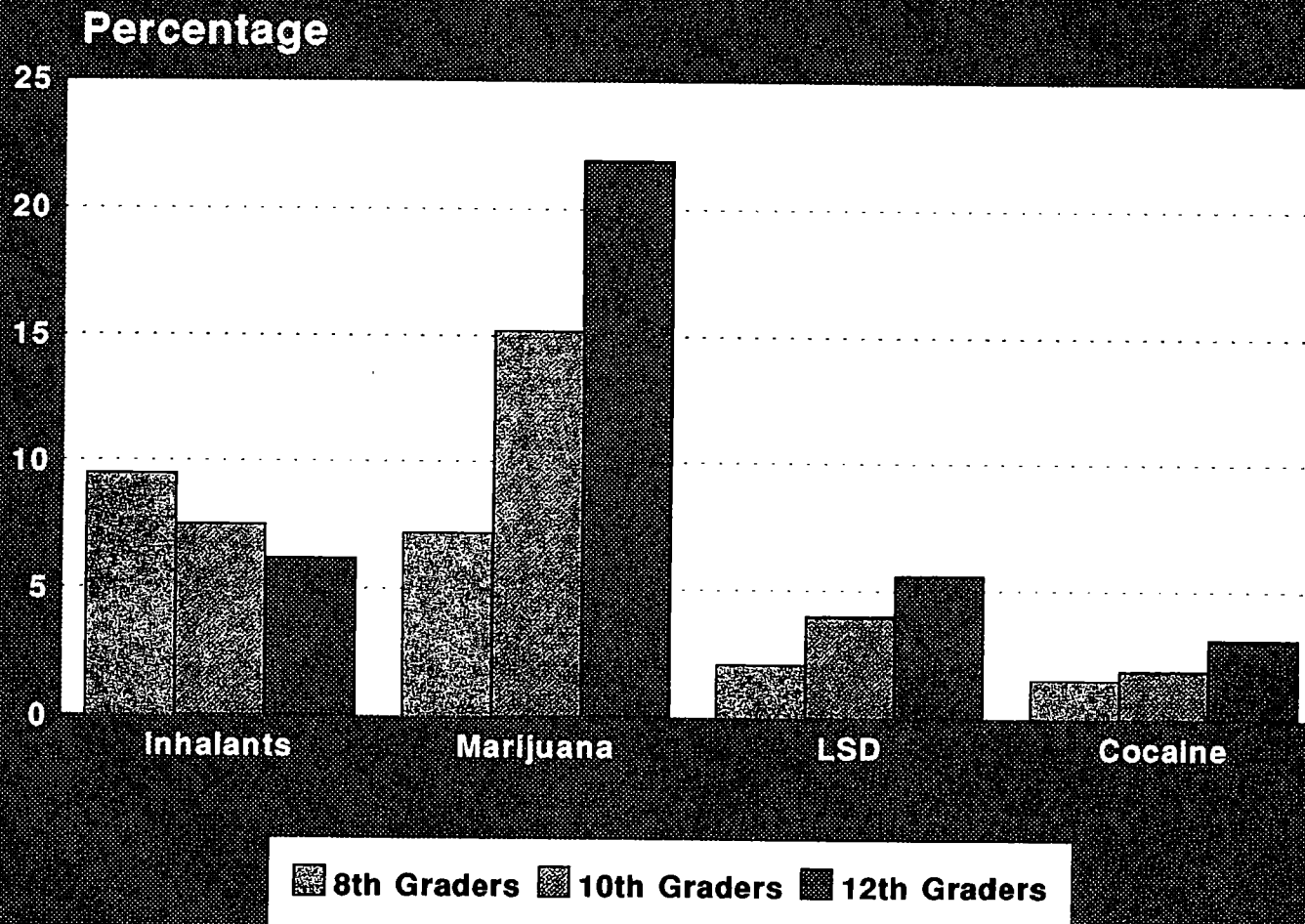
Seniors & 8th Grade Students



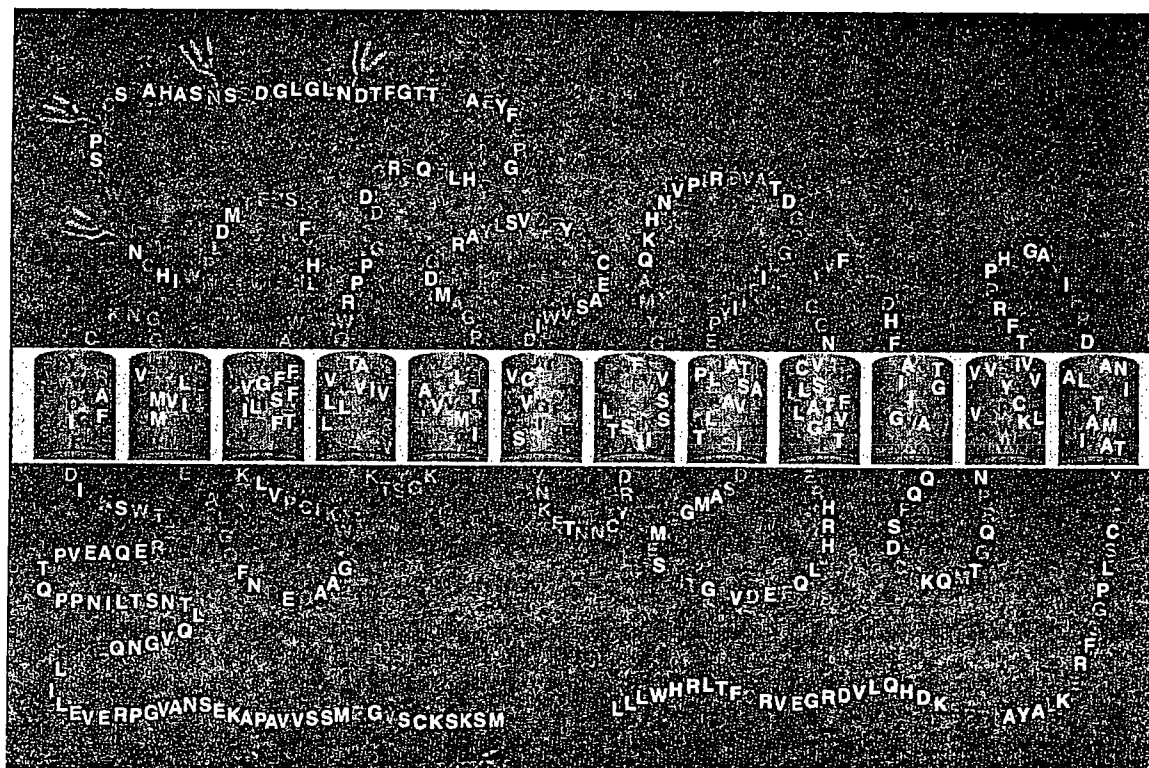
■ Lifetime (8th) ● Past Year (8th) ▲ Past Month (8th)
 ■ Lifetime (Seniors) ● Past Year (Seniors) ▲ Past Month (Seniors)

Source: Monitoring the Future Survey

Past Year Use of Selected Substances by Grade

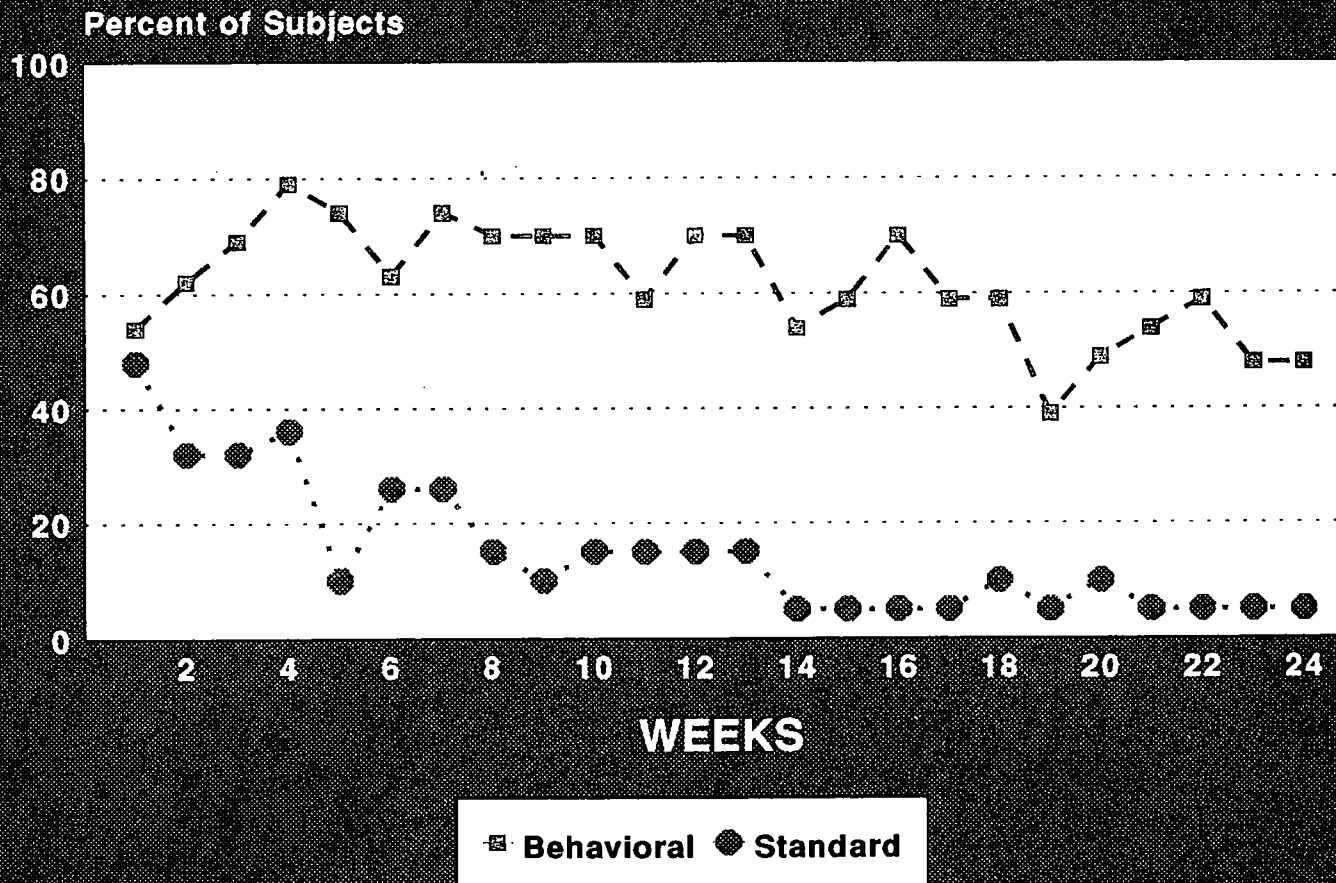


Source: Monitoring the Future Survey



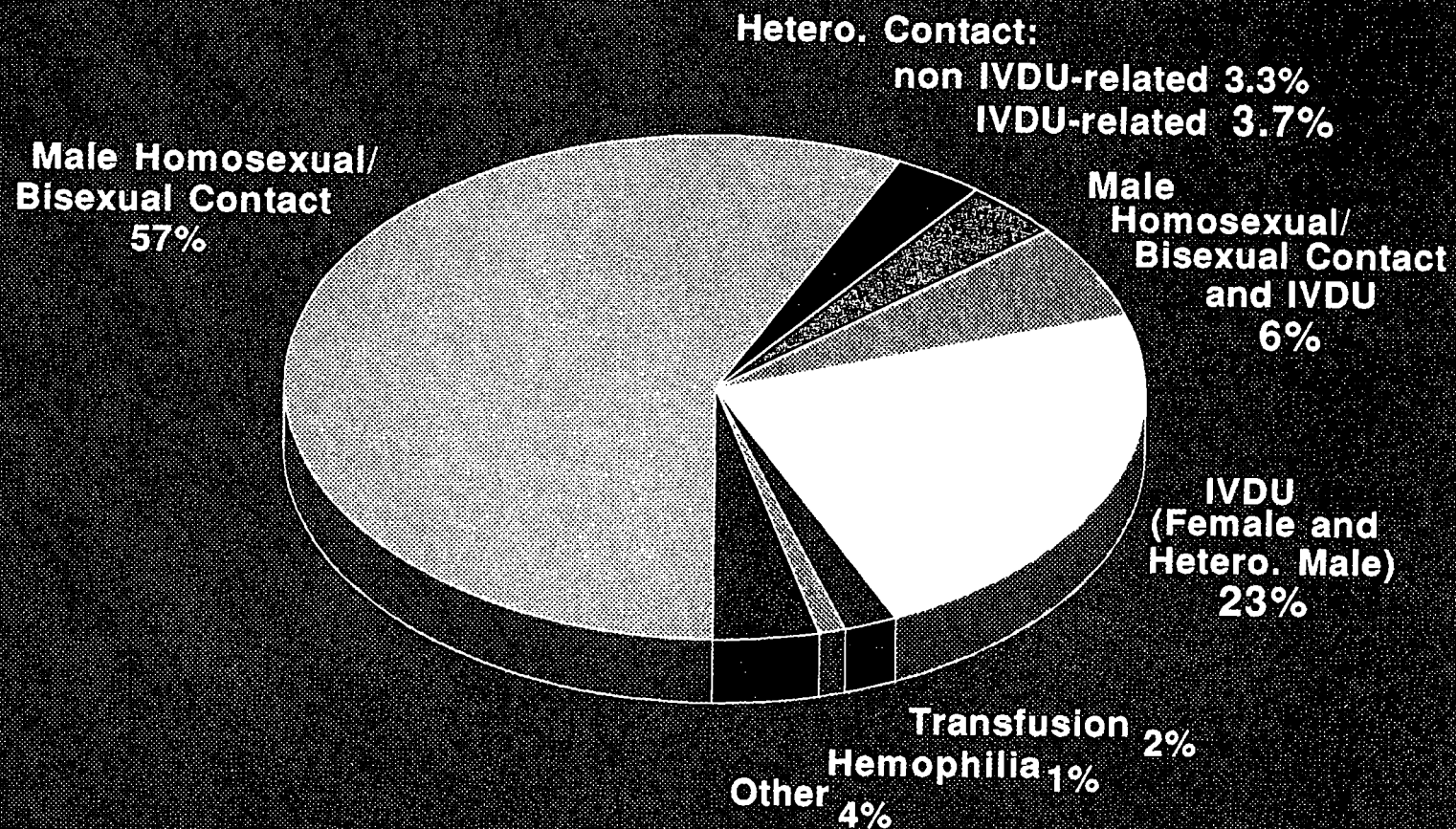
Amino acid sequence of the human dopamine transporter/cocaine receptor.

Continuous Cocaine Abstinence During Treatment for "Standard" 12-Step and Behavioral Treatment Approaches



Source: Higgins, ST and Budney, AJ. Treatment of cocaine dependence via the principles of behavior analysis and behavioral pharmacology. In LS Onken, JD Blaine, and JJ Boren (Eds), Behavioral Treatments for Drug Abuse and Dependence. NIDA Research Monograph, In press.

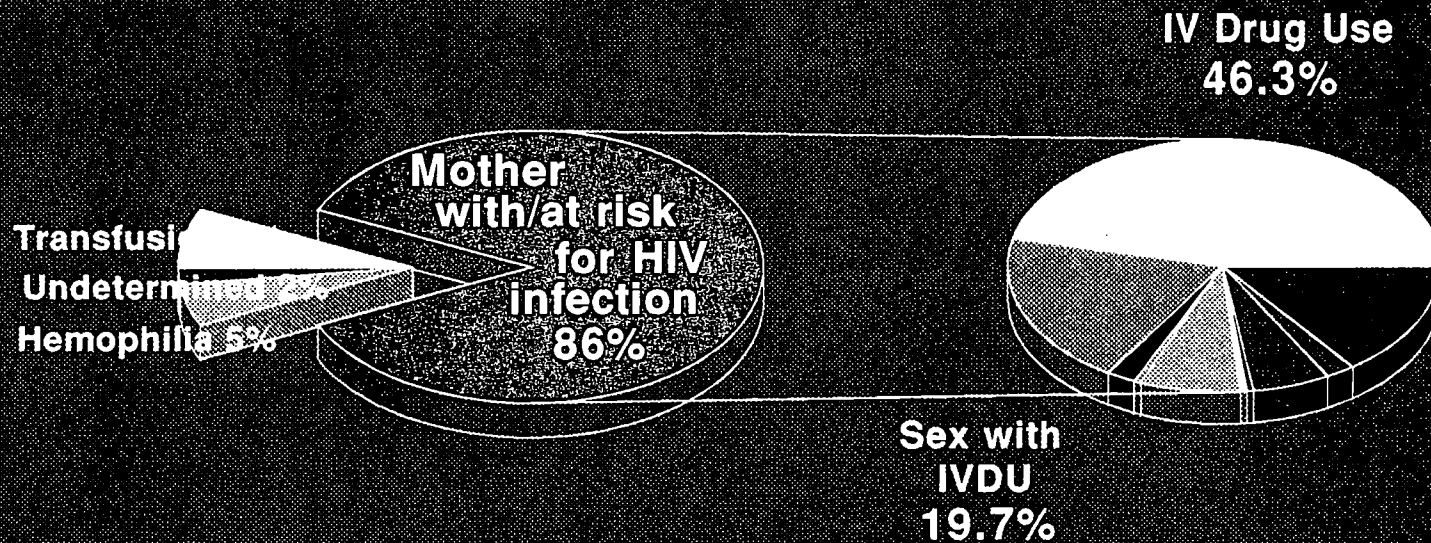
Adult/Adolescent AIDS Cases by Exposure Category through December, 1992, U.S.



N=249,199 (98.3% of Total Cases)

Source: CDC HIV/AIDS Surveillance Report, February, 1993.

Pediatric (< 13 years old) Exposure Category



N=4,249 (1.7% of Total Cases)

Source: CDC HIV/AIDS Surveillance Report, February, 1993.

NIDA'S PRIORITY AREAS

Neuroscience

Medications Development

Nonpharmacological Treatment

AIDS

Maternal/Paternal/Fetal Effects

Epidemiology/Prevention

Health Services Research

Research Training

Minority Efforts

Women's Health Issues

NEUROSCIENCE RESEARCH

- **Utilize brain imaging techniques to understand the underlying neural mechanisms and neuroanatomical substrates mediating the behavioral effects of drugs of abuse, learning and memory, and the brain reward system.**
- **Employ innovative molecular biological techniques to elucidate the neurobiological basis of addiction, the neuroanatomical impact of drug use on the genome and the role of genetics in drug abuse.**
- **Facilitate the development of effective medications for treating cocaine through studies of drug interactions with brain transporter proteins, neurotransmitter receptors, and other membrane components, such as ion channels.**
- **Develop analgesics with non-addicting properties and fewer undesirable side effects through studies of endogenous opioid and other peptide systems, including peptides that reduce inflammation but do not cross the blood brain barrier (eg CRF).**

- **Determine the neurotoxicological and behavioral toxicological effects of acute and chronic administration of drugs of abuse, including prenatal effects and long-term neuroplastic changes in the CNS.**
- **Investigate the neurobiological and neurobehavioral effects of anabolic steroid use, including effects on the brain reward system, cognitive function and long-term consequences.**

MEDICATIONS DEVELOPMENT RESEARCH

Goals of the Program:

- To identify, evaluate, develop and ensure approval of medications that will reduce or stop crack/cocaine use, prolong periods of abstinence, treat pregnant addicts and drug exposed neonates, and treat crack/cocaine overdose.
- To identify, evaluate, develop and ensure approval of medications for opiate addiction that will not cross the placental barrier, be less dependence producing, and devise a new formulation of methadone that will achieve the same results with a lower dose and is less susceptible to diversion.

Strategy of the Program:

- **Focus on medications that have already received FDA approval or are currently under review. NIDA will strive to reduce the average 8 years it takes to get a new medication on the market for drug abuse treatment.**
- **Engage emerging neuroscience companies who are interested in \$30 - \$50 markets.**

NONPHARMACOLOGICAL TREATMENT

- **Development and testing of new psychosocial treatment approaches including: drug counseling, behavioral approaches and psychotherapies.**
- **The development of therapy-specific diagnostic approaches to successfully match clients with the most appropriate treatment modality.**
- **Improved integration of psychosocial and pharmacological treatments.**
- **Identification of factors which increase client compliance, increase retention, and influence completion of treatment programs.**
- **Clarification of the interpersonal and environmental factors associated with treatment entry, recovery and relapse.**

AIDS RESEARCH

- **Develop and test new methods to prevent both injection related and sexually transmitted HIV infections in drug abusers and their sex partners, especially women. Over 80% of perinatal HIV infections are attributable to maternal drug abuse or sexual partnership with a drug abuser.**
- **Develop new ways to increase the efficacy of existing drug treatments. Effective addiction treatment diminishes the risk of HIV infection to the uninfected and the risk of transmission from the infected.**
- **Develop new treatments that are both effective and attractive for a variety of drug abusers. NIDA's highest priority is now to develop treatments for cocaine smokers and injectors, who are at highest risk of HIV infection, but for whom effective treatments are not yet available.**
- **Develop new, effective outreach and intervention strategies for drug abusers not yet willing to enter treatment or give up their drug abuse. Use of bleach to clean injection equipment prior to re-use decreases but does not eliminate the risk of HIV infection. NIDA is developing new strategies and field testing them through cooperative agreements in multiple sites.**

- **Develop better epidemiologic methods to find and assess the hidden, drug abusing populations at risk for HIV infection. This will be critical in preventing the further spread of the epidemic. NIDA will actively explore new epidemiologic methods such as use of surrogate markers and systematic street sampling.**
- **Address the resurgent specter of TB and MDR-TB, especially among HIV-infected drug abusers. This is already increasing the social marginalization of this vulnerable population. It also increases the urgency of NIDA's program to develop new behavioral methods to ensure compliance with medical treatment in patients for whom this may not be a priority.**

MATERNAL/PATERNAL/FETAL EFFECTS

- **Develop studies on the prevalence and impact of prenatal drug use to evaluate effectiveness of prevention and treatment efforts and the public health policy implications.**
- **Develop epidemiologic studies to clarify the relationship between in utero drug exposure, pregnancy outcome, and effects in children versus non-exposed infants.**
- **Develop new medications to improve cocaine and opioid pharmacotherapy in pregnant women (i.e., agents that do not cross the placenta).**
- **Establish a program to validate biologic measures of prenatal and pre-conception exposure to illicit drugs to determine the time/course/dose effects of drug use on the child and conduct studies to determine the consequences of paternal drug use on infants.**

- **Initiate studies of the effects of prenatal drug use on neurodevelopment, of behavioral and neurotoxic effects, of maternal/fetal pharmacokinetics and pharmacology to foster the understanding of the basic mechanisms of drug effects on the fetus and child.**

EPIDEMIOLOGY AND PREVENTION RESEARCH

- **Develop standardized definitions and measurements of drug using behaviors and validation of self-reported drug use data among various population groups while using a wide range of methodologies.**
- **Identify risk factors associated with progression from initiation of illicit drug use to abuse and addiction.**
- **Establish and conduct multi-cohort drug abuse epidemiologic studies at several regional research centers to examine incidence, prevalence, vulnerability, and consequences of illicit drug use.**
- **Improve strategies to prevent and treat chronic diseases prevalent in drug abusers including HIV, TB, and the hepatitis viruses.**
- **Increase resources to develop and assess new, more effective strategies for reducing prevalence of drug abuse and incidence of HIV infection in drug abusers while emphasizing the biological, behavioral, familial, social, and environmental factors that increase risk for initiation and progression of drug abuse.**

- **Develop effective prevention approaches and culturally relevant procedures to apply these techniques to a wide variety of populations.**

HEALTH SERVICES RESEARCH

- **Assessment of the impact of the organization, structure, financing, management, and staffing of treatment programs on the availability and accessibility of treatment service resources, on program content and function, and on treatment effectiveness.**
- **Investigation of the role of the treatment environment and operation on mechanisms of service delivery as they relate to treatment, retention in treatment, compliance with treatment, or treatment outcomes.**
- **Analysis of the effectiveness of technology-based approaches on modifying the organization and delivery of health care services.**
- **Development of methods for improving the ability of treatment programs to match clients with appropriate types and levels of treatment services.**
- **Development of effective methods to best target services to the needs of special populations.**

- **Development of accurate techniques to measure the cost effectiveness of drug abuse treatment.**
- **Evaluation of relapse and AIDS prevention strategies.**
- **Evaluation of drug abuse prevention strategies for high risk youth or individuals who demonstrate multiple problem behaviors.**
- **Evaluation of prevention intervention strategies used in a variety of settings including the school, the community, and the workplace.**

RESEARCH FINDINGS DISSEMINATION

INFORMATION DISSEMINATION

- **Press**
- **Speeches**
- **Presentations**
- **Publications**
- **Journal Articles**
- **Exhibits**

COMMUNITY EDUCATION

- **Mass Media Campaigns**
- **Training and Technical Assistance**
- **Material Promotion and Distribution**

TECHNOLOGY TRANSFER

- **Videotapes**
- **Technology Transfer Packages**
- **Conferences and Workshops**

TECHNOLOGY TRANSFER

Program Goal:

To translate NIDA's research findings so that drug abuse prevention and treatment strategies which have been identified as effective can be understood, applied, adopted and adapted by treatment practitioners as appropriate.

Strategies:

- **Conducting or sponsoring research intended to identify potentially utilizable technologies.**
- **Evaluation of the potential of specific technologies for wider use.**
- **Design and development of technology transfer packages utilizing a variety of media appropriate to the subject matter being transferred.**
- **Field testing and evaluation of these packages and their impact on drug abuse prevention, treatment, and rehabilitation services.**

- **Showing drug abuse practitioners how to use research findings and providing technical assistance on the utilization process.**

RESEARCH TRAINING

- **Increase the number of clinical drug abuse researchers, which is critical to the success of NIDA's critical treatment research initiatives, including the Medications Development Program.**
- **Develop a culturally diverse drug abuse research workforce to enable NIDA to more effectively address the problems of drug abuse in minority populations.**
- **Increase support of traditional and innovative training mechanisms (e.g., increase student interest in drug abuse research; provide resources and programs to train individuals pursuing research careers in areas related to drug abuse and addiction; and improve the retention of trained investigators).**
- **Double the percent of NIDA's total extramural research budget devoted to research training within five years.**

MINORITY RESEARCH ACTIVITIES

- **Broaden special populations research, training, and development efforts including:**
 - **Epidemiologic studies on the nature and extent and the causes and consequences of drug abuse and addiction among minority and other underserved populations.**
 - **Assess efficacious prevention and treatment efforts to ensure their cultural relevance and effectiveness for specific racial and ethnic groups.**
 - **Increase the participation of ethnic and racial minorities in NIDA research through NIDA's Special Populations Research and Development Program.**
 - **Establish a new initiative directed at Historically Black Colleges and Universities (HBCUs) to provide capital, infrastructural and support needs required to further ongoing research at HBCUs.**

WOMEN'S HEALTH

- **Examine the medical, ethical, and legal barriers to including women in clinical studies during their childbearing years, with emphasis on the clinical assessment of new pharmacotherapies of drug abuse.**
- **Support research on the effects of drug abuse on women, including:**
 - **Exploring the underlying mechanisms of action of drug abuse (especially cocaine) in women focusing on endocrine and physiological function, genetics, teratology, and pharmacokinetics.**
 - **Expanding epidemiological research (e.g., the National Longitudinal Labor Survey) to determine the extent of drug use by pregnant and nonpregnant women.**
 - **Conducting research on the fetal, neonatal, and maternal consequences of maternal drug use.**
 - **Establishing a research center devoted to studying the effects of drug abuse on female physiology.**

- **Initiating a program to develop treatment medications that are safe for use during pregnancy.**

CLINICAL NEUROSCIENCE

MEDICATIONS DEVELOPMENT

BEHAVIORAL THERAPIES

NIDA 
NATIONAL INSTITUTE ON
DRUG ABUSE

NIDA INITIATIVES FOR FY 1994

CLINICAL NEUROSCIENCE

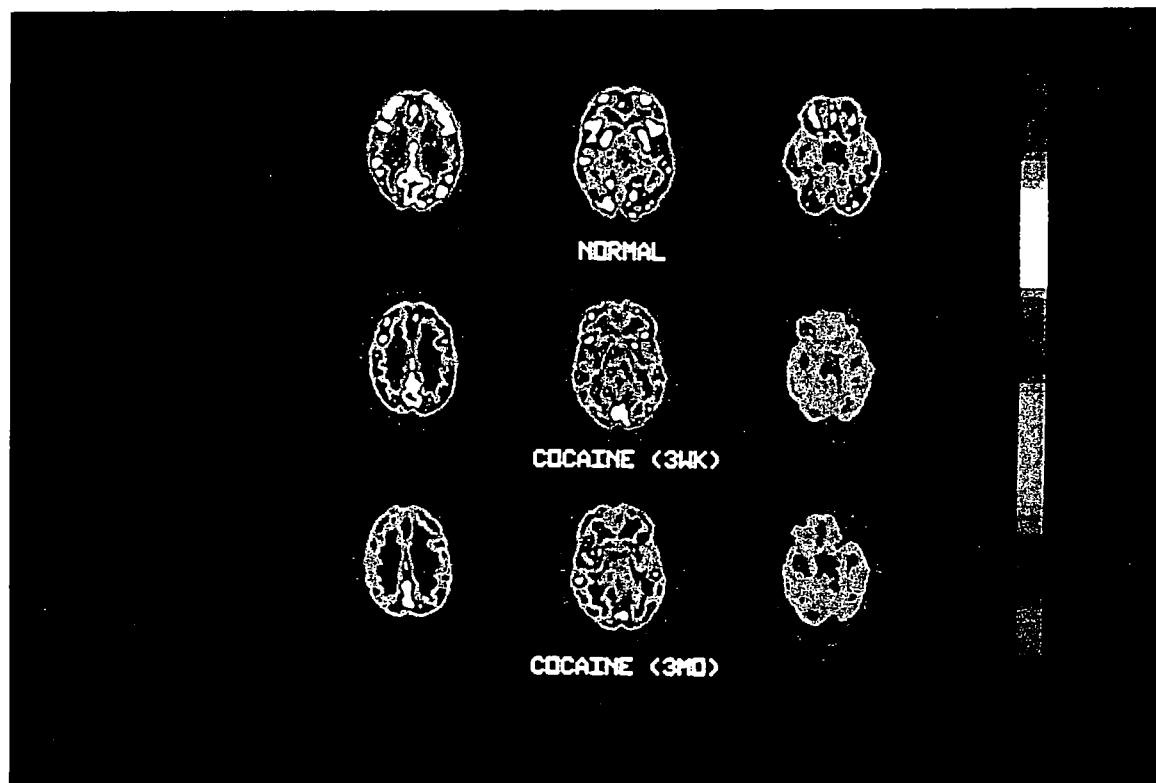
- To develop, integrate, and validate non-invasive technologies for use in drug abuse diagnosis and treatment.
- Establishment of a series of regional multidisciplinary neuroscience research facilities, having state of the art neuroimaging facilities as their focal point and conducting both animal and human studies, with emphases on both drug abuse prevention and treatment.

MEDICATIONS DEVELOPMENT

- Development of medications which will block the effects of addictive drugs; reduce craving for these substances; and block or reverse their toxic effects.
- Development of medications to treat drug addiction that do not cross the placenta

BEHAVIORAL THERAPIES

- **Building on the knowledge gained from basic behavioral studies to identify, formulate, and systematically test promising therapies.**



Brain glucose metabolism for a normal control and a cocaine abuser tested 3 weeks after detoxification and again after 3 months of detoxification. Images were obtained using ^{18}F -deoxyglucose and PET.

Clinical Trials

Medications to Treat Opiate Addiction

Buprenorphine

Buprenorphine/Naloxone

Dynorphin

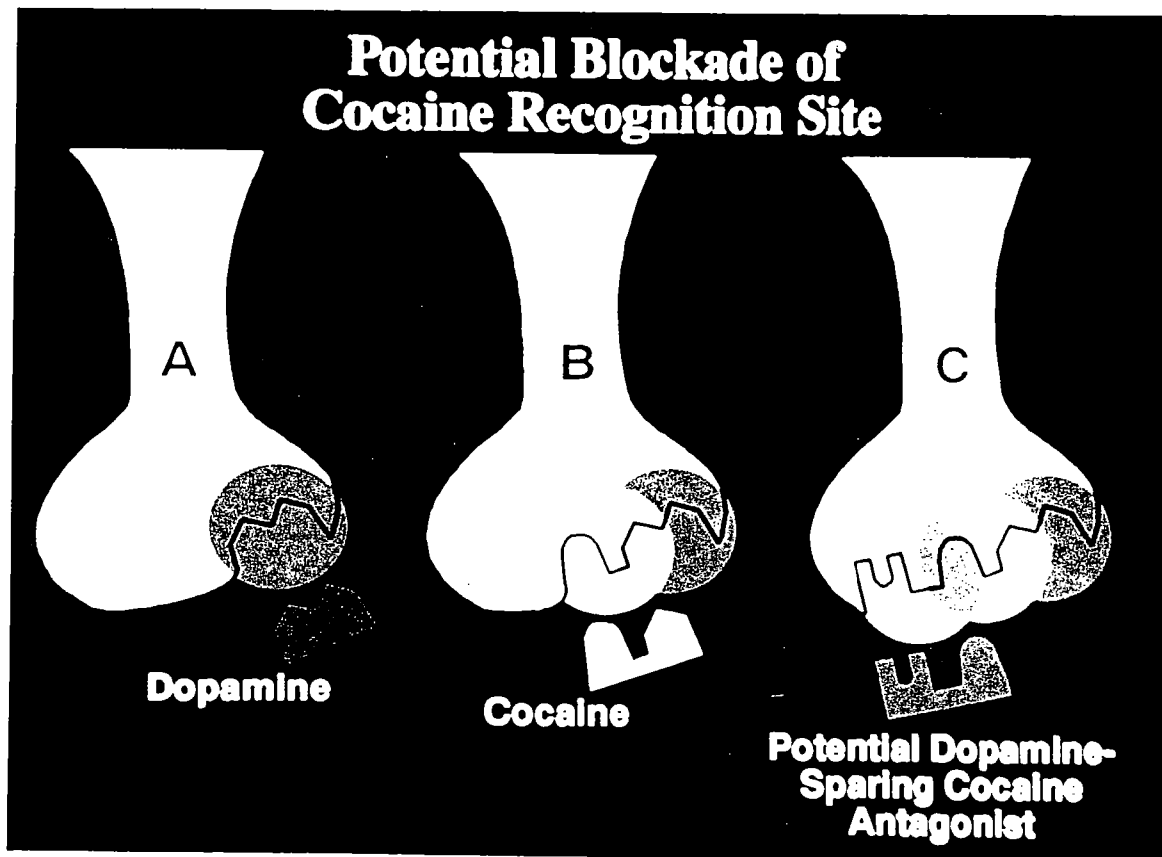
Gepirone

LAAM

Naltrexone

Kappa/Delta Compounds

Enkephalinase Inhibitors



A schematic representation of potential blockade by a dopamine-sparing cocaine antagonist.

Clinical Trials

Medications to Treat Cocaine Addiction

Amantadine

Bromocriptine

Bupropion

Carbamazepine

Clomipramine

Desipramine

Fluoxetine

Flupenthixol

Mazindol

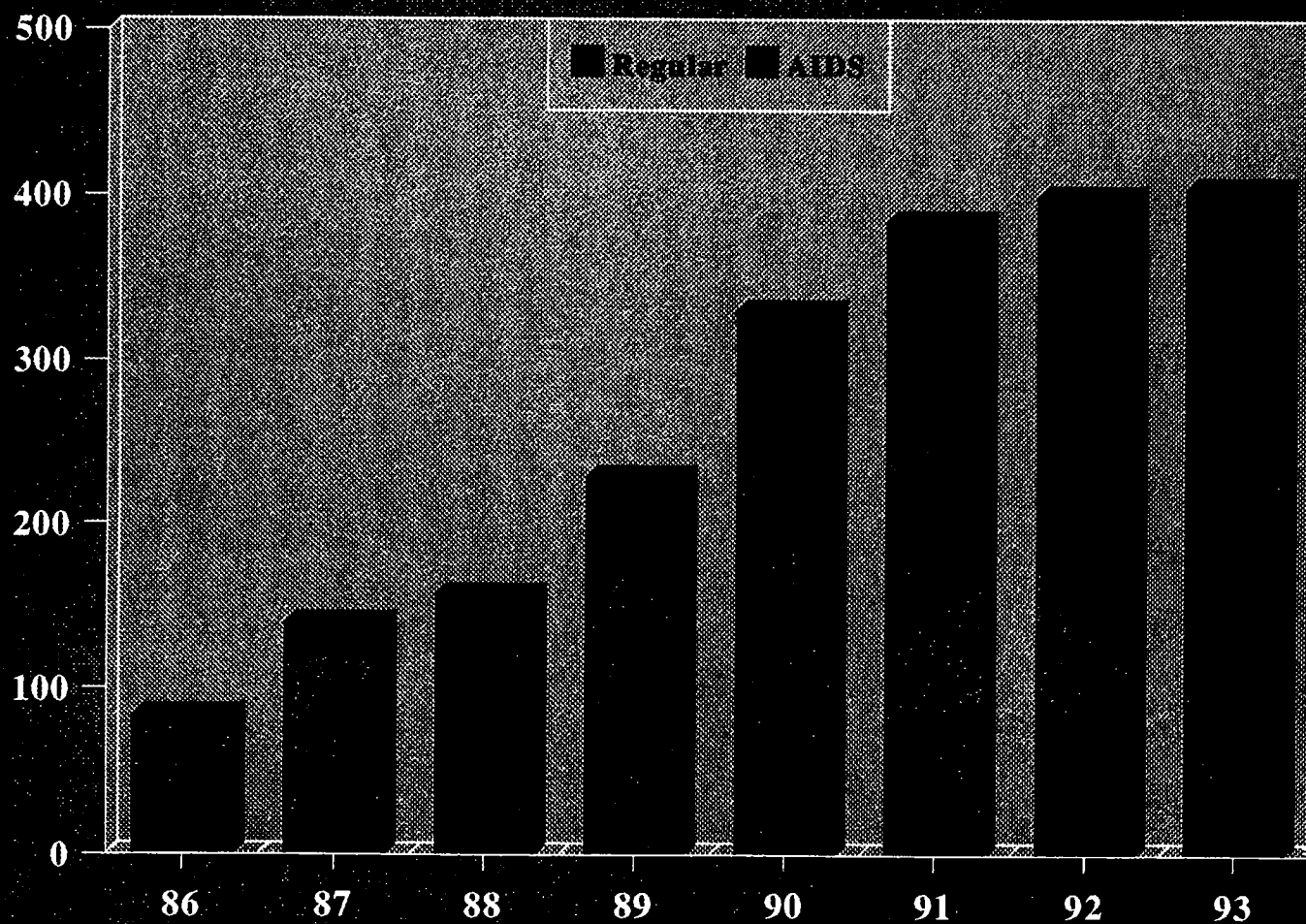
Nimodipine

Ondansetron

NIDA BUDGET HISTORY

Research and Research Demonstrations

Dollars in Millions



FISCAL YEAR

NIDA 