

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records
Subgroup/Office of Origin: National AIDS Policy Office
Series/Staff Member: Patsy Fleming
Subseries: National AIDS Strategy

OA/ID Number: 9002
FolderID:

Folder Title:
Introduction-Litsearch [2]

Stack:	Row:	Section:	Shelf:	Position:
S	66	5	10	2

OTA BACKGROUND PAPER

THE EFFECTIVENESS OF AIDS PREVENTION EFFORTS

Office of Technology Assessment
Congress of the United States

OTA-BP-H-172

September 1995

Technology Assessment Board of the 103d Congress*

EDWARD M. KENNEDY, Massachusetts, *Chairman*
DON SUNDQUIST, Tennessee, *Vice Chairman*

SENATE

ERNEST F. HOLLINGS, South Carolina
CLAIBORNE PELL, Rhode Island
ORRIN G. HATCH, Utah
CHARLES E. GRASSLEY, Iowa
DAVE DURENBERGER, Minnesota

HOUSE

GEORGE E. BROWN, JR., California
JOHN D. DINGELL, Michigan
JIM McDERMOTT, Washington
AMO HOUGHTON, New York
MICHAEL G. OXLEY, Ohio

ROGER C. HERDMAN
(Nonvoting)

Technology Assessment Advisory Council

JAMES C. HUNT, *Chairman*
Distinguished Professor, Health Sciences Center
University of Tennessee
Memphis, Tennessee

MAX LENNON, *Vice Chairman*
President and CEO
Eastern Foods, Inc.
Atlanta, Georgia

CHARLES A. BOWSHER
Comptroller General of the United States
Washington, D.C.

LEWIS M. BRANSCOME
Director, Science, Technology & Public
Policy Program, Harvard University
Cambridge, Massachusetts

HERBERT (TED) DOAN
President (Ret.), The Dow Chemical Company
Midland, Michigan

NEIL E. HARR
Charles F. Curtiss Distinguished Professor
Iowa State University
Ames, Iowa

JOSHUA LEDERBERG
Professor, Rockefeller University
New York, New York

DANIEL MULHOLLAN
Director, Congressional Research Service
The Library of Congress
Washington, D.C.

THOMAS J. PERKINS
General Partner
Kleiner, Perkins, Caufield and Byers
San Francisco, California

JOHN F.M. SIMS
Vice President, Marketing
Usibelli Coal Mine, Inc.
Fairbanks, Alaska

L. DOUGLAS SMOOT
Dean, College of Engineering & Technology
Brigham Young University
Salt Lake City, Utah

MARINA V.N. WHITMAN
Professor, Institute of Public Policy Studies
University of Michigan
Ann Arbor, Michigan

* The TAB for the 104th Congress has not yet been appointed.

PROJECT STAFF

Michael Gluck
Eric Rosenthal
Project Directors

Hellen Gelband
Senior Associate

Romulo Colindres
Research Assistant

Laura Esslinger
Research Assistant

Clyde J. Behney
Assistant Director, OTA

Sean R. Tunis
Health Program Director

ADMINISTRATIVE STAFF

Louise Staley
Office Administrator

Carolyn Swann
PC Specialist

Monica Finch
Word Processing Specialist

Charlotte Y. Brown
Word Processing Specialist

CONTRACTORS

Thomas J. Coates, Ph.D.
Center for AIDS Prevention Studies
University of California at San Francisco

Donald C. Des Jarlais, Ph.D.
Chemical Dependency Institute
Beth Israel Medical Center
New York, NY

Anke Ehrhardt, Ph.D.
HIV Center
Columbia University
New York, NY

Douglas Kirby, Ph.D.
ETR Associates
Santa Cruz, CA

Barbara VanOss Marin, Ph.D.
Center for AIDS Prevention Studies
University of California at San Francisco

Steve Rabin, J.D.
Porter/Novelli
Washington, DC

Jane E. Sisk, Ph.D.
Columbia University
School of Public Health
New York, NY

Marc A. Zimmerman, Ph.D.
University of Michigan
School of Public Health
Ann Arbor, MI

CONTENTS

Key Findings 1

Background 3

Trends in Numbers of AIDS Cases 5

Gay and Bisexual Men 6
Injecting Drug Users 8
Ethnic and Racial Minorities 8
Women 9
Youth and Children 9

Approaches to AIDS Prevention—Changing Behavior 10
Judging Effectiveness 12

General and Targeted Efforts 13
Defining Groups 14

Counseling and Testing 14
Evaluation of Counseling and Testing 16

Efforts Designed For the American People as a Whole 16
Mass Communication Campaigns 17
AIDS Prevention by Physicians 18

Preventing AIDS Among Injecting Drug Users 20
Sexual Partners of Injecting Drug Users 22

Preventing AIDS in Racial and Ethnic Minority Populations 23

Preventing Heterosexual HIV Transmission to Women 24

Preventing AIDS Among School-Aged Youth 24

Preventing AIDS Among Children 25

Social Marketing 26

Economic Evaluation 28
Findings From Economic Evaluations 28
Potential For Greater Use of Economic Evaluation 29

REFERENCES 31

THE EFFECTIVENESS OF AIDS PREVENTION EFFORTS

OTA first addressed the question, *How Effective Is AIDS Education?* (91) in 1988. At that time, we concluded that "knowledge about the effectiveness of particular programs and of specific elements of programs has been slow to accumulate." The Sub-committee on Health and the Environment of the House of Representatives Committee on Commerce asked OTA to take a fresh look at the question, and this background paper is the result. In 1995, there still is a need for additional research and for development and use of more carefully-refined research methods, but we know now that certain interventions can successfully reduce the risk behaviors¹ associated with Human Immunodeficiency Virus (HIV) transmission in certain groups at high risk of AIDS. The details of what is known and still unknown are reviewed in this background paper.

Most of the information comes from a series of commissioned papers written by experts on the following topics:

¹ "Risk" and "risk behavior" are used in this paper to mean behavior that may lead to the transmission of HIV.

- ◆ *HIV/AIDS Prevention for Injecting Drug Users*
- ◆ *Does HIV Prevention Work for Men Who Have Sex with Men?*
- ◆ *AIDS Prevention Among African-Americans and Latinos in the United States*
- ◆ *A Review of Educational Programs Designed To Reduce Risk-Taking Behaviors Among School-Aged Youth in the United States*
- ◆ *A Review of HIV Interventions for At-Risk Women*
- ◆ *Applications of Social Marketing Principles to AIDS Education*
- ◆ *Economic Evaluation of HIV/AIDS Education and Primary Prevention*
- ◆ *HIV / AIDS Education: National Surveys, Counseling and Testing Programs and the Role of Physicians*

KEY FINDINGS

- ◆ Much has been learned since 1988 about which interventions are effective in changing risk behaviors related to HIV infection and AIDS among certain key subpopulations. Adult gay and bisexual men who do not belong to ethnic minority groups

have been the most intense focus of AIDS prevention, and most is known about which interventions work in this population.

- ◆ There still are major gaps in what is known about interventions for certain high-risk populations. African Americans and Latinos account for a disproportionately large share of people with AIDS, yet relatively little research has been directed toward prevention in these population groups.
- ◆ Younger gay and bisexual men of all ethnic groups still need to be reached, and continued efforts are required for the entire population of gay and bisexual men, to make sure that those who have changed their behavior do not lapse back into early, risky behaviors. Intravenous drug use is also a very important risk factor for HIV transmission among gay and bisexual men.
- ◆ Interventions developed through in-depth preliminary work with the target population, that consist of small-group programs that are interactive and include skills development, have been among the most successful at reducing risky sexual and drug-related behaviors.
- ◆ The availability of sterile needles does not increase the incidence of illicit drug use and they can play an important role in reducing the transmission of HIV among injection drug users. Other approaches--including the increased availability of drug treatment and changes in

methadone prescribing policies--while not the focus of much research, also are potential tools for reducing HIV transmission in this population.

- ◆ Sex education and AIDS education directed at school-aged youth do not increase sexual activity. Some specific sex and AIDS education programs have been shown to reduce unprotected sexual activity, either by delaying the onset of intercourse, reducing the number of sexual partners, or increasing the use of condoms.
- ◆ Voluntary HIV "testing and counseling"--the combination of HIV blood tests and the information provided before and after testing--are of variable impact, possibly because they are done differently in different places, in some cases more effectively than others. Done correctly, they have an important role in serving as a bridge to appropriate AIDS preventive, medical, and social referrals, and in some cases, altering behavior.
- ◆ Mandatory testing of certain low-prevalence populations (e.g., marriage license applicants) is an expensive way of detecting HIV positive individuals, and there is no evidence that interventions to change behavior would be effective with mandatory testing.
- ◆ Maintaining safe sex and needle use behavior over the long term once a change is made--perhaps over the course of one's lifetime--is likely to be important for individuals at risk of

HIV, but little is known about the interventions needed to maintain these changes.

- ◆ The value of the research on AIDS prevention that has been conducted has been diminished by poor study design. Flaws include poor basic design, small study groups, short evaluation periods, and lack of control or comparison groups. (These same flaws are common to a surprisingly high percentage of research in all areas of medicine, and are not necessarily more problematic in the AIDS area than in others.)
- ◆ There is a gap between what is known about effective interventions and what is actually delivered as prevention. Community-based organizations, which deliver a significant amount of prevention, often are not able to or simply do not take advantage of current knowledge about program effectiveness.
- ◆ "Social marketing"—the application of commercial marketing strategies to societal issues—offers a possible method of inducing behavior change and maintaining non-risk behavior. Although social marketing has not been widely applied to AIDS prevention in the United States, it has demonstrated impact on other health problems in this country and on HIV transmission in some other countries. Although potentially very effective, social marketing programs can also be very expensive.
- ◆ Programs of voluntary, testing, counseling, referral, and partner

notification, as exemplified by sites funded by CDC, appear to be cost-saving in the long run, i.e., the costs of the programs are exceeded by the long-term savings (discounted) in AIDS treatment costs averted. This is true if only about 7 percent of infected people notified change their behavior to avoid further HIV transmission. Needle exchange and bleach distribution programs for injecting drug users also appear to be cost-saving.

- ◆ AIDS prevention resources could be used much more effectively, even with current technology. In some instances, social and cultural influences have impeded their use. Specifically, there has been reluctance to encourage condom use, and there are societal and legal barriers to making sterile needles available to injection drug users.

BACKGROUND

HIV disease and AIDS are progressive conditions. They begin with infection with HIV and conversion from HIV seronegative to HIV seropositive. HIV may remain in the body for up to ten years or more without causing any apparent symptoms, and an individual may be HIV seropositive for many years without being diagnosed as having HIV disease or AIDS. During this period they are infectious. A person who has not been tested for the presence of HIV antibodies or antigens is unlikely to be aware of the infection. All the while though, HIV attacks certain cells of the immune system and causes the system to

erode. Eventually, the body falls prey to "opportunistic" infections (e.g., bacterial and viral infections of the respiratory and digestive tract) that are able to take hold due to the body's weakened immune defenses. A formal diagnosis of AIDS is not made until at least one of a certain group of infections occurs or until the immune system reaches a certain, critical level of deterioration. In most cases these infections—not HIV directly—incapacitate patients and cause illness and death.

HIV is transmitted in relatively clearly defined and understood ways, all of which involve the transfer of blood, semen or certain other body fluids from one individual to another (including transmission from infected woman to fetus). Transmission occurs in the course of certain behaviors, generally sexual or those associated with injecting drug use. HIV also may be transmitted from a seropositive pregnant woman to her fetus during pregnancy or birth and, in rare cases, to health care workers through needlesticks and other injuries.²

Rapid progress was made in identifying HIV as the causative agent of AIDS, in developing a test for antibodies to it, and in finding prophylaxis and treatment regimens for some of the opportunistic diseases associated with AIDS, but there is no short-term prospect for a preventive vaccine or any kind of cure. Currently available antiviral treatments are of temporary value at best. Consequently, the only

viable method for stopping the spread of AIDS is prevention, which depends almost entirely on individual behavior change (95).

Like other areas of medicine and health, public and private funding for HIV/AIDS has supported biomedical research and development more heavily than behavioral and social science research. It is noteworthy that the first preventive intervention shown through rigorous evaluation to be efficacious was a device-based technology: the HIV-antibody test for blood. Moreover, development of the blood test responded to a pervasive fear that people receiving blood products could become infected independently of their behavior. Developers of the antibody test could thus count on a large, secure market among mainstream health organizations, such as hospitals and blood banks.

By contrast, behavioral and social science research has received less emphasis and less funding, even though behavior change could prevent almost all further HIV transmission. This situation at least partly reflects the conflicting views within funding organizations and society about the behaviors associated with HIV transmission, namely sex, reproduction, and drug abuse. It has also characterized work on other sexually-transmitted diseases and drug abuse generally. Only in recent years has more rigorous research using experimental designs become common in behavioral and social science research, a development notable from the 1988 OTA report to the current background papers. Many of the

² Through the end of 1994, there were 42 documented cases of occupational transmission of HIV to health care workers and 91 possible cases (104).

economic evaluations of the early 1990s in fact grew out of such research funded by the Centers for Disease Control and Prevention (45,51,52).

The Federal Government has appropriated funds primarily through the Centers for Disease Control and Prevention (CDC) for AIDS prevention and education. Beginning in 1985, the Federal Government appropriated \$33 million for AIDS prevention and education. The appropriated funds have grown to \$589 million, the estimated expenditure for Fiscal Year 1995.

Even where AIDS prevention programs have been developed and tried, judging how effective they are remains a difficult task. It is challenging--particularly so when interventions are multifaceted and community-wide--to design studies that allow cause-and-effect to be inferred. Debate is ongoing about what types of studies and other types of evidence are sufficiently rigorous that they can be relied on to provide evidence of effectiveness, and some progress has been made in developing methods to evaluate the effectiveness and cost-effectiveness of particular interventions.

Interventions have been studied more in some communities and populations than in others, and not necessarily in relation to their importance to the current spread of HIV. Much more is known, for example, about how to prevent HIV transmission among white, gay and bisexual men over 30 than among sexually active young people or heterosexual African American or Hispanic men or women. And among injecting drug users, efforts have been directed mainly at changing their drug-taking

behavior, but not their sexual behavior, through which they can infect others. Because this paper is largely a review of literature, it reflects the balance of what has been done, which is not always the right balance for new efforts. It is particularly important to recognize that women and people of color are glaringly absent from much of the work on interventions. It is these groups among whom transmission is increasing the fastest, and they deserve higher priority in research and intervention programs than they have had up to now.

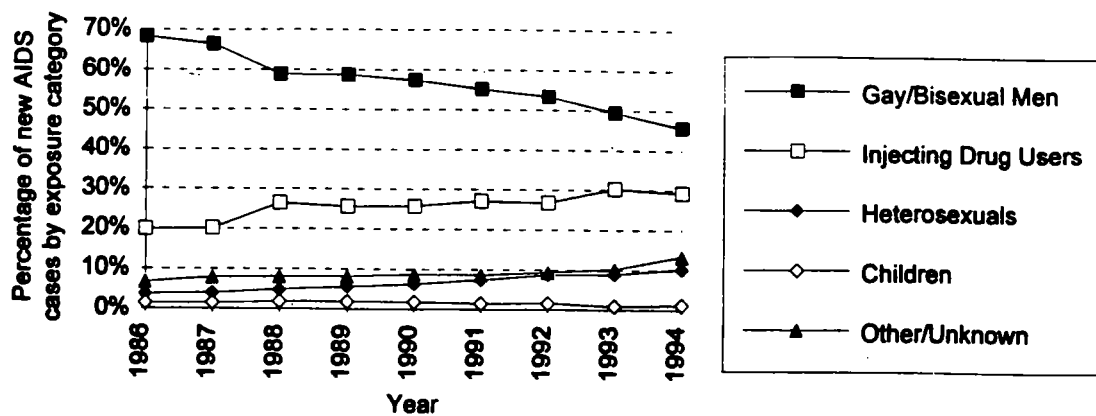
TRENDS IN NUMBERS OF AIDS CASES

The first cases of AIDS in the United States were reported in 1981. By the end of 1994, 442,000 Americans had been diagnosed with AIDS and 271,000 had died from symptoms related to the disease. The number of AIDS cases in the United States increased by about 3 percent from 1992 to 1993 and another 3 percent from 1993 to 1994.³ Women, African Americans, Hispanics, and people in the South and Northeast accounted for higher proportions of cases in 1994 than in 1993. The largest decline in the proportion of reported cases was among gay and bisexual men (figure 1).⁴

³ Because the AIDS surveillance case definition was expanded in 1993, AIDS incidence trends from 1993 to 1994 are evaluated using the estimated incidence of AIDS-defining opportunistic illnesses (103) in order to make accurate comparisons over time.

⁴ The term "gay and bisexual men" is used here to refer to all men who have sexual relationships with other men regardless of their identification or sexual orientation.

Figure 1: Trends in New AIDS Cases by Category



SOURCE: OTA, 1995.

AIDS strikes the relatively young. In 1993, it became the largest killer of Americans aged 25-44. This group accounts for about three-quarters of the cases. It also is the leading cause of death in that age group in 79 out of the 169 American cities with populations larger than 100,000 (1). In 1992, AIDS was responsible for the fourth greatest number of years of potential life lost for people under 65 years of age.⁵ AIDS was the only major cause of years of potential life lost to show a significant increase--11 percent--from the previous year (102). An estimated one million Americans are infected with the human immuno-deficiency virus (HIV), the virus that causes AIDS. HIV is one of the most virulent human viruses known, with death rates exceeding 75 percent of those infected, and the ability to infect large numbers of people.

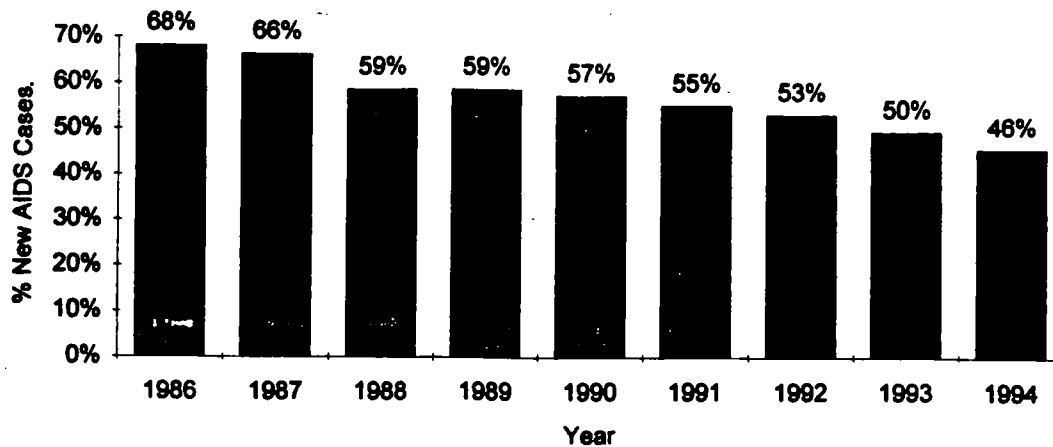
⁵ Years of potential life lost is a public health measure that reflects the impact of deaths occurring in years preceding a conventional cut-off of age, in this case 65 years old. It is a measure that takes into account number of deaths and age of decedents.

Gay and Bisexual Men

At the end of 1994, AIDS cases among gay and bisexual men, the largest group of people with AIDS, constituted 228,954 or 53 percent of the cumulative case load (figure 2). An additional 28,521, or 7 percent, of the cases are in gay and bisexual men who also inject illicit drugs (104). Gay and bisexual men represent a decreasing percentage of newly-diagnosed cases of AIDS, both because their rate of increase has slowed in recent years⁶ (1989 through 1994) and because the epidemic is growing more rapidly in other segments of the population (105). Gay and bisexual men have reduced their sexual risk behavior, including reductions in multiple sexual partners and reductions in incidence of unprotected sex, since the start of the AIDS epidemic. But gay and bisexual men continue to constitute the largest

⁶ Because the AIDS surveillance case definition was expanded in 1993, AIDS incidence trends in the study being discussed are evaluated using the estimated incidence of AIDS-defining opportunistic illnesses (103) in order to make accurate comparisons over time.

Figure 2: Percentage of New AIDS Cases Represented by Gay and Bisexual Men



SOURCE: OTA, 1995.

portion of people with newly-diagnosed AIDS, so success in controlling the AIDS epidemic depends on preventing new cases among this group.

The AIDS epidemic among gay and bisexual men, like the AIDS epidemic more generally, is a composite of epidemics among different groups, with different times of onset and patterns of spread. The rate of new cases among certain subcategories of gay and bisexual men, especially white gay and bisexual men, originally hardest hit by AIDS, is slowing (table 1). However, rates of growth are increasing among other groups less affected early in the epidemic (105). Rates of AIDS among

African American gay and bisexual men were highest in 1994 and showed the greatest increase since 1989. The rates of increase among other ethnic minority (Hispanic, Asian/Pacific Islander, and American Indian/Alaskan Native) gay and bisexual men also exceeded that for whites. In New York, Los Angeles, and San Francisco, where 27 percent of the AIDS cases among gay and bisexual men have occurred, the rate for white men decreased (20 percent, 16 percent, 3 percent, respectively) and for African American men, it increased (49 percent, 48 percent, 53 percent, respectively).

AIDS continues to spread beyond major metropolitan areas. The number

Table 1. Increases in the rate of newly-diagnosed cases of AIDS among gay and bisexual men from 1989 to 1994 and the rate of AIDS among gay and bisexual men per 100,000 men in mid 1994 are shown by race and ethnic group.

Race/Ethnicity	Increase from 1989 - 94	Rate in Mid 1994 (per 100,000)
African American	79 percent	37.3
Hispanic	61 percent	22.6
Native American/Alaskan	77 percent	6.9
Asian/Pacific Islander	55 percent	6.2
White	14 percent	12.2

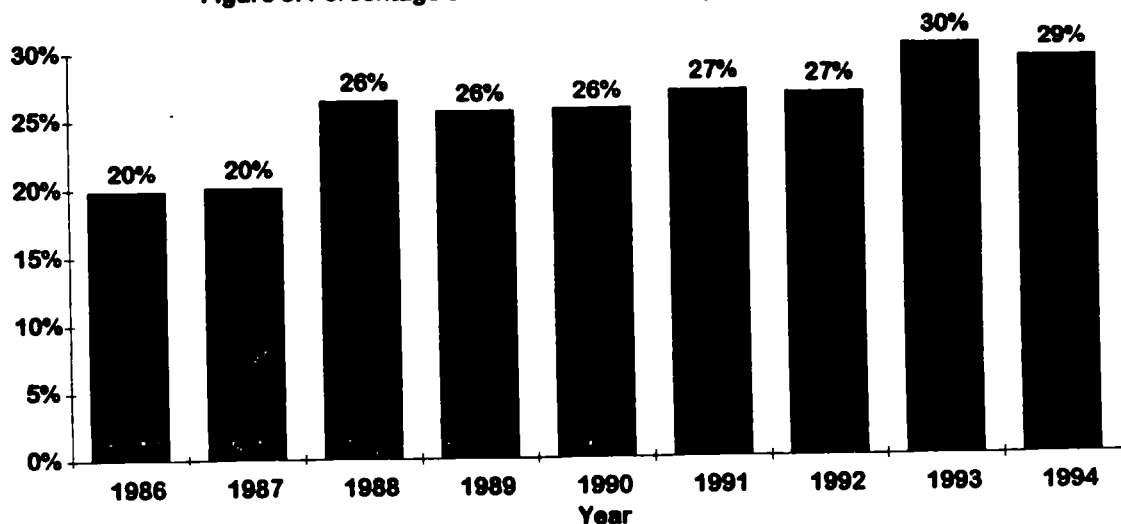
Table 2. Increases in the rate of newly-diagnosed cases of AIDS among gay and bisexual men from 1989 to 1994 and the rate of AIDS among gay and bisexual men per 100,000 men in mid 1994 are shown by size of area.

Size of Area (population)	Increase from 1989 - 94	Rate in Mid 1994 (per 100,000)
<50,000	69 percent	4.4
50,000 - 1 million	55 percent	10.2
>2.5 million	19 percent	24.8

of cases continues to be greatest in the West and Northeast and in urban areas, but the highest rate of growth is occurring in the South and Midwest, and in less populated areas (table 2). From 1989 to 1994, the number of AIDS cases

diagnosed among gay and bisexual men increased most in the Midwest (51 percent) and in the South (49 percent) and least in the West (21 percent) and the Northeast (13 percent) (105).

Figure 3: Percentage of New AIDS Cases Represented by Injecting Drug Users



SOURCE: OTA, 1995.

Injecting Drug Users

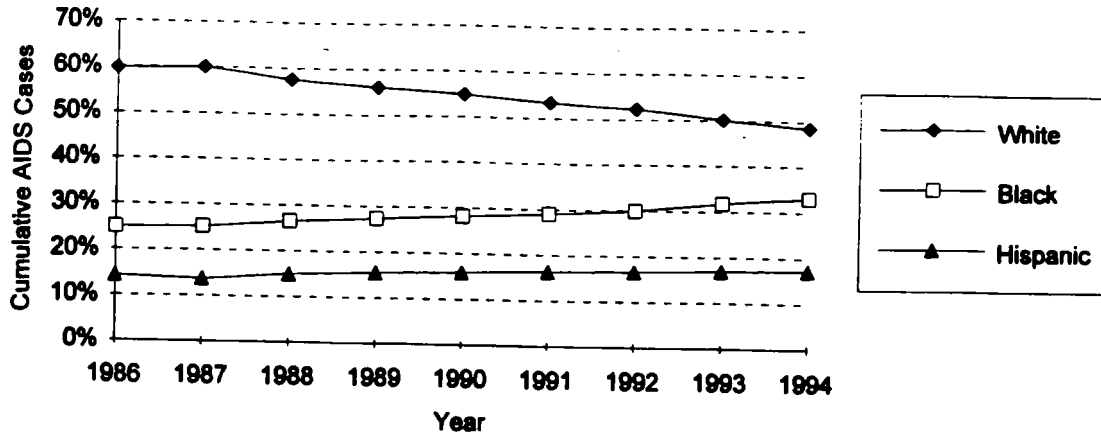
As many as 138,000 (32 percent) of the diagnosed AIDS cases reported through the end of 1994 are the result of injecting drug use⁷ (figure 3) (104). Estimates of new HIV infections in the United States suggest that injecting drug use is associated with a plurality of new

infections (43), which has implications for the future course of AIDS cases.

Ethnic and Racial Minorities

Ethnic and racial minorities represent a disproportionate and increasing share of AIDS cases in the United States (figure 4). Fifty-one percent of all cases have been among people of racial minorities, which comprise only 23 percent of the population. One-third of all cases are African Americans, 17

⁷ These figures include the categories "injecting drug use" (109,393 cases) and "men who have sex with men and inject drugs" (28,521 cases), as used in the HIV/AIDS Surveillance Report.

Figure 4: Trends in Cumulative AIDS Cases by Race

SOURCE: OTA, 1995.

are Latinos, 0.7 percent are Asian/Pacific Islanders, and 0.2 percent are Native Americans, compared to 11 percent, 8 percent, 3 percent, and 0.8 percent, respectively, in the population as a whole (104). Data from HIVseroprevalence studies suggest that the proportion of racial minorities diagnosed with AIDS will continue to grow in the coming years (38,75,93).

Ethnic minority groups are often viewed as homogeneous clans but, in fact, there is enormous variety in the demographic characteristics, immigration history, and cultural values of ethnic subgroups. HIV infection also is not spread evenly within these groups. For instance, there is a high concentration of HIV among Latinos in the Northeast United States, who have come mainly from Puerto Rico and the Dominican Republic. Much lower incidence and prevalence rates are reported for Latinos from the West and Southwest, who have come mainly from Mexico and Central and South America.

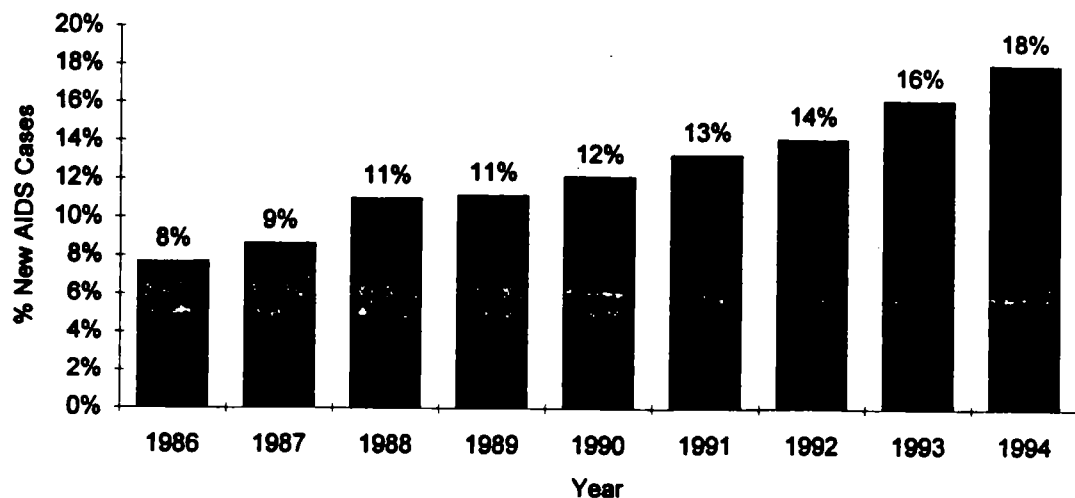
Women

The proportion of AIDS cases among women tripled from 1985 to 1994, rising to 18 percent of all new adult and adolescent cases (figure 5). Thirty-eight percent of the 14,000 cases among women diagnosed in 1994 were contracted from heterosexual sexual partners and 41 percent from injecting drugs (106). Seventy-seven percent of the 1994 cases were among African American and Hispanic women.

Youth and Children

Many young people are at risk for HIV transmission through their sexual practices. Through the end of 1994, 68,000 males and 14,000 females age 20 to 29 were diagnosed with AIDS (104). Because the period between HIV infection and onset of AIDS may be up to ten years, it is likely that many of these people, who represent almost one-fifth of AIDS cases, were infected with HIV as teenagers. Most of these cases were among gay and bisexual males,

Figure 5: Percentage of New AIDS Cases Represented by Women



SOURCE: OTA, 1995.

male and female injecting drug users, and heterosexual female sexual partners of injecting drug users.

There were 6,000 pediatric AIDS cases in the United States as of the end of 1994,⁸ representing just under 1.5 percent of the cumulative cases. The rate of pediatric AIDS cases has remained fairly constant at between 1 percent and 2 percent of the total new cases of AIDS each year.

APPROACHES TO AIDS PREVENTION—CHANGING BEHAVIOR

More than 40,000 cases of new HIV infection occur each year in the United States, despite a clear understanding of how the virus is transmitted. Although a

small number of infections arise from accidental transmission (i.e., blood transfusions, organ transplants, and needlestick injuries), nearly all infections are potentially preventable if behavior could be changed. This does not mean, however, that prevention depends entirely on persuading people to change their behaviors. It also involves access to the necessary information and technologies, and structural changes that make it easy for people to practice preventive behaviors.

With respect to Americans who are sexually active outside of a mutually monogamous relationship with an uninfected individual, behavior change means abstaining from certain sexual practices, using condoms, or both.⁹ For

⁸ The CDC defines pediatric AIDS as AIDS occurring in children less than 13 years old.

⁹ Although refraining from intercourse with an infected individual remains the most effective way to prevent sexual transmission of HIV, the Centers for Disease Control and Prevention has found that consistent and correct use of latex

individuals who inject illicit drugs, behavior change means ceasing to inject drugs, using only sterile needles, or not sharing needles.¹⁰

To be judged as effective, an intervention must reduce or eliminate the transmission of HIV. No prevention measure for any disease is 100 percent effective--many nowhere close to that--but they are still considered valuable. Likewise, attempts to change behavior will never stop all HIV transmission. But if an intervention even delays transmission, there is a beneficial effect both for the individual and for the course of the epidemic. An individual who avoids risk behavior even temporarily may avoid becoming infected or avoid infecting someone else. Partial success also may have benefits in diminishing the number of sexually transmitted diseases, unwanted pregnancies, and abortions.

Most premature deaths in the United States spring from "choices" people make--though not necessarily informed or "free" choices--and from social conditions that promote health or disease. These choices may be about sexual behavior, illicit drug use, smoking, drinking, diet, exercise, seat belt use, or recreation. Like these activities, HIV transmission depends on individual behavior choices. Similarly, HIV prevention is part of a spectrum of disease-fighting efforts that depend on risk avoidance, long-term behavior

change, and the development of policies that promote health and prevent disease. In most cases, simply telling an individual that HIV is spread through certain sexual and drug-use behaviors is not sufficient to alter that person's behavior, just as simply providing information on risk factors for heart disease or cancer is not sufficient. To be most effective, prevention strategies should provide information, motivation, skills, modification of perceived norms, and social or peer reinforcement. Just as important, long-term prevention requires long-term prevention efforts, so that positive behavior changes are sustained once they begin.

At least some attempts to change behavior to improve individual and public health historically have been beneficial, even though they have achieved only partial success. Campaigns to reduce smoking, the most important single cause of death in the United States, were initiated over three decades ago, but still about a quarter of Americans smoke. Attempts to increase exercise and improve dietary habits have found far less than full acceptance. The American Cancer Society and the National Cancer Institute recommend breast cancer screening through both mammography and clinical breast examinations for asymptomatic women aged 50 years or older. In a 1992 study, the CDC found that while 64 percent of women in the previous year had at least one of the exams, only 40 percent of women complied with the recommendation to have both (108).

condoms is highly efficacious for preventing HIV transmission (107).

¹⁰ For the purposes of this paper, "needle sharing" and "needle exchange" includes sharing or exchange of syringes and other drug injection equipment.

Evidence shows that behavior change is difficult for most people and sustained behavior change even more so. Public

health messages must compete with natural human desires, many of which are pleasurable (e.g., sexual relations) as well as with frequently appealing counter messages from entertainment media (e.g., to engage in sexual activity) or from peers (again, to engage in sexual activity or to use illicit drugs). These counter messages provide a constant challenge to AIDS prevention.

Judging Effectiveness

The biggest barrier to knowing which interventions are most effective at preventing the spread of HIV is that, considering the size of the problem and the amount of effort that has gone into solving it, too few interventions have been evaluated formally. And of those that have, many of the evaluations have not been rigorous enough to provide highly reliable information.

Some interventions have been studied in some locations and populations, but not others. More studies of gay men (mostly white) have been carried out than of any of the other important target groups, including women; younger, and non-white gay and bisexual men; adolescents and young adults generally; people with other sexually transmitted diseases; military personnel; prostitutes, and incarcerated populations. In addition, evaluation has, of necessity, focused on relatively short-term changes, in an area where the need is for changes that persist over a lifetime.

Many individuals—especially those in communities targeted for special prevention efforts—are subject to many influences on their behavior. If someone is taking part in a formal study of an

intervention's effectiveness, they will almost always be exposed to information (e.g., news reports) or events (e.g., a friend or relative sick with or dying from AIDS) external to the study. The only reliable way to determine what effects the planned intervention had, versus the effects of other influences, is to compare the behavior of people who got the intervention with that of a "control" group which, other than the study intervention, had similar inputs. The intervention and control groups should, ideally, be allocated by a method that gives an equal chance of getting into one group or the other, regardless of the individual's (or group's) characteristics, and this requires some form of randomization. The "unit of randomization" may be the individual, the community, the school, or some other unit. It is often difficult and expensive (and in some cases, not feasible) to apply randomized controlled conditions to real world intervention projects, but in fact, it is possible and the method should not be abandoned as facilely as it often is. This is not to say that other types of studies can't produce useful information, but the results of other types of studies will never be as reliable as the results of randomized studies. Even the strongly-held opinions of professionals about what does and doesn't work in AIDS prevention are not, by themselves, reliable guides for further programs.

The methodological challenges in studying and validating interventions to change behavior are even greater than for many other medical interventions (e.g., pharmaceuticals, surgical procedures). Trying to generalize the results of individual studies to the broader population is also more difficult.

Interventions to change individual behaviors can usually be considered "complex interventions," with the following features: First, the intervention itself can be highly variable, depending on who actually conducts it. For example, the counseling portion of a testing program may vary substantially according to the style and knowledge of the provider. Much of this variability may not be easily characterized or even detected. Second, contextual factors may be important variables in the effectiveness of the intervention. For example, an educational program delivered to teenagers in a schoolroom may have a different impact than the same program offered in a community center. Third, complex interventions are characterized by a range of possible endpoints that could be used to determine effectiveness. The effects of an educational leaflet could be measured by how many are distributed, by surveys of how knowledge changes among the target population, by measuring changes in condom sales, or by tracking the prevalence of HIV.

In a practical sense, this means that an intervention found to be extremely effective in an individual study is not necessarily transferable directly to another population group or geographic area. It may be that the key factor in its success is the process by which the intervention was developed and implemented (e.g., with strong community input), rather than the actual content of the intervention. In reviewing the literature, therefore, it may not be possible to make a list of interventions that work, but it may be possible to list the characteristics of interventions and studies that have been successful.

GENERAL AND TARGETED EFFORTS

The overwhelming majority of new HIV infections continues to be concentrated in relatively few geographic areas ("communities") and demographic groups ("populations"), though some cases occur in every community and population. Controversy has surrounded the issue of whether to target funds intensively to the communities and populations with the largest number of new HIV infections or to stress universal risk to the entire U.S. population (19,86,96). The dilemma arises for two reasons: first, concerns about stigmatizing people in targeted groups, and second, because HIV can infect anyone who engages in certain sexual or drug-related behaviors with a person who is seropositive. It has the potential to spread more widely throughout society as it has, for example, in some African countries. In the United States, however, most people with AIDS are concentrated in small segments of the population¹¹ which are largely self-contained in terms of risk behavior. If HIV were spread exclusively within clearly defined communities, it might make sense to concentrate efforts only in these communities. However, risk behavior is not completely confined in this way and individuals outside these communities may become infected.

¹¹ For instance, at the end of 1994, 73.5 percent of the cumulative AIDS cases were in California, Florida, Georgia, Illinois, Maryland, New Jersey, Pennsylvania, New York, Texas and Puerto Rico. In addition, at least 88.3 percent of the adult and adolescent cases were among gay and bisexual men, injection drug users and their sexual partners.

Effective AIDS prevention depends, therefore, on a combination of universal and targeted approaches. Universal education informs individuals who do not identify with a target population but may be at risk for infection. It also serves as reinforcement for targeted efforts. In order to reduce the spread of HIV, anyone, heterosexual or homosexual, who is potentially sexually active or who considers illicit drug use should understand his or her risk and how infection can be avoided. Universal AIDS prevention programs also can help reduce discrimination against people with HIV infection or AIDS. However, most new HIV infections could be prevented by intensive efforts aimed at the populations in which HIV is spreading, including gay and bisexual men, injecting drug users, and heterosexuals with high rates of sexually transmitted diseases (19). Intensive efforts in certain groups also could provide the continuing support individuals would need to maintain non-risk behavior over time.

Defining Groups

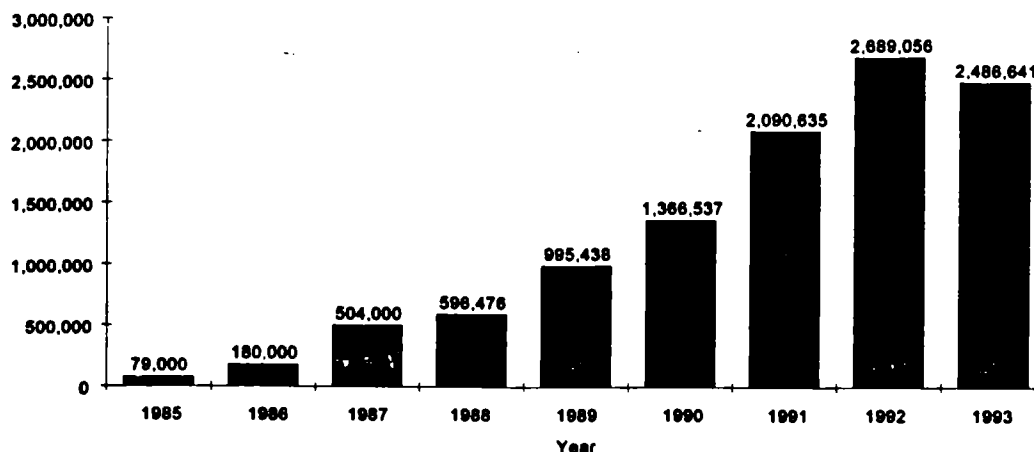
People often are defined for the purposes of AIDS education by the group or groups to which they belong—usually demographic or geographic. Many times, the groups are adopted conveniently from the epidemiological perspective, i.e., the groups for which data are reported. But in fact, the United States is a "complicated patchwork of behaviors, incomes, and ethnic backgrounds that confound simple cultural labeling" according to consumer marketers (85).

This suggests the need for a fresh look at how individuals are grouped for prevention efforts. Among African Americans, for example, there are varieties of consumption patterns and health indices depending, among other things, on location and aspects of heritage. In addition, many people fall into several groups. The commercial sector relies on statistical clusters based on geography, lifestyle, behavior, financial status, and attitudes more than on race alone. African Americans, Hispanics, Asians, and Native Americans should not automatically be lumped together as "minorities" if AIDS prevention efforts are to be most effective. Traditional consumer marketing also tends to segment the population along age lines rather than along the "risk group" lines suggested by epidemiological data. With half of the new infections occurring in individuals under 25, adolescents at risk may have more in common with each other than with individuals of similar race, ethnicity, or sexual orientation, but of different ages.

COUNSELING AND TESTING

The CDC spends substantial funds on its program of counseling, testing, referral, and partner notification (CTRPN), much of which has been mandated by Congress. The program began in 1985 with 79,000 people tested. By the end of 1993 11 million tests had been performed (figure 6). An additional 5 million tests had been performed in private physicians' offices and health maintenance organizations through 1990 (101).

Figure 6: HIV Tests in CDC Sites by Year



SOURCE: OTA, 1995.

The four main functions of counseling and testing, according to CDC are: (1) to provide a convenient opportunity for persons to learn their current HIV serostatus; (2) to help initiate behavior changes to avoid infection or, if already infected, to prevent transmission to others; (3) to refer individuals to additional medical and other services as needed; and (4) to provide prevention services and referrals to sex and needle-sharing partners of people with AIDS or HIV infection. (111). Counseling and testing also protect the blood supply and provide a method to notify sexual partners of seropositive individuals of potential risk (45).

In addition to the testing itself, each person is to receive counseling both at the time of providing a blood sample and upon receiving test results. The pre-test counseling is intended to assess the client's personal risk for HIV infection, discuss the elements of the test, and answer questions. The post-test counseling informs the client of his or her serostatus and discusses its

implications. If the result of the test is negative, the counselor should discuss the importance of adopting or continuing risk reduction behaviors. If a client tests positive, the counselor also provides emotional support and referrals for appropriate medical and other services. Many programs include a mechanism for notifying partners of infected individuals (36). Unfortunately, pre- and post-test counseling, as conducted currently, often are inadequate to assess the potential for risky behavior, and in many places, there are too few medical and prevention services available for referral.

Except for uniformed military personnel, Jobs Corps applicants, foreigners who attempt to immigrate to the United States, and some other selected groups (e.g., State Department employees, sex offenders, prostitutes, prisoners, blood donors), most HIV testing has been voluntary. One exception was an Illinois law requiring that couples be tested for HIV and receive their results before they could get a marriage license. In the six months

after the law took effect, only eight out of the 70,846 applicants tested seropositive. During the same time, applications for marriage licenses decreased by 22.5 percent, and licenses issued to Illinois residents in surrounding states increased. Research suggests the possibility that residents most likely to test seropositive were most likely to seek out-of-state licenses. Testing costs were paid by the applicants, not by the state, but the cost per case of HIV identified was estimated to be \$312,000, compared with \$2,000 per case identified through the state's voluntary counseling and testing program. The law was repealed and the Director of the Illinois Department of Public Health concluded that the experience "provides a strong argument against widespread mandatory or publicly supported HIV antibody testing of low-prevalence populations" (100).

There also is evidence that individuals, especially high-risk individuals, are more likely to come forward if they have the option of anonymous testing. In an Oregon study, anonymous HIV testing, as opposed to confidential testing, increased the number of people who came in to be tested and increased the proportion found to be seropositive (28).

Evaluation of Counseling and Testing

Counseling and testing programs have been difficult to evaluate because of the variety of study populations, research designs, methodologies, analyses, and results (42). In addition, testing is often performed without counseling (though CDC's guidelines require counseling with testing) (41). There is evidence that

counseling and testing can lead to reduced sexual and drug risk behavior associated with viral transmission (42,45). The effects vary, however, by serostatus, population, and the quality of the counseling and testing service.

The single area with clear data for behavior changes associated with reduced risk of HIV transmission following counseling and testing concerns both gay and heterosexual discordant couples (one partner infected with HIV and the other not). It is important to note, however, that this finding comes from programs in which the counseling extended beyond that typically received by most people who are tested. In several studies of discordant couples, there was a substantial increase in condom use over time. These results suggest that intensive counseling over a sustained period may be effective in reducing risk behavior for individuals at high risk for HIV infection (21,53,81,98,114). They may point to ways to improve counseling for other groups.

EFFORTS DESIGNED FOR THE AMERICAN PEOPLE AS A WHOLE¹²

Education and prevention efforts aimed at the American people as a whole have several aims. In addition to the obvious aim of promoting safe practices, others are to reduce discrimination against infected people and to reduce anxiety among low-risk people by giving

¹² This section is based largely on a paper prepared under contract to OTA by Zimmerman, Pham, and Steinman (120).

them good information about how HIV is and is not transmitted. To a large extent these efforts are intended to reach sexually active heterosexual youth and adults for whom there are few targeted community-based programs. This group accounts for relatively few AIDS cases, but the percentage of heterosexual adolescents and adults among AIDS cases who do not belong to a defined high-risk category is growing. From 1988 to 1994, the percentage of newly-diagnosed AIDS cases in this group increased from 5 percent to 10 percent. AIDS is becoming a particular problem in some heterosexual subpopulations, particularly African-Americans and Hispanic-Americans (7,74).

Knowledge about HIV transmission has increased from 1987 to 1992, though there continue to be significant gaps (88). This increased knowledge may be explained by a combination of several influences, including media attention, high profile cases such as Magic Johnson and Ryan White, and school-based AIDS education. Americans are more likely to understand how AIDS can and cannot be transmitted. However, in 1992, 55 percent did not know whether latex condoms and natural-membrane condoms conferred the same protection against HIV/AIDS, and 60 percent did not know whether oil-based lubricants can cause latex condoms to break, two important factors in condom effectiveness.

Knowledge usually is necessary for behavior change, but there is no clear and consistent evidence that accurate AIDS knowledge alone necessarily changes behavior (4). Many sexually active heterosexual Americans may be at

modest risk for HIV transmission because they engage in sexual activity with more than one sexual partner, often without a condom (2,7,8,23).¹³ Despite the risk for transmitting HIV through heterosexual activity, few interventions have been evaluated to determine their impact on this behavior.

Mass Communication Campaigns

National surveys indicate that television is the most frequently cited source of information about AIDS. Thus, the mass media are well-positioned to play the dual role of influencing people who are not reached by other interventions and serving to reinforce non-risk behavior for those who are. The CDC developed America Responds to AIDS (ARTA), a national public service advertisement and public relations campaign designed to reach as many Americans as possible with information about HIV and how to prevent its spread. The campaign ran from 1987 to 1991, using electronic and print media, as well as public events. ARTA focused on providing information about AIDS rather than urging behavior change. It shied away from strong prevention messages, because the behavior changes needed to reduce the spread of HIV involve controversial topics such as sexual behavior and drug use. For instance, the public service announcements usually failed directly to address risk-reduction behaviors such as the use of condoms. In addition, there

¹³ Most Americans who engage exclusively in heterosexual sexual activity are at less risk for infection than most gay and bisexual men simply because the incidence of HIV is lower among heterosexuals than among gay and bisexual men.

are inherent limitations to public service announcements as opposed to paid commercials because television and radio station personnel determine if and when the commercials run. They are motivated primarily by the needs of the station, not by public health considerations. Further, to be most effective, mass media campaigns must be implemented for a sustained period of time and heard repeatedly, which is not likely with public service announcement campaigns. The media potentially offers an important source of AIDS prevention because of its reach, but the opportunity has not yet been used effectively.

AIDS Prevention by Physicians

Physicians are seen by the public as sources of reliable health care and prevention information (14,117) and physician counseling can lead to healthier behaviors (65). As yet, however, physicians have not played a major role in informing people about their risk of infection with HIV, or counseling them about how to avoid it. They represent a potential source of influence for the 60 percent of Americans who see a physician each year--though many of the people at highest risk may not see a physician.

The U.S. Surgeon General, the CDC, the Agency for Health Care Policy and Research, and many professional medical associations have encouraged physicians to assess their patients' risk behaviors and counsel them to prevent HIV transmission, but no clear guidelines about what steps to take with patients have been put forth. It appears that most physicians do not counsel about HIV or AIDS (6,35,110).

(Physicians often do a poor job with other prevention opportunities as well, e.g., influenza vaccines for older people, rubella screening for potentially pregnant women.)

Lack of information about and training in AIDS, discomfort in addressing sexual conduct, and incorrect assumptions about high risk behaviors may be holding back some physicians from counseling. Some research has shown that physicians are uncomfortable with AIDS, at least partially because most people with AIDS are gay or are members of other stigmatized groups (119). Other barriers to effective physician prevention efforts include rushed visits and limited or nonexistent reimbursement for counseling and testing. Finally some people cannot afford to visit doctors, choose not to see them regularly, or see them in settings not conducive to prevention counseling (69).

A nationwide program of AIDS Education and Training Centers (AETCs), set up through the Health Resources and Services Administration of the Public Health Service, began in 1987 to train physicians, nurses, and dentists. Most AETC activities are for training health care personnel to care for people with AIDS, but about 25 percent of the training activities are directed towards prevention (13), and there also are private sector continuing medical education programs on the topic. Few studies have evaluated the effects of training physicians or other health care workers, but some evidence suggests that training may improve risk assessment and prevention counseling for HIV (29,44). Any future efforts

should be subjected to rigorous evaluation.

PREVENTING AIDS AMONG GAY AND BISEXUAL MEN¹⁴

Carefully designed studies have demonstrated that interventions can be effective in lessening risk behavior among gay and bisexual men. The interventions studied included individual or small-group counseling, HIV counseling and associated testing, and community approaches. In these studies, reduction in risk behavior was defined as statistically significant increases in condom use or reductions in anal intercourse without a condom. The studies showed that positive behavior changes can be both short-term and relatively long-term (greater than one year). Evidence suggests that interventions can be effective with gay and bisexual men generally, including African Americans and adolescents. No studies of Latinos have been published, however.

Multiple session, small group counseling can result in both short-term and long-term increase in condom usage and less unprotected sexual activity (57,112), including with African American gay and bisexual men (83). No controlled studies have been conducted considering the effects of counseling on gay and bisexual adolescents, but in two uncontrolled studies, reductions in risk behavior were associated with counseling interventions.

Data suggest that HIV counseling and testing may play a role in HIV risk reduction for gay and bisexual men (42). Gay and bisexual men who have been tested tend to engage less often in sexual risk behavior. However, it is difficult to isolate the effects of HIV counseling and associated testing from other factors that may affect risk behavior, including the same personal factors that cause some people to be tested and others not to be.

Community-level interventions seek to modify the norms of entire groups of people in which there is a high level of HIV infection, so that there can be social and peer reinforcement for non-risk behavior. Several projects included pre- and post-intervention evaluations that suggest that community interventions may have an effect on reducing risk behavior (11,54,55). For example, the STOP AIDS Project in San Francisco conducts outreach and workshops for gay and bisexual men. An evaluation, conducted with the Center for AIDS Prevention Studies, revealed that of the last 505 pre- and post-test evaluations, 25.1 percent of the men reported unprotected intercourse prior to the workshop and 19.4 percent after, with greater differences observed for seropositive individuals (9). (None of these studies have randomized communities to have the intervention or not, or have had control communities, so it is not clear how much of the change can be attributed to the intervention.) In a study of small-town gay men who go to bars, training a small group of "trendsetters" in non-risk sexual behavior altered the norms of the group. "If risk reduction is an expected and accepted norm within one's peer and social network, individuals will be

¹⁴ This section is based largely on a paper prepared under contract to OTA by Coates et al. (10).

encouraged to adopt precautionary patterns (58)."

Determining whether HIV infection prevention is working "on the ground" is difficult because of the small number of controlled studies and the lack of consistent, established surveillance systems to provide regular and reliable information about HIV transmission rates. Studies have found sharp declines in risk behavior among gay and bisexual men in San Francisco, New York, and other cities during the 1980s. Reported behavior changes early in the AIDS epidemic among gay and bisexual men were among the most profound in public health (11,27,71,72,73). There have been declines in seroconversion from HIV negative to positive (50), declines in potentially unsafe sexual relations (20,24), declines in other sexually transmitted diseases, and declines in the rate of new AIDS cases. For example, the San Francisco Department of Health projects the number of people in that city who will become infected with HIV between 1994 and 1997 at 1,000 per year (an estimated 650 among gay men), down from 8,000 in 1982. These changes appear to have continued into the 1990s (89) and cannot be explained simply by saturation of high-activity core groups (50). They almost certainly represent benefits gained through behavior change (but not necessarily from particular programs).

It must be underscored that while there is evidence of improvement for gay and bisexual men as a group, there continues to be high rates of new infections among some racial and ethnic groups and among younger gay and bisexual men. Young gay and bisexual

men are forging another wave of HIV infections. Existing intervention strategies do not appear to be successful in reaching these populations. In addition, there is some indication that gay and bisexual men who initially adopted low-risk behaviors may have failed to maintain these behaviors (11,27,56,94). These data collectively demonstrate a need to focus on and find more effective interventions for younger and non-white gay and bisexual men, while continuing to pursue prevention and maintenance strategies for all gay and bisexual men.

PREVENTING AIDS AMONG INJECTING DRUG USERS¹⁵

The exchange of blood through sharing of injecting drug equipment by two or more people is the second most common cause of HIV transmission after unprotected sexual intercourse between men. The major mechanism for the spread of HIV infection among injecting drug users is injection with traces of blood from contaminated needles or other paraphernalia previously used by an HIV infected individual. Providing previously used equipment to another injection drug user is often seen as an act of solidarity or as a service for which one may legitimately charge a small fee.

Transmission of HIV within the population of injecting drug users may be lessened by eliminating or reducing illicit drug injection, reducing needle sharing, or using sterile injection equipment. Without intervention, HIV

¹⁵ This section is based largely on a paper prepared under contract to OTA by Des Jarlais (16).

can spread rapidly among injecting drug users. In certain areas, the rate of infection has increased from 10 percent to 40 percent or more within just one or two years (17). In turn, HIV is often spread from infected injecting drug users to their sexual partners.

Successful drug detoxification and treatment are the best methods of AIDS prevention among injecting drug users but are not a completely satisfactory solution. Only 15 percent of active drug users are in treatment on any given day, and there are not enough treatment slots to meet the demand from drug users. In addition, many drug users do not want to enter treatment. Treatment programs can lead to substantial reductions in illicit drug use (47), but treatment does not guarantee ending risk behavior or preventing a return to drug use. Education at drug rehabilitation sites and "street outreach" to active drug users, including education, needle exchange, and instruction on needle sterilization were attempted in some places.

The National Institute of Drug Abuse (National AIDS Demonstration Research /AIDS Targeted Outreach Model) funded street outreach prevention efforts in 41 projects in 50 cities. These programs offered participants information about HIV and AIDS, personal risk assessment, and HIV counseling and testing. Results were somewhat mixed, but the interventions were followed by a decline in needle sharing and an increase in sterile needle use.

Needle Exchange

Needle exchange and bleach disinfectant efforts have proven

controversial, with some critics asserting they encourage illicit drug use or that they implicitly endorse the use of illicit drugs. In the United States, unlike in several European countries, no Federal funds may be used to support exchanges of needles or any distribution of sterile injection equipment to illicit drug users. In addition, many states prohibit the sale of such equipment without a prescription. By contrast, providing legal access to sterile injection equipment, either through expanded pharmacy sales, needle exchange or both is now a standard part of HIV prevention in many other industrialized countries.

Local needle exchange programs have been established in at least 102 U.S. sites through at least 37 programs. Programs provide a sterile needle in exchange for a used one. In addition, many of the programs make referrals to drug detoxification and treatment programs and distribute condoms, bleach, health pamphlets, and other AIDS prevention information. About half of the needle exchange programs are legal under the law of the state in which they operate. About one-quarter are not legal but receive support from a local elected body. The remainder operate outside of the law and without such support (52).

Several U.S. needle exchange programs have been evaluated. In every published study, including one conducted by the General Accounting Office (GAO) in 1993, no evidence was found that the programs result in any increase in illicit drug use. In fact, one program studied by GAO found a decrease in drug use in association with the implementation of a local effort (52). In addition, there is evidence that

outreach programs and needle exchange programs uncovered demand for drug detoxification and treatment and were a significant source of referrals to such treatment (3,49,79).

The National AIDS Demonstration Research/AIDS Targeted Outreach Model and other studies (18) have found that HIV infection rates are much lower in areas that permit over-the-counter sales of sterile injection equipment as opposed to areas that restrict them by requiring prescriptions for their purchase. In one study, incidence of HIV infection was lower by half in areas with legal over-the-counter sales of needles (30). Studies of injecting drug users participating in needle exchange programs in several U.S. cities also have found a low rate of HIV transmission among participants (39,78,80,82).

A study of hepatitis B and hepatitis C infection in Tacoma, WA provides good evidence for the effectiveness of needle exchange programs on reducing transmission of blood-borne viruses, particularly because the study used biological outcomes and a controlled experimental design. Failure to use the local needle exchange program was strongly associated with both hepatitis B and hepatitis C infection. Injecting drug users who did not use needle exchange were five times as likely to become infected with hepatitis B and seven times as likely to become infected with hepatitis C (18,40).

Taken together, these data and others provide evidence that access to sterile

injection needles has a beneficial effect on the drug-related behavior that puts individuals at risk for contracting HIV.

In addition to attempts to prevent the sharing and reuse of needles, there are interventions which involve teaching illicit drug users to clean their equipment with bleach which kills HIV. However, studies have raised questions about the effectiveness of this type of intervention, and it is not clear there is a relationship between self-reported use of bleach disinfectant "in the field" and protection from HIV infection.

Sexual Partners of Injecting Drug Users

HIV also is transmitted from infected injecting drug users to their sexual partners. By the end of 1994, heterosexual sexual activity between injecting drug users and individuals who do not inject drugs accounted for about 16,000 cases of AIDS (104). Injecting drug users have changed their sexual risk behavior more than heterosexuals in the United States generally (62), but studies have shown less success in persuading them to change their sexual risk behavior than their needle-sharing behavior (31). Thus, sexual relationships between injecting drug users and their partners continue to provide a route of HIV transmission into larger populations. Finding effective ways to persuade injecting drug users to avoid risk behavior during sexual activity is a critical challenge in slowing the spread of AIDS.

PREVENTING AIDS IN RACIAL AND ETHNIC MINORITY POPULATIONS¹⁶

Research focusing on AIDS prevention among minority populations has lagged behind research on other groups, despite the disproportionately high (and worsening) rate of HIV infection among African Americans and Latinos. Before 1988, only one research report focusing on a minority population had been published. In 1995, 41 reports, published (or accepted for publication) in peer reviewed journals, focused entirely or mainly on African Americans, Latinos, or both. (There still have been no studies published on Native Americans or Asian/Pacific Islanders.) Of these studies, 13 were randomized trials. In four of those, the interventions were very effective, and in five others, of moderate or mixed effectiveness. Even from this small literature, however, some general findings emerge, and they are consistent with interventions in other populations.

The most successful interventions were developed through extensive preliminary work with the target population, and used formal behavior change theory in their development. The preliminary work consisted mainly of focus groups and individual interviews. These exchanges provided information, for instance, about the barriers to safer behavior and about the level of skills that people had to deal with difficult situations. They also served to help develop and test the research

questionnaires and role playing materials before formal data collection began.

The four most effective interventions emphasized behavioral skills and practice (e.g., practice for teenagers in refusing to engage in unsafe behavior, negotiating about condom use, and putting on condoms), and were generally more interactive and less didactic than the less effective interventions. African American adolescents were the target of two of the particular programs that were most successful, and the interventions were, in one case, eight weekly group meetings of 90 minutes to two hours each, focusing on behavioral skills, condom use skills, and refusal skills; and in the second case, a five-hour program of information, videos, games, exercises, and skills practice. A third successful program, this one for high-risk mostly African American women, consisted of a series of group sessions with a variety of information, role playing, and other activities. The fourth program was for African American and Latino sexually-transmitted-disease patients, and consisted of culturally appropriate videos, 20-minute group sessions, skills building, role playing, and discussions.

There are large gaps in the AIDS prevention research for minority populations. Most strikingly, almost no work has been done with African American and Latino drug users or gay men, two groups affected heavily by the AIDS epidemic. Interventions targeting adult men who are not injection drug users have been rare, except for studies of STD patients. Adolescents have been studied to some extent in schools, but not in neighborhoods or juvenile

¹⁶This section is based largely on a paper prepared under contract to OTA by Marin (70).

detention settings, where many of these youth are more likely to be.

Research has gone slowly with African Americans and Latinos for several reasons. Funding agencies have not specially targeted these groups, and researchers may have shied away from taking on studies of high-risk, hard-to-reach populations. Few non-minority researchers have demonstrated interest in these groups, and there are too few minority researchers in positions to undertake the needed work.

PREVENTING HETEROSEXUAL HIV TRANSMISSION TO WOMEN¹⁷

Little is known about the effectiveness of AIDS prevention activities targeted towards women. Multiple counseling and skills sessions targeted at female injecting drug users, female sexual partners of injecting drug users, and inner-city or low-income women seem to provide a benefit in terms of increased condom use (26,87). A controlled study of a program of peer outreach combined with distribution of written material containing risk-reduction strategies increased condom use among female sexual partners of injecting drug users living in public housing projects (99). A methodologically sound HIV counseling and testing study found no benefit at either two weeks or three months (48).

¹⁷ This section is based largely on a paper prepared under contract to OTA by Ehrhardt, Exner, and Seal (25).

As with many other subpopulations, often studies enlisted very small samples, failed to provide enough information to be assessed, had unclear or very short follow-up periods, were not randomized, or did not use control or comparison groups. This deficiency is a serious matter given the rate of increase in AIDS cases among women. More work is needed in this area in order to develop effective prevention programs. The variety of techniques studied must be expanded, especially to include community-level interventions. Maintenance of non-risk behavior should be studied as well.

PREVENTING AIDS AMONG SCHOOL-AGED YOUTH¹⁸

There have been various studies evaluating school, community, and health clinic-based sex and AIDS education and prevention efforts targeted towards youth. The weight of the evidence indicates that sex and AIDS education programs, in general, increase the use of condoms (or other forms of contraception) by a small amount, and that more targeted programs can increase condom use by a greater amount. Still, overall, there are large gaps in knowing how to prevent HIV transmission among young people.

All 50 states either mandate or recommend AIDS education in their schools (15,34). Schools have the advantage of reaching almost every young person in society before he or she begins potentially risk-associated

¹⁸ This section is based largely on a paper prepared under contract to OTA by Kirby (59).

intervention in the community depends on the mother's knowledge of her serostatus, her access to prenatal care, her confidence in her doctor, and her ability and willingness to use AZT. The effect seen in the clinical trial also might be larger than it is likely to be in the community.

Studies have shown that a program of testing only pregnant women who appear to fall into a traditional exposure category for HIV infection will fail to identify many of the women who in fact are seropositive (22,37). Consequently, a program of voluntary testing might be a better method to screen for HIV among pregnant women. Most pregnant women who may be at risk for HIV infection will agree to be tested if they are in prenatal care and the service is offered. In an eight-month pilot study done in 1989 in six Los Angeles County public clinics, 76 percent of 9,069 women accepted voluntary HIV testing. Results also suggested that when the HIV antibody test was presented as a routine rather than a special, optional test, acceptance was nearly universal (12). In 1987, routine prenatal HIV screening was offered as part of a battery of tests to 3,472 women at Grady Memorial Hospital, which serves a poor, intercity population in Atlanta. The HIV test was singled out from the others and the women received written information about the test and its implications, along with a consent form agreeing to the test. Even though at the time there was no treatment known to prevent transmission from infected mother to child, 96 percent of the women agreed to be tested (66). Testing and counseling pregnant women can be an effective part of reducing perinatal HIV transmission if

seropositive women have access to AZT and to related medical care and support services.

SOCIAL MARKETING¹⁹

People and their needs change constantly, and this includes the information and stimulation they need to practice healthy behaviors. Even proven methods may have to be tailored (e.g., through community-based planning) to be successful in different subpopulations and over time. An effective approach may be social marketing, which seeks to borrow consumer product marketing techniques from the private sector and use them for health promotion. Social marketing has been talked about but little used in AIDS prevention in the United States, though it has been used in other countries for AIDS prevention and for other health promotion campaigns. Social marketing takes the approach that prevention must be "sold" and that there may be a need to "resell" it even to the "converted" in order to maintain behavior change, just as there is with consumer products. "No one at Coca Cola would argue that selling Coke is something you accomplish once and forever, especially when everyone knows about Coke and likes it. Selling Coke is something you do every day, in ever new ways, to meet an ever changing consumer (92)."

Social marketing in an AIDS prevention context would use private-sector product marketing approaches to

¹⁹ This section is based largely on a paper prepared under contract to OTA by Rabin and Porter (84).

expense, and many questions remain about whether it can achieve an acceptable level of effectiveness to make it worthwhile.

ECONOMIC EVALUATION²⁰

A central question for policymakers is which strategies are most cost-effective in preventing further HIV infection? The aim would, of course, be to choose the mix of interventions that would prevent the largest number of infections with the amount of money available for AIDS prevention programs. As is the case in most areas of medicine and health, the cost-effectiveness information that one would need ideally to make "rational" choices is quite limited. Only in recent years has sufficient evidence of the efficacy and effectiveness of interventions accumulated to begin to support such analyses.

A total of 25 economic evaluations of AIDS primary prevention interventions meeting minimum methodological criteria were found in the published literature in 1995 (90). Some of these studies look at interventions that are not basically "educational," such as screening donated blood, and screening health care workers, and are not discussed in this report. Interventions that do fall within the scope of this report and are the subjects of economic evaluations are:

- ◆ voluntary counseling and testing of injecting drug users, high- and low-

risk populations (based on a model), the general public, pregnant women, and women age 13-44;

- ◆ mandatory testing of marriage license applicants and premarital couples,
- ◆ notifying partners of infected people and injection drug users;
- ◆ bleach distribution to injection drug users;
- ◆ needle exchange for injection drug users; and
- ◆ treatment of drug dependency.

Many of the interventions—even some for which there is some evidence of efficacy and effectiveness—discussed earlier in this report have not been subject to economic analysis. This includes the important category of small group counseling (except as included in the studies of injection drug users) and virtually all the large-scale education programs aimed at the public and at various risk groups.

Findings From Economic Evaluations

The major types of economic evaluation—cost-effectiveness, cost-benefit, and cost-utility analyses—all take into account the costs and effects of interventions. In the case of AIDS prevention, as with many other preventive services, the costs of intervening occur in the present, and many, if not all, the benefits occur sometime in the future. Discounting is a technique used to allow all the costs and benefits to be expressed in current dollars, recognizing that money spent today is worth more than the same amount of money spent 10 years from now. Having everything in the same currency is necessary for making

²⁰ This section is based largely on a paper prepared under contract to OTA by Sisk (90).

comparisons, but money spent today must materialize in a particular budget, while money counted in the future need not.

Programs of counseling, testing, referral, and partner notification, as exemplified by the CDC-funded sites, produce benefits greater than their costs. If only about 7 percent of the infected people notified subsequently changed their behaviors to avert further transmission, savings in discounted lifetime AIDS treatment costs (about \$85,000 in 1990 dollars, 6 percent discount rate) would more than compensate for program costs. If savings in future earnings are added, net benefits would exceed costs if only slightly more than 1 percent of infected people notified averted further spread of HIV.

A similar pattern emerges for several interventions targeted to injection drug users. Savings in treatment costs avoided are likely to exceed program costs for counseling and testing, partner notification, and bleach distribution. Even using conservative assumptions about injection and sexual behavior for more controversial needle exchange programs, their savings in treatment costs are likely to outweigh program costs.

The results for testing marriage license applicants were less clear, partly because there is little information about how effective this type of testing would be in changing sexual behavior. Testing women of childbearing age would produce most benefits in preventing infection among adult contacts, and less in preventing the birth of infected

newborns, so it really reflects testing part of the adult population. Screening women could potentially produce more benefits than the costs of the program if it were targeted at high-risk women and the HIV prevalence were above a certain level.

Potential for Greater Use of Economic Evaluation

The use of cost-effectiveness analysis and other forms of economic evaluation in AIDS prevention policymaking is limited by the still meager literature on the topic and by the variability in analytic methods used. This situation is changing, however, as the potential value of this type of work is appreciated and more is being undertaken by independent academics and others. In addition, CDC is encouraging the use of economic analysis by the HIV Prevention Community Planning Groups that it funds. Developments in the field of cost-effectiveness analysis itself may also help solidify this work. The U.S. Public Health Service has formulated recommendations for economic principles to be applied in economic analyses, which should improve the rigor and comparability of future work.

References

1. Altman, L. K., "AIDS is Now the Leading Killer of Americans from 25 to 44," *New York Times*, p. A7, Jan. 31, 1995.
2. Anderson, J.E. and Dahlberg, L.L., "High-Risk Sex Behavior in the General Population: Results from a National Survey, 1988-1990," *Sexually Transmitted Diseases* 19(6):320-325, 1992, cited in Zimmerman (120).
3. Ashery, R.S., Davis, H., Davis, W.H., et al., "Entry into Treatment of IDUs Based on the Association of Outreach Workers with Treatment Programs," *Handbook on Risk of AIDS*, B.S. Brown and G.M. Beschner (eds.) (Westport, CT:Greenwood Press, 1993), cited in Des Jarlais (16).
4. Becker, M.H. and Joseph, J.G., "AIDS and Behavioral Change to Reduce Risk: A Review," *American Journal of Public Health* 78:394-410, 1988.
5. Berger, D.K., Perez, G., Kyman, W., et al., "Influence of Family Planning Counseling in an Adolescent Clinic on Sexual Activity and Contraceptive Use," manuscript, no date, cited in Kirby (59).
6. Caretta, R.A., Mangione, T.W., Marson, P.F., et al., "AIDS Education Practices Among Massachusetts Physicians," *Journal of Community Health* 15(3):147-162, 1990, cited in Zimmerman (120).
7. Catania, J.A., Coates, T.J., Stall, R., et al., "Prevalence of AIDS-Related Risk Factors and Condom Use in the United States," *Science* 258:1101-1106, 1992, cited in Zimmerman (120).
8. Choi, K.H., Catania, J.H., and Dolcini, M., "Extramarital Sex and HIV Risk Behavior Among U.S. Adults: Results from the National AIDS Behavioral Survey," *American Journal of Public Health* 84(12):2003-2007, 1994, cited in Zimmerman (120).
9. Coates, T., Director, Center for AIDS Prevention Studies, University of California, San Francisco, CA, personal communication, Feb. 28, 1995.
10. Coates, T. J., Faigle, M., Koijane, J., et al., Center for AIDS Prevention Studies, University of California, San Francisco, CA, "Does HIV Prevention Work for Men Who Have Sex with Men?," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, September 1995.
11. Coates, T.J., "Strategies for Modifying Sexual Behavior for Primary and Secondary Prevention of HIV Disease," *Journal of Consulting and Clinical Psychology* 58(1):57-69, 1990, cited in Coates (10).
12. Cozen, W., Mascola, L., Enguidanos, R., et al., "Screening for HIV and Hepatitis B Virus in Los Angeles County Prenatal Clinics: A Demonstration Project," *Journal of Acquired Immune Deficiency Syndromes* 6:95-98, 1993.

- Services, Rockville, MD, personal communication, June 1, 1995.
14. David, A.K. and Boldt, J.S., "A Study of Preventive Health Attitudes and Behaviors in a Family Practice Setting," *Journal of Family Practice* 11:77-84, 1980, cited in Zimmerman (120).
 15. DeMauro, D., "Sexuality Education 1990: A Review of State Sexuality and AIDS Curricula," *SEICUS Report* 18(2):1-9, 1990, cited in Kirby (59).
 16. Des Jarlais, D. C., Beth Israel Medical Center, New York, NY, "HIV/AIDS Prevention for Injecting Drug Users," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, September 1995.
 17. Des Jarlais, D.C., Friedman, S.R., Choopanya, K., et al., "International Epidemiology of HIV and AIDS Among Injecting Drug Users," *AIDS* 6:1053-1068, 1992, cited in Des Jarlais (16).
 18. Des Jarlais, D.C., Goldberg, D., Tunving, K., et al., "Characteristics of Prevented HIV Epidemics," presented at the *Ninth International Conference on AIDS*, Berlin, Germany, 1993, cited in Des Jarlais (16).
 19. Des Jarlais, D. C., Padian, N.S., and Winkelstein, W., "Targeted HIV-Prevention Programs," *The New England Journal of Medicine* 331(21):1451-1453, Nov. 24, 1994, cited in Des Jarlais (16).
 20. Detels, R., English, P., Visscher, B.R., et al., "Seroconversion, Sexual Activity, and Condom Use Among 2915 HIV Seronegative Men Followed for up to Two Years," *Journal of Acquired Immune Deficiency Syndrome* 2:77-83, 1989, cited in Coates (10).
 21. DeVincenzi, I. and Park, R.A., "Heterosexual Transmission of HIV: Follow-up of a European Cohort of Couples," presented at the *Sixth International Conference on AIDS*, San Francisco, CA, June 21, 1990, cited in Zimmerman (120).
 22. DiFrancesco, E., "Routine Prenatal HIV Testing More Effective Than Recommended Policy," *Infectious Diseases in Children* 3:3, 1990.
 23. Dolcini, M., Catania, J.A., Coates, T.J., et al., "Demographic Characteristics of Heterosexuals with Multiple Partners: The National AIDS Behavioral Surveys," *Family Planning Perspectives* 25(5):208-214, 1993, cited in Zimmerman (120).
 24. Doll, L.S., Judson, F.N., Ostrow, D.G., et al., "Sexual Behavior Before AIDS: The Hepatitis B Studies of Homosexual and Bisexual Men," *AIDS* 4:1067-1073, 1990, cited in Coates (10).
 25. Ehrhardt, A. A., Exner, T. M., and Seal, D., Columbia University, New York, NY, "A Review of HIV Interventions for At-Risk Women," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, September 1995.
 26. El-Bassel, N., and Schilling, R.F., "15-Month Followup of Women Methadone Patients Taught Skills to Reduce Heterosexual HIV Transmission," *Public Health Reports* 107(5):500-504, 1992, cited in Ehrhardt (25).
 27. Ekstrand, M.L. and Coates, T.J., "Maintenance of Safer Sexual Behaviors and Predictors of Risky Sex: The San Francisco Men's Health Study," *American Journal of Public Health* 80:973-977, 1990, cited in Coates (10).
 28. Fehrs, L.J., Foster, L.R., Fox, V., et al., "Trial of Anonymous Versus Confidential Human Immunodeficiency Virus Testing," *Lancet* 2(8607):379-382, Aug. 13, 1988..
 29. Feit, L.R., Metzler, S.M., Vermund, S.H., et al., "Impact of and AIDS

28. Fehrs, L.J., Foster, L.R., Fox, V., et al., "Trial of Anonymous Versus Confidential Human Immunodeficiency Virus Testing," *Lancet* 2(8607):379-382, Aug. 13, 1988..
29. Feit, L.R., Metzler, S.M., Vermund, S.H., et al., "Impact of and AIDS Symposium on Attitudes of Providers of Pediatric Health Care," *Academic Medicine* 65:461-463, 1990, cited in Zimmerman (120).
30. Friedman, S.R., Jose, B., Neaigus, A., et al, "Over-the-Counter Syringe Sales and HIV Among Drug Injectors in the United States," manuscript, no date, cited in Des Jarlais (16).
31. Friedman, S.R., Des Jarlais, D.C., Ward, T.P., et al., "Drug Injectors and Heterosexual AIDS," *AIDS and the Heterosexual Population*, L. Sherr (ed.) (Chur, Switzerland:Harwood Academic Publishers, 1993), cited in Des Jarlais (16).
32. Gallup, G., *Gallup Poll Public Opinion 1935-1971* (New York, NY:Random House, 1972), cited in Kirby (59).
33. Gallup, A., "The 19th Annual Gallup Polls of the Public's Attitudes Toward the Public School," *Gallup Poll* 69(1):1987, cited in Kirby (59).
34. Gambrell, A. E. and Haffner, D., *Unfinished Business: A SEICUS Assessment of State Sexuality Education Programs* (New York, NY:SEICUS, 1993), cited in Kirby (59).
35. Gemson, D.H., Colombotos, J., Elinson, J., et al., "Acquired Immunodeficiency Syndrome Prevention. Knowledge, Attitudes, and Practices of Primary Care Physicians," *Archives of Internal Medicine* 151:1102-1108, 1991, cited in Zimmerman (120).
36. Giesecke, J., Ramstedt, K., Granath, F., et al., "Efficacy of Partner Notification for HIV Infection," *Lancet* 338(8775):1096-100, Nov. 2, 1991, cited in Zimmerman (120).
37. Goedert, J.J. and Cote, T.R., "Editorial: Public Health Interventions to Reduce Pediatric AIDS," *American Journal of Public Health* 84(7):1065-1066, 1994.
38. Gwinn, M., Pappaiaonou, M., George, R., et al., "Prevalence of HIV Infection in Childbearing Women in the United States," *Journal of the American Medical Association* 265(13):1704-1708, 1991, cited in Marin (70).
39. Hagan, H., Des Jarlais, D.C., Friedman, S.R., et al., "Risk for Human Immunodeficiency Virus and Hepatitis B Virus in Users of the Tacoma Syringe Exchange Program," *Proceedings: Workshop on Needle Exchange and Bleach Distribution Programs* (Washington, DC:National Academy Press, 1994), cited in Des Jarlais (16).
40. Hagan, H., Des Jarlais, D.C., Friedman, S.R., et al., "Reduced Risk of Hepatitis B and Hepatitis C Among Injecting Drug Users Participating in the Tacoma Syringe-Exchange Program," *American Journal of Public Health*, in press, cited in Des Jarlais (16).
41. Henry, K., Maki, M., Willenbring, K., et al., "The Impact of Experience with AIDS on HIV Testing and Counseling Practices: A Study of U.S. Infectious Disease Teaching Hospitals and Minnesota Hospitals," *AIDS Prevention and Education* 3(4):313-321, 1991, cited in Zimmerman (120).
42. Higgins, D.L., Galavotti, C., O'Reilly, K.R., et al., "Evidence for the Effects of HIV Antibody Counseling and Testing on Risk Behaviors," *Journal of the American Medical Association* 266:2419-2429, 1991, cited in Coates (10).
43. Holmberg, S.D., "Emerging Epidemiological Patterns in the USA," unpublished paper presented at the *Sixth Annual Meeting of the National*

- Association* 80(1):31-35, 1990, cited in Zimmerman (120).
45. Holtgrave, D.R., Valdiserri, R.O., Gerber, A.R., et al., "Human Immunodeficiency Virus Counseling, Testing, Referral, and Partner Notification Services--A Cost-Benefit Analysis," *Archives of Internal Medicine* 153(10):1225-1230, 1993.
 46. Howard, M. and McCabe, J., "Helping Teenagers Postpone Sexual Involvement," *Family Planning Perspectives* 22: 253-263, 1990, cited in Kirby (59).
 47. Hubbard, R.L., Marsden, M.E., Rachel, J.V., et al., *Drug Abuse Treatment: A National Study of Effectiveness* (Chapel Hill, NC:University of North Carolina Press, 1989), cited in Des Jarlais (16).
 48. Ickovics, J.R., Morrill, A.C., Beren, S.E., et al., "Limited Effects of HIV Counseling and Testing for Women," *Journal of the American Medical Association* 272(6):443-448, 1994, cited in Ehrhardt (25).
 49. Jackson, J. and Rotkiewicz, L., "A Coupon Program: AIDS Education and Drug Treatment," presented at the *Third International Conference on AIDS*, Washington, DC, 1987, cited in Des Jarlais (16).
 50. Jacquez, J.A., Koopman, J.S., Simon, C.P., et al., "Role of the Primary Infection in Epidemics of HIV Infection in Gay Cohorts," *Journal of Acquired Immune Deficiency Syndromes* 7:1169-1184, 1994, cited in Coates (10).
 51. Kahn, J.G., Washington, A.E., Showstack, J.A., et al., *Updated Estimates of the Impact and Cost of HIV Prevention in Injection Drug Users*, Prepared for the U.S. Centers for Disease Control, Division of STD/HIV Prevention, Institute for Health Policy Studies, University of California, San Francisco, CA, September 30, 1992, cited in Sisk (90).
 52. Kahn, J.G., "Are NEPs Cost-Effective in Preventing HIV Infection?" Lurie, P., and Reingold, A.L. (eds.) *The Public Health Impact of Needle Exchange Programs in the United States and Abroad*, Prepared for the Centers for Disease Control and Prevention, School of Public Health, University of California, Berkeley, CA, and Institute for Health Policy Studies, University of California, San Francisco, CA, 1993, cited in Sisk (90).
 53. Kamenga, M., Jingu, K., Hassig, S., et al., "Condom Use and Associated HIV Seroconversion Following Intensive Couples Counseling of 122 Married Couples in Zaire with Discordant HIV Serology," presented at the *Fifth International Conference on AIDS*, Montreal, Canada, June 6, 1989, cited in Zimmerman (120).
 54. Kegeles, S.M., Hays, R.B., and Coates, T.J., "Mobilizing Young Gay and Bisexual Men for HIV Prevention: A Two-Community Study," manuscript, 1995, cited in Coates (10).
 55. Kegeles, S.M., Hays, R.B., and Coates, T.J., "The Mpowerment Project: A Community-Level HIV Prevention Intervention for Young Gay and Bisexual Men," *American Journal of Public Health*, in press, cited in Coates (10).
 56. Kelly, J.A., St. Lawrence, J.S., and Brasfield, T.L., "Predictors of Vulnerability to AIDS Risk Behavior Relapse," *Journal of Consulting and Clinical Psychology* 57:60-67, 1991, cited in Coates (10).
 57. Kelly, J.A., St. Lawrence, J.S., Hood, H.V., et al., "Behavioral Intervention to Reduce AIDS Risk Activities," *Journal of Consulting and Clinical Psychology* 57:60-67, 1989, cited in Coates (10).
 58. Kelly, J.A., St. Lawrence, J.S., Stevenson, L.Y., et al., "Community AIDS/HIV Risk Reduction: The

57. Kelly, J.A., St. Lawrence, J.S., Hood, H.V., et al., "Behavioral Intervention to Reduce AIDS Risk Activities," *Journal of Consulting and Clinical Psychology* 57:60-67, 1989, cited in Coates (10).
58. Kelly, J.A., St. Lawrence, J.S., Stevenson, L.Y., et al., "Community AIDS/HIV Risk Reduction: The Effects of Endorsements by Popular People in Three Cities," *American Journal of Public Health* 82(11):1483-1489, Nov., 1992, cited in Coates (10).
59. Kirby, D., "A Review of Educational Programs Designed to Reduce Sexual Risk-Taking Behaviors Among School-Aged Youth in the United States," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, September 1995.
60. Kirby, D., Barth, R., Leland, N., et al., "Reducing the Risk: A New Curriculum to Prevent Sexual Risk-Taking," *Family Planning Perspectives* 23(6):253-263, 1991, cited in Kirby (59).
61. Koo, H.P., Duntelman, G.H., George, C., et al., "Reducing Adolescent Pregnancy Through School and Community-Based Education: Denmark, South Carolina Revisited, 1991," *Family Planning Perspectives* 26(5):206-217, September/October, 1994, cited in Kirby (59).
62. Laumann, E.O., Gagnon, J.H., Michael, R.T., et al., *The Social Organization of Sexuality: Sexual Practices in the United States* (Chicago, IL:University of Chicago Press, 1994), cited in Des Jarlais (16).
63. Leigh, B.C., Temple, M.T., and Trocki, K.F., "The Sexual Behavior of U.S. Adults: Results from a National Survey," *American Journal of Public Health* 83(10):1400-1408, 1993.
64. Levy, S.R., Perhats, C. Weeks, K., et al., "Impact of a School-Based AIDS Prevention Program on Risk and Protective Behavior for Newly Sexually Active Students," *Journal of School Health* 65(4):145-151, 1995, cited in Kirby (59).
65. Li, V.C., Coates, T.J., Ewart, C.K., et al., "The Effectiveness of Smoking Cessation Advice Given During Routine Medical Care: Physicians Can Make a Difference," *American Journal of Preventive Medicine* 3:81-86, 1987, cited in Zimmerman (120).
66. Lindsay, M.K., Peterson, H.B., and Feng, T.I., "Routine Antepartum Human Immunodeficiency Virus Infection Screening in an Inner-City Population," *Obstetrics and Gynecology* 74(3):289-94, 1989.
67. Louis Harris and Associates, *Public Attitudes Towards Teenage Pregnancy, Sex Education and Birth Control* (New York, NY:1988), cited in Kirby (59).
68. Main, D.S., Iverson, D.C., McGloin, J., et al., "Preventing HIV Infection Among Adolescents: Evaluation of a School-Based Education Program," *Preventing Medicine* 23:409-417, 1994, cited in Kirby (59).
69. Makadon, H.J. and Saline, J., "A Review of HIV Prevention in Primary Care: Current Practices, Future Possibilities," *Annals of Internal Medicine*, in press.
70. Marin, B.V., "Analysis of AIDS Prevention Among African-Americans and Latinos in the United States," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, September 1995.
71. Martin, J., "The Impact of AIDS on Gay Male Sexual Behavior Patterns in New York City," *American Journal of Public Health* 77:578-581, 1987, cited in Coates (10).
72. Martin, J., Dean, L., Gracie, M., et al., "The Impact of AIDS on a Gay Community: Changes in Sexual Behavior, Substance Use, and Mental Health," *American Journal of*

74. Michael, R.T., Gagnon, J.H., Laumann, E., et al., *Sex in America: A Definitive Survey* (New York, NY: Little Brown & Co., 1994).
75. Miller, H., Turner, C., and Moses, L.E. (eds.), *AIDS: The Second Decade* (Washington, DC: National Academy Press, 1990), *cited in* Marin (70).
76. Moberg, D.P. and Piper, D.L., "An Outcome Evaluation of Project Model Health: A Middle School Health Promotion Program," *Health Education Quarterly* 17(1):37-51, spring, 1990, *cited in* Kirby (59).
77. Nicholas, S.W., Bateman, D.A., Stephen, K.C., et al., "Maternal-Newborn Human Immunodeficiency Virus Infection in Harlem," *Archives of Pediatric and Adolescent Medicine* 148:813-819, 1994.
78. O'Brien, M., Murray, J.R., Rahemian, A., et al., "Three Topics From the Chicago Needle Exchange Cohort Study: Seroconversion; the Behavior of HIV-Positive NX Users; and the Need for Additional Prevention Around Non-Needle Injection Risks," presented at *The Annual North American Syringe Exchange Conference*, Santa Cruz, CA, 1994, *cited in* Des Jarlais (16).
79. O'Keefe, E., Kaplan, E., and Khoshnood, K., *Preliminary Report: City of New Haven Needle Exchange Program* (New Haven, CT: New Haven Health Department, July, 1991), *cited in* Des Jarlais (16).
80. Oliver, K., Maynard, H., Friedman, S.R., et al., "Behavioral and Community Impact of the Portland Syringe Exchange Program," *Proceedings of the Workshop on Needle Exchange and Bleach Distribution Programs* (Washington, DC: National Academy Press, 1994), *cited in* Des Jarlais (16).
81. Padian, N.S., O'Brien, T.R., Chang, Y.C., et al., "Prevention of Heterosexual Transmission of Human Immunodeficiency Virus Through Couple Counseling," *Journal of Acquired Immune Deficiency Syndromes* 6(9):1043-1048, 1993, *cited in* Zimmerman (120).
82. Paone, D., Des Jarlais, D.C., Caloir, S., et al., "New York City Syringe Exchange: An Overview," *Proceedings: Workshop on Needle Exchange and Bleach Distribution Programs* (Washington, DC: National Academy Press, 1994), *cited in* Des Jarlais (16).
83. Peterson, J.L., Coates, T.J., Hauck, W., et al., "An HIV Prevention Strategy for African American Gay and Bisexual Men," manuscript, no date, *cited in* Coates (10).
84. Rabin, S.A. and Porter, R.W., "Application of Social Marketing Principles to AIDS Education," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, September 1995.
85. Rabin, S.A., "A Private Sector View of Health, Surveillance, and Communities of Color," *Public Health Reports* 109(1):42-45, 1994.
86. Rogers, D.E. and Osborn, J.E., "AIDS Policy: Two Divisive Issues," *Journal of the American Medical Association* 270(4):2436, July 28, 1993.
87. Schilling, R.F., El-Bassel, N., Schinke, S.P., et al., "Building Skills of Recovering Women Drug Users to Reduce Heterosexual AIDS Transmission," *Public Health Reports* 106(3):297-304, 1991, *cited in* Ehrhardt (25).
88. Schoenborn, C.A., Marsh, S.L., and Hardy, A.M., "AIDS Knowledge and Attitudes for 1992: Data from the National Health Interview Survey," *Advance Data from Vital and Health Statistics*, No. 243, Public Health Service, U.S. Department of Health and Human Services, DHHS Pub. No.

88. Schoenborn, C.A., Marsh, S.L., and Hardy, A.M., "AIDS Knowledge and Attitudes for 1992: Data from the National Health Interview Survey," *Advance Data from Vital and Health Statistics*, No. 243, Public Health Service, U.S. Department of Health and Human Services, DHHS Pub. No. (PHS) 94-1250 (Hyattsville, MD:Feb. 23, 1994).
89. Silvestre, A.J., Kingsley, L.A., Wehrman, P., et al., "Changes in HIV Rates and Sexual Behavior Among Homosexual Men," *American Journal of Public Health*, 83:578-580, 1993, cited in Coates (10).
90. Sisk, J.E., "Economic Evaluation of HIV/AIDS Education and Primary Prevention," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, September 1995.
91. Sisk, J.E., Hewitt, M., and Metcalf, K.L., *How Effective is AIDS Education?*--staff paper #3 in OTA's Series on AIDS-Related Issues (Washington, DC:Office of Technology Assessment, U.S. Congress, May 1988).
92. Smith, W., Strand, J., and Smith, R., "Social Marketing: Two Approaches to HIV/AIDS Prevention," presented at *Translating International Experiences into National HIV/AIDS Prevention Objectives: Lessons for the Future*, conference sponsored by the Henry T. Kaiser Family Foundation, Centers for Disease Control and Prevention, and the U.S. Agency for International Development, Washington, DC, Oct. 20, 1994.
93. St. Louis, M., Conway, G., Hayman, C., et al., "Human Immunodeficiency Virus Infection in Disadvantaged Adolescents," *Journal of the American Medical Association* 266(17):2387-2391, 1991, cited in Marin (70).
94. Stall, R., Elkstrand, M., Pollack, L., et al., "Relapse from Safer Sex: The Next Challenge for AIDS Prevention Efforts," *Journal of Acquired Immune Deficiency Syndromes* 3:1181-1187, 1990, cited in Coates (10).
95. Stryker, J., Coates, T.J., DeCarlo, P., et al., "Prevention of HIV Infection Looking Back, Looking Ahead," *Journal of the American Medical Association* 273(14):1143-1148, 1995.
96. Stryker, J. and Bayer, R., "AIDS Policy: Two Divisive Issues," (letter), *Journal of the American Medical Association* 270(20):2436, Nov. 24, 1993.
97. Thomas, B., Mitchell, A., Devlin, M., et al., "Small Group Sex Education at School: the McMaster Teen Program," *Preventing Adolescent Pregnancy* B. Miller, J. Card, R. Paikiff, J. Peterson (eds.) (Newbury Park, CA:Sage Publications, 1992), cited in Kirby (59).
98. Tice, J., Allen, S., Serufulira, A., et al., "Impact of HIV Testing on Condom/Spermicide Use Among HIV Discordant Couples in Africa," presented at the *Sixth International Conference on AIDS*, San Francisco, CA, June 23, 1990, cited in Zimmerman (120).
99. Tross, S., Abdul-Quader, A.S., Simons, P.S., et al., "Evaluation of a Peer Outreach HIV Prevention Program for Female Partners of Injecting Drug Users (IDUs) in New York City (NYC)," presented at the *Ninth International Conference on AIDS*, Berlin, Germany, June 6-11, 1993, cited in Ehrhardt (25).
100. Turnock, B.J. and Kelly, C.J., "Mandatory Premarital Testing for Human Immunodeficiency Virus," *Journal of the American Medical Association* 261:3415-3418, 1989.
101. U.S. Department of Health and Human Services, Public Health Service, *AIDS Knowledge and Attitudes for April-*

- Prevention, National Center for Health Statistics, *Health United States*, 1994, DHHS Pub. No. (PHS) 95-1232 (Hyattsville, MD:1995).
103. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, "Update: Trends in AIDS Diagnosis and Reporting Under the Expanded Surveillance Definition for Adolescents and Adults --United States, 1993," *Mortality and Morbidity Weekly Report* 43(45): 826-831, Nov., 18, 1994.
 104. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Prevention Services, Division of HIV/AIDS Prevention, *HIV/AIDS Surveillance Report* 6(2):1995.
 105. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, "Update: Trends in AIDS Among Men Who Have Sex with Men--United States, 1989-1994," *Mortality and Morbidity Weekly Report* 44(21):401-404, June 2, 1995.
 106. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, "Update: AIDS Among Women--United States, 1994," *Mortality and Morbidity Weekly Report* 44(5):81-84, Feb. 10, 1995.
 107. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, *Background Information on The Morbidity and Mortality Weekly Report: The Effectiveness of Condoms Update*, Aug. 3, 1993, including "Update: Barrier Protection Against HIV Infection and Other Sexually Transmitted Diseases," *Mortality and Morbidity Weekly Report* 42(30):589-597, Aug. 6, 1993.
 108. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, "Mammography and Clinical Breast Examinations Among Women Aged 50 Years and Older--Behavioral Risk Factor Surveillance System, 1992," *Mortality and Morbidity Weekly Report* 42(38):737-741, Oct. 1, 1993.
 109. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, "Surveillance for Occupationally Acquired HIV Infection," *Mortality and Morbidity Weekly Report* 41:823-825, 1992.
 110. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, "HIV Prevention Practices of Primary Care Physicians--U.S., 1992," *Mortality and Morbidity Weekly Report* 42(51-52):988-992, Jan. 7, 1994, cited in Zimmerman (120).
 111. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, *1992 HIV Prevention Program Guidance*, cited in Zimmerman (120).
 112. Valdiserri, R.O., Lyter, D.W., Leviton, L.C., et al., "AIDS Prevention in Homosexual and Bisexual Men: Results of a Randomized Trial Evaluating Two Risk-Reduction Interventions," *AIDS* 3:21-26, 1989, cited in Coates (10).
 113. Vincent, M., Clearie, A., and Schluchter, M., "Reducing Adolescent Pregnancy Through School and Community-Based Education," *Journal of the American Medical Association* 257(24):3382-3386, 1987, cited in Kirby (59).
 114. Volger, M., Dugan, T., and Seidlin, M., "Changes in Sexual and Reproductive Behavior in Heterosexual Couples After HIV Testing," presented at the

- Community-Based Education," *Journal of the American Medical Association* 257(24):3382-3386, 1987, cited in Kirby (59).
114. Volger, M., Dugan, T., and Seidlin, M., "Changes in Sexual and Reproductive Behavior in Heterosexual Couples After HIV Testing," presented at the *Fifth International Conference on AIDS*, Montreal, Canada, June 5-9, 1989, cited in Zimmerman (120).
 115. Walter, H.J. and Vaughn, R.D., "AIDS Risk Reduction Among a Multi-Ethnic Sample of Urban High School Students," *Journal of the American Medical Association* 270(6):725-730, 1993, cited in Kirby (59).
 116. Warren, W.K. and King, A.J.C., *Development and Evaluation of an AIDS/STD/Sexuality Program for Grade 9 Students*, Social Program Evaluation Group (Kingston, Canada:1994), cited in Kirby (59).
 117. Weaver, F.J., Herrick, K.L., Ramirez, A.G., et al., "Establishing a Community Base for Cardiovascular Health Education Programs," *Health Values* 2:249-256, 1978, cited in Zimmerman (120).
 118. Winter, L. and Breckenmaker, L.C., "Tailoring Family Planning Services to the Special Needs of Adolescents," *Family Planning Perspectives* 23(1):24-30, January-February, 1991, cited in Kirby (59).
 119. Yedidia, M.J., Barr, J.K., and Berry, C.A., "Physicians' Attitudes Toward AIDS at Different Career stages: A Comparison of Internists," *Journal of Health and Social Behavior* 34:272-284, 1993.
 120. Zimmerman, M.A., Pham, C.T., and Steinman, K.J., "HIV/AIDS Education: National Surveys, Counseling and Testing Programs and the Role of Physicians," unpublished contractor report prepared for the Office of Technology Assessment, U.S.

Congress, Washington, DC, September 1995.

ACKNOWLEDGEMENTS

Judy Auerbach, Ph.D.
National Institutes of Health
Bethesda, MD

Lourdes Baezconde-Garbanati, Ph.D.
Institute of Preventive Research
University of Southern California School of
Medicine
Los Angeles, CA

Barbara Cambridge, Ph.D.
Department of Obstetrics and Gynecology
University of Texas Southwestern Medical
Center
Dallas, TX

James W. Curran, M.D. M.P.H.
Centers for Disease Control and Prevention
Atlanta, GA

Theresa Exner, Ph.D.
College of Physicians and Surgeons
Columbia University
New York, NY

Nicholas Freudenberg, Dr.Ph.
Center on AIDS, Drugs, and Community Health
School of Health Sciences
Hunter College
New York, NY

Robert Fullilove, Ed.D.
HIV Center for Clinical and Behavioral Studies
Columbia University School of Public Health
New York, NY

David Holtgrave
Center for AIDS Intervention Research
Medical College of Wisconsin
Milwaukee, WI

Jeffrey Kelly, Ph.D.
Department of Psychiatry
Medical College of Wisconsin
Milwaukee, WI

Ronald King
Whitman-Walker Clinic
Washington, DC

David L. Kirp, LL.B.
Graduate School of Public Policy
University of California at Berkeley

Len McNally, M.P.H.
The New York Community Trust
New York, NY

Walt Odets, Ph.D.
Berkeley, CA

Randy Pope
Michigan Department of Public Health
Lansing, MI

Mark Schuster, MD, PhD
Senior Natural Scientist, RAND
Assistant Professor of Pediatrics
University of California at Los Angeles

Jane Silver
American Foundation for AIDS Research
Washington, D.C.

Jeff Stryker
Center for AIDS Prevention Studies
University of California at San Francisco

Ron Valdiserri, M.D., M.P.H.
Division of STD and HIV Prevention
Centers for Disease Control and Prevention
Atlanta, GA

Performance Partnership Grants

OPTIONAL FORM 99 (7-95)

FAX TRANSMITTAL

of pages ► 22

To	EVA Seiler	From	ILAW
Dept./Agency		Phone #	
Fax #		Fax #	

NSN 7540-01-317-7688

5099-101

GENERAL SERVICIES ADMINISTRATION

What are Performance Partnerships?

Performance Partnerships are agreements between HHS and a state to work towards achieving specific health status improvements over a multi-year period

Principles Related to Grant Consolidation

- **Improve the nation's health status**
- **Increase State Flexibility**
- **Strengthen State and Local Infrastructure**
- **Assure Accountability**
- **Maintain Visibility for Important Public Health Priorities**
- **Maintain Federal Role in Research, Surveillance, Demonstrations, Evaluation and Technical Assistance**

Challenges Related to Performance Partnership Grants

- Competition among programs
- National versus state and local priorities
- Ensuring that national surveillance continues
- Ability to redirect resources in outbreak situations
- Community planning
- Assure that capability and support being built at the local and state levels are not lost as a consequence of streamlined grants

Performance Partnerships Objectives Consultation

April - May 1995

Introduce PPG concept

June - November 1995

Consultation with:

- Summer 1995: Intergovernmental meetings, including NGA, NCSL, NACO, USCM, NLC
- Summer/Fall 1995: HHS Regional Meetings, American Public Health Association Meeting and other key groups and professional associations

December 1995

Publish draft of Performance Objectives in Federal Register for public comment

February 1996

Release consensus of PPG Performance Objectives

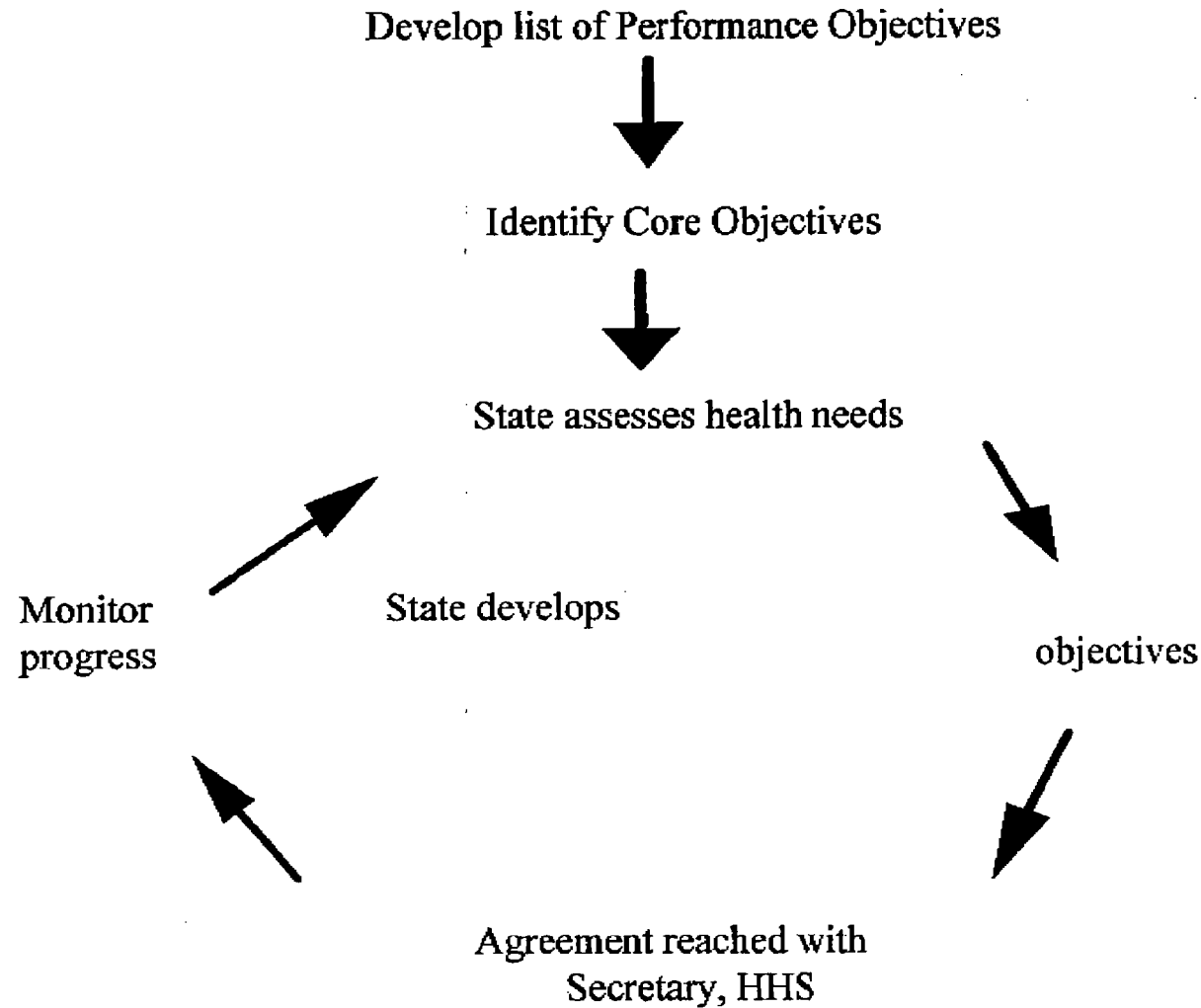
Spring-Summer 1996

**States prepare draft PPG agreements
Negotiate final agreements**

October 1996 (FY 1997)

Implementation of new PPG agreements

Performance Partnership Development



Performance Partnership Negotiations

State

- Provides detailed knowledge and understanding of unique problems and priorities of the state and localities
- Identifies health objectives for State's Partnership agreement
- Determines how to achieve results
- Gathers and reports data on objectives

HHS Secretary

- Maintains data base on state and national health status
- Monitors the State's progress
- Ensures that problems of national significance are addressed
- Provides leadership, technical assistance, training, and support

Overview of Performance Partnership Grants

Combines over 35 narrowly focused grants into five proposed new partnership grants:

- | | |
|---|-----------------|
| ▶ Substance Abuse | \$1.294 Billion |
| ▶ Mental Health | \$304.6 Million |
| ▶ HIV/STD/TB | \$488 Million |
| ▶ Immunizations | \$176.7 Million |
| ▶ Chronic Diseases and
Disabilities Prevention | \$118.1 Million |

The existing Preventive Health and health Services block grants will be modified to become a PPG.

HIV/STD/TB Formula

- total population (20% population)
- population in poverty (25% pop. at or below poverty level)
- geographic area (5% size)
- morbidity (15% HIV, 15% AIDS, 10% STD, 10% TB)

Performance Partnership Grant \$488 Million

HIV/AIDS

STD

TB

HIV/STD/TB Funding Requirements

- Available funds total \$488 million
 - \$31 million reserve for surveillance system
 - 5 percent reserve for disease outbreaks
 - up to 10 percent reserve for incentive grants
 - 3 percent reserve for tribes and tribal organizations
- Grants equal to at least 90%
- For FY 96-98, allocations for HIV, STD, and TB equal to proportions allocated in FY 95
- Cities that received funding in FY 1995 for HIV, STD, or TB will receive funding in FY 1996, FY 1997, and FY 1998
- Community Based Organizations that received funding in FY 1995 for HIV, STD, or TB will receive funding in FY 1996
- Formula will be reviewed in light of demographic changes occurring after FY 1994

HIV Funds Included

- Surveillance
- Health education/risk reduction
 - IDU health education/risk reduction
- Counseling, testing, partner notification
 - IDU counseling, testing, partner notification
- HIV prevention among drug users
- Public information
- State and local minority initiative
- Minority community-based organization funding
- Women & infant perinatal HIV reporting

Sexually Transmitted Diseases Funds Included

- Prevention & Control
- Infertility Prevention
- Surveillance/Monitoring Disease Trends
- STD Accelerated Prevention Campaign

Tuberculosis Funds Included

- Prevention Control and Elimination
- Surveillance Assessment
- Research Demonstration
- TB Laboratory Capacity
- TB/HIV

Funds Included

Substance Abuse

\$1.294B

Earmarks and Requirements *

- 35% for drug activities
- 35% for alcohol activities
- Pregnant women set-aside;
priority placement
- IDU - mandatory placement
- TB-services
- Group Home Revolving Fund
- Improving Referral Systems
- Continuing Education
- Independent peer review of
facilities

Mental Health

\$304.6M

Earmarks and Requirements *

- 1994 Funding Level for
Children's Services
- Requirement that 12
detailed areas be
addressed in state plan
- Penalties for non-
implementation
- Independent Peer Review
Facilities

***Eliminated in Performance Partnerships**

Funds Included

Immunization

\$176.7M

- State operation
- Parent/patient notification
- Surveillance & response
- Infrastructure
- Program-based incentives
- National & state specific
immunization level assessment

Chronic Disease and Disability

\$118.1M

- Behavioral Risk Factor Surveillance
- Cancer registries
- Diabetes
- Disabilities
- Breast and cervical cancer
- Tobacco

Partnership Objectives

- Results oriented; progress can be measured over the period of a grant
- Specify what is being measured, to who, by when, and to what degree

HIV/STD/TB

Sample Partnership Objectives

- **Reduce proportion of adolescents who have engaged in sexual intercourse to 15% (age 15) and 40% (age 17) by year 2001**
FY 1996 State baseline: 40% (age 15) and 66% (age 17)

- **Reduce incidence of gonorrhea to 153 cases per 100,000 population by year 2001**
FY 1996 State baseline: 170 cases per 100,000 population

- **Increase proportion of patients with TB who complete appropriate therapy within twelve months to 85% by year 2001**
FY 1996 State baseline: 75%

Regional Meetings

Regional Meetings will be held with States and other partners to solicit performance measurements.

Dates of Meetings

Regions VIII and X	December 4 - 5, 1995	Portland
Regions IV and VI	February 1 - 2, 1996	New Orleans
Region IX	February 22 - 23, 1996	San Francisco
Regions V and VII	March 7 - 8, 1996	Chicago
Regions I, II, and III	March 14 - 15, 1996	New York City

Regional Meetings

Purpose of Regional Meetings

- **Develop a list of appropriate public health program results**
 - that will be used to establish objectives
 - that will form the basis for future management of grants
 - that will set national standards

Subject programs include:

- **Chronic disease prevention**
- **HIV/STD/TB prevention**
- **Immunization**
- **Substance abuse prevention**
- **Mental health**
- **Emergency medical services and prevention of sexual assault and rape**

Developing Performance Objectives

“Develop information that will enhance the process of decision-making with respect to performance measurement in public health programs. Additionally, identify what we hope to achieve with our resources, to establish performance objectives, and to develop the data that both parties need to support program management.”

Process:

Phase I

Hold regional meetings to solicit views about what are key results

Phase II

Develop a preliminary menu of objectives using the National Academy of Sciences (NAS), Committee on National Statistics (CNSTAT)

Phase III

Consult with national organizations and other stakeholders on the report of the technical panel

Phase IV

Develop a State partnership plan

Phase V

Negotiate the proposed State partnership plan

NIH AIDS Research Program Evaluation Working Group

September 13, 1995

**Omni Shoreham
Washington, DC**

PUBLIC SESSION MINUTES

IN ATTENDANCE:

BARRY R. BLOOM, Ph.D.
Weinstock Professor
HHMI Investigator
Department of Microbiology and Immunology
Albert Einstein College of Medicine

DANI P. BOLOGNESI, M.D.
James P. Duke Professor
Department of Surgery
Duke University Medical School

REBECCA H. BUCKLEY, M.D.
Professor
Department of Pediatrics and Immunology
Duke University

CHARLES CARPENTER, M.D.
(Chair, OAR Advisory Committee)
Professor of Medicine
Brown University School of Medicine

THOMAS J. COATES, Ph.D.
Director
Center for AIDS Prevention Studies

LYNDA DEE, ESQUIRE
Executive Director
AIDS Action Baltimore, Inc.

ANKE A. EHRHARDT, Ph.D.
Director, HIV Center for Clinical and Behavioral Studies
Professor of Clinical Psychology
Department of Psychiatry
College of Physicians and Surgeons
Columbia University

EMILIO EMINI, Ph.D.
Executive Director
Department of Antiviral Research
Merck Research Laboratories

IN ATTENDANCE: (Continued)

HAROLD S. GINSBERG, M.D.
(Co-Chair, AIDS Research Evaluation Working Group)
Professor Emeritus
Department of Microbiology and Medicine
Columbia University College of Physicians and Surgeons
and
Expert Scientist
National Institute of Allergy and Infectious Diseases
National Institutes of Health

DIANE E. GRIFFIN, M.D., Ph.D.
Professor and Chair
Molecular Microbiology and Immunology
Johns Hopkins University
School of Hygiene and Public Health

MARK HARRINGTON
Activist
Treatment Action Group (TAG)

KING HOLMES, M.D., Ph.D.
Director
University of Washington Center AIDS and STDs

KIYOSHI KUROMIYA
Project Director
Critical Path AIDS Project, Inc.

ARNOLD J. LEVINE, Ph.D.
(Co-Chair, AIDS Research Evaluation Working Group)
Chair, Department of Molecular Biology
Louis Thomas Laboratory
Princeton University

MALCOLM MARTIN, M.D.
Chief, Laboratory of Molecular Microbiology
National Institute of Allergy and Infectious Diseases
National Institutes of Health

IN ATTENDANCE: (Continued)

ROBERT T. SCHOOLEY, M.D.
Professor of Medicine and Infectious Diseases
University of Colorado Health Science Center

P. ROY VAGELOS, M.D.
Chairman
Regeneron Pharmaceuticals, Inc.

Public Presentations

Anna Forbes (AIDS and Women's Health
Policy Consultant)

Testimony of Howard Greenspan, M.D.

Mark Milano (private citizen)

Carola Burroughs (Brooklyn AIDS Task Force)

Testimony of Alberto Avendano, M.D.

Michelle Lopez (private citizen)

Martin Delaney (Project Inform)

Jamie Gross (ACT UP/New York)

Julie Davids (ACTU Community Advisory Board,
Philadelphia)

Fred Schiach (AmFAR and International Foundation
for Alternative Research on AIDS)

Bob Lederer (Direct AIDS Alternative
Information Resources)

Lloyd C. Blake (MXWorldwide)

Paul Davis (ACT UP/Philadelphia)

Reverend Brother Jim E. du Pont Wortman
(Homeward Bound)

Katherine A. DeLeon (Native American
AIDS Caucus)

Chuck Thomas (Marijuana Policy Report)

Testimony of A. Arthur Gottlieb, M.D.

Keith Burroughs (private citizen)

Jeanmarie Zippo, RN (ActionAIDS, Inc.)

Public Presentations (Continued)

Kate Sorenson (ACT UP/Philadelphia)

Hassan Jann Gibbs (We The People Living With
HIV and AIDS/Philadelphia)

Testimony of Mary Lucey

Testimony of Maxine Wolfe, Ph.D.

Testimony of Carl Goodkin, M.D., Ph.D.

Norberto Stuart (private citizen)

Gabriel Guimares (AIDS Cure Coalition)

Orlando Torres (private citizen)

George Carter (private citizen)

Diana Williamson, M.D. (private citizen)

Mike Ruff (private citizen)

Kaiya Montaoceaw (private citizen)

Public Session

Introduction

William E. Paul, M.D., Director, Office of AIDS Research, welcomed the public to the meeting and provided background on the National Institutes of Health (NIH) AIDS Research Program Evaluation Working Group and its Area Review Panels. He noted that reviewers include distinguished AIDS investigators, scientists from related fields, and representatives from community groups. He pointed out that the Working Group is an independent body that will report its findings to the NIH Office of AIDS Research Advisory Council (OARAC) early next year. This report will help guide future AIDS research at NIH.

Arnold Levine, Ph.D., Co-Chair of the Working Group, also welcomed the public, and he asked members of the Working Group and Area Review Panels to introduce themselves. After these introductions, Dr. Levine described the goals of the Working Group and explained that the Panels have been gathering data on NIH intramural and extramural programs and budgets and are beginning to evaluate this information and identify scientific opportunities as well as program gaps.

Presentations on Area Review Panel Methodologies

The six Area Review Panel Chairs, or their designees, proceeded to describe the activities and approaches of their Panels. They reviewed the Panel membership lists, described the subpanels, noted the topics reviewed at Panel meetings, and mentioned some of the issues already identified. Their presentations focused on the process of gathering information on Institutes, Centers, and Divisions (ICDs) programs and budgets, the evaluation and review of this information, and the preparation of written materials necessary to develop their recommendations. They also described links with other Panels in areas that span more than one Panel, and they mentioned plans for future meetings, including those that will be open to the public.

Natural History, Epidemiology, and Prevention Panel

King Holmes, M.D., Ph.D., Chair, described the Panel's five subpanels in the areas of sexual transmission; perinatal and postnatal transmission; parenteral/injecting drug use (IDU) transmission; disease progress/opportunistic infections; and methodological issues. He described the Panel's major objective to define what has been done, what is in progress, what is needed and what the Panel should recommend. To date, the Panel has found that the proposed objectives established by the Office of AIDS Research cover many important areas which include: the assessment of biomedical and behavioral interventions and non-intervention strategies to reduce/prevent HIV transmission; the characteristics of risk factors and mechanisms of HIV transmission; an elucidation of the progression of HIV infection; the reduction or prevention of OIs; and the evaluation of assays and behavioral and statistical methodologies for epidemiology research.

Dr. Holmes said the Panel has identified a need to coordinate the evaluation effort among the Panels in cases where the topics cross Panels; coordinate research between Federal agencies,

scientific research institutes, and international centers for research; and develop a unified, comprehensive prevention research strategy. Among specific needs identified are studies to examine the impact of therapy on mucosal HIV shedding (a potential surrogate marker for transmission); studies of the effect of lifestyle on disease progression; studies on the differences in virulence between HIV-1 and HIV-2 and among subspecies and molecular variants; an examination of the availability of specimens in NIH repositories; and the need for an international database for research in progress.

Etiology and Pathogenesis Panel

Diane Griffin, M.D., Ph.D., Panel member, said that seven subpanels were formed to cover the broad area of etiology and pathogenesis: HIV Structure and Replication, Virus-Host Interactions, Virus Life Cycle, Host Defenses/Immune Depletion, Animal Models, Neuropathogenesis, and Opportunistic Infections (OIs). At the Panel's four meetings, members identified goals and prepared a list of scientific questions, acquired the data on funds being spent, and received testimony from ICD program directors, and began to synthesize this data in order to identify potential scientific areas of research needed.

Clinical Trials Panel

Ms. Lynda Dee, Esquire, Panel member, described the Panel's six focus areas, which are broken down along ICD lines. In addition, three subpanels have been formed to examine clinical trials efforts:

- **The National Cancer Institute (NCI) Subpanel** focuses on NCI's extramural and intramural programs as well as the intramural programs of the National Institute of Allergy and Infectious Diseases (NIAID) intramural program.
- **The NIAID Subpanel** focuses on NIAID's extramural program including the Adult AIDS Clinical Trials Group (ACTG), the Division of AIDS Treatment Research Initiative (DATRI), the Community Programs for Clinical Research on AIDS (CPCRA), the Strategic Program for Innovative Research on AIDS Treatment (SPIRAT), Studies of the Ocular Complications of AIDS (SOCA), and the Neurological AIDS Research Consortium (NARC). This Subpanel also is reviewing the extramural programs of the National Eye Institute (NEI) and the National Institute of Neurological Disorders and Stroke (NINDS).
- **The Pediatric Subpanel** focuses on pediatric programs, sponsored by the National Institute of Child Health and Human Development (NICHD) and NIAID, which together sponsor the Pediatric ACTG, and the National Heart, Lung, and Blood Institute (NHLBI). This Subpanel will also review NCI's intramural pediatric program as well as the General Clinical Research Centers (GCRCs), which are sponsored by the National Center for Research Resources (NCRR).

Ms. Dee noted that the Clinical Trials Panel will examine infrastructure support (including statistical centers, operations offices, and programs for quality assurance as well as specific data on AIDS clinical trials, including the number of sites and patients, decision-making criteria, networks among programs, financial data, and duplication among trials.

Behavioral, Social Science, and Prevention Research Panel

Thomas Coates, Ph.D., Chair, said the Panel's highest priority is primary prevention intervention research, supported by basic social and behavioral science research, clinical research on the consequences of HIV infection, and methodological research. He described the issues the Panel will examine in evaluating the NIH research portfolio and how the Panel has defined its priorities by the major modes of transmission and by the population groups most affected by the epidemic. The Panel has focused on a number of important objectives: assessing the effects on HIV transmission by alcohol and drug use; understanding individual and societal differences in human sexual behavior; identifying the determinants of relapse, preventing the spread of infection from infected individuals; decreasing morbidity; understanding, preventing, and treating neurological and psychiatric disease; and maintaining the quality of life. Dr. Coates said that the Panel also is examining the relative priorities given to types of studies (e.g., intervention versus basic science). He noted that while primary intervention strategies have traditionally focused on small group interventions, innovative public health mechanisms that focus on society as a whole may be needed.

Vaccine Panel

Dani Bolognesi, M.D., Chair, described the focus of the Vaccine Panel's three Subpanels in the areas of Basic Research, Targeted Research, and Clinical Trials. Most vaccine research is conducted by the NIAID, NCI, and NCI. Training in international vaccine research is supported by the Fogarty International Center (FIC). He noted that the major "engine" for driving discovery and for encouraging more industry participants is basic biomedical research. The Panel has identified the major components of the NIH vaccine research program as well as questions that need to be addressed. Dr. Bolognesi also noted that the Panel is interested in utilizing the vaccine infrastructure for other purposes, i.e., facilitating prevention and behavioral research, which is being reviewed by the Natural History and Behavioral Research Panels.

Drug Discovery Panel

Emilio Emini, Ph.D., Chair, reviewed the activities of the Drug Discovery Panel, which has defined five focus areas: (1) Basic and Targeted Drug Discovery Research on HIV; (2) Targeted Research on OIs, (3) NCDDG/SPIRATs programs, (4) Animal Models, (5) Molecular Studies of HIV Targets, and (6) NCI's Drug Discovery Program. While the Subpanels cover these same areas, the first two focus areas have been organized as the HIV Immunology Subpanel and the OI Subpanel (each will examine both basic and targeted research).

Dr. Emini noted that the Panel has reviewed funding and program accomplishments in the focus areas and will make recommendations for future directions. Among the important issues to be examined are the translation of basic research to clinical practice through interactions with industry, the availability of Regional Primate Research Center resources, the evaluation of screening assays, and the work of NCI FCRDC contractors.

General Discussion

Dr. Levine opened the floor to questions and discussion from the public. The following individuals asked questions and/or provided verbal testimony.

- **Mr. Mark Milano** of ACT UP New York asked why the Clinical Trials Panel was organized by ICDs and not by issues. He noted that this approach may limit it to the existing structure. Ms. Dee responded by saying that the Panel's first goal is to examine the strengths and weaknesses of current programs; it then will identify overlaps and gaps.
- **Mr. Bob Lederer** of the Direct AIDS Alternative Information Resources in New York and a reporter for POZ magazine, asked why the Panels have not mentioned alternative medicines, which many HIV-infected individuals are already using. He said that there is only one grant for alternative medicine given by the NIH Office of Alternative Medicine and suggested that the Panels should consult with herbalists and others who are not "at the table" when the ACTG committees decide what trials to conduct. Ms. Dee agreed that this is a gap and suggested that it falls within the purview of the Drug Discovery Panel. Dr. Emini then said that two of the Drug Discovery Subpanels will address the issue of alternative medicines.
- **Ms. Anna Forbes**, an AIDS and Women's Health Policy Consultant, asked Dr. Coates why there was no mention of studies on women-controlled HIV-prevention methods such as the female condom. Dr. Coates responded by stating that her point was well taken, and that the use of female-controlled methods as well as alternative ways of stopping heterosexual transmission is a very important priority. Dr. Anke Ehrhardt, Working Group member, added that research on this topic is being conducted and a conference will be held in New York City in the spring.
- **Ms. Michelle Lopez** expressed concern about the lack of HIV-infected individuals on the Panels. Dr. Levine said that the Working Group has tried to be responsive to suggestions from community groups and that HIV-infected individuals serve on the Panels.
- **Ms. Kathy DeLeon** of the Native American AIDS Caucus of New York asked Dr. Holmes why there have been few natural history studies of minority groups and asked why there are no people of color on the Panels. Dr. Holmes agreed that such studies are needed. He noted that the Panels include one Latino man and two African-American women.
- **Mr. Orlando Torres** of New York said that he is a poor person infected with HIV who has difficulty finding out about AIDS research. He noted the need for greater outreach to people like himself and greater consideration of the HIV-infected population living in poverty.

Mr. George Carter of ACT UP said that the panels should assess alternative therapies, e.g., nutritional regimens, both singly and in combination. Dr. Levine invited Mr. Carter to provide detailed information about these therapies, which he would then share with the Panels. Dr. Levine also stated that representatives from 11 community organizations are on the Panels and that these individuals make up 13 percent of the total membership of the Panels. He hopes that these individuals will provide input in areas that Mr. Carter has addressed including nutritional therapies.

- **Dr. Diana Williamson, M.D.**, of Mt. Sinai Medical Center, New York, cited the need for epidemiologic studies of HIV in the incarcerated population. Dr. Coates responded that relatively little is known about HIV infection in this group, which includes a disproportionate number of African Americans, the poor, and injecting drug users (IDUs). He said that research on female prisoners and female partners of male prisoners also is needed. Dr. Holmes added that epidemiologists have not focused on the prison population, although the Centers for Disease Control and Prevention (CDC) may include it in its surveillance studies. Mr. Kiyoshi Kuromiya noted that the prison population is one of his priorities.
- **Mr. Andy Stettner** of ACT UP New York asked for greater efforts to publicize the meetings open to the public and to make information about new Working Group research proposals available. In response to his question about problems in the Women's Interagency HIV Study (WIHS), Dr. Holmes said that this issue is being assessed by the Natural History Panel.
- **Mr. David Miller**, a member of ACT UP and the Interfaith Living With AIDS Project Collective of New York, asked why Dr. Levine has refused to appoint various persons suggested by ACT UP, such as Ms. Carola Burroughs, Drs. Howard Greenspan and Leanna Standish, and why it has not included experts in holistic medicine. Dr. Levine said that the *vitaes* submitted from ACT UP New York had been reviewed and three persons on this list were invited and have joined the Panels.
- **Mr. Norberto Stuart** of ACT UP asked about the potential crackdown on sex clubs and the Government's refusal to address sex education issues. Dr. Coates responded by saying that he considers policy change issues to be very important, noting that a Connecticut law allowing free distribution of syringes reduced needle sharing by 40 percent.
- **Ms. Carola Burroughs** asked why Dr. Levine has not contacted the Bastyr University AIDS Research Center and why he stated that its research was methodologically unsound. She said that Bastyr is developing an observational database and is conducting a survey of technical assistance to community-based practitioners working with AIDS patients. Dr. Levine thanked Ms. Burroughs for her comments, and stated that to the best of his recollection, he could not recall making that statement.
- **Ms. Ann Northrup**, an HIV/AIDS educator and ACT UP member, said that the AIDS Research Evaluation Working Group must more openly solicit the views of persons affected by the epidemic, and she also asked about research on lesbians and AIDS.

Dr. Ehrhardt said that gay and lesbian youth are being studied and that this topic will be addressed by the Behavioral Research Panel.

- **Mr. Keith Burroughs** of Youth Health Empowerment of Philadelphia introduced himself as a young person living with HIV and stressed the need to reach out in a positive approach to HIV-infected youth.
- **Mr. Jamie Gross** of ACT UP New York commented that ACT UP is one of the few groups represented today because of the poor publicity generated about the meeting. He said that the names of persons submitted by ACT UP for consideration as Panel members include persons not connected to ACT UP. He added that ACT UP is "doing the Working Group's work" by identifying these persons.
- **Mr. John Perrino** of ACT UP New York asked about research on serodiscordant couples. Dr. Ehrhardt said that a group in New York has submitted a grant proposal to study this topic.
- **Mr. Lederer** strongly expressed that his opinion that the Working Group members were not answering questions substantively and that the lack of attention to the composition of the panel membership was outrageous. He asked what steps will be taken now to put alternative medicine experts, women, and youth on the panels. Dr. Levine responded that he would be glad to discuss these issues further and to discuss criteria for panel membership. Ms. Carola Burroughs reiterated the request for more input from representatives of the alternative medicine community. Mr. Kuromiya responded by saying that he will seek input from the community about alternative medicines.

Public Presentations

The following persons made statements and/or read printed testimony to be included in the transcript.

1. **Ms. Anna Forbes** focused on the need for increased research on the role of nutritional adequacy (particular vitamin A) in preventing vertical HIV transmission and the need for additional research to develop a safe vaginal microbicide for HIV prevention, particularly through the use of a topical buffering substance. She asked OAR to initiate a four-arm study to measure viral load longitudinally in pregnant and nonpregnant women who are receiving either zidovudine (AZT) or a regimen of nutritional supplements. Dr. Holmes responded that these types of biomedical prevention research are of interest to his panel; he noted that NIH has funded at least one vitamin A trial in Malawi. Ms. Forbes added that the studies should measure a wide range of nutritional elements and should be conducted in the United States.
2. **Dr. Howard Greenspan's** testimony was read by an individual who stated that this testimony was requested for inclusion at this meeting by ACT UP New York. The testimony was originally written in response to Dr. Levine's request for an update on the status of research in the area of oxidative stress (OS) and HIV/AIDS. The reader

first explained that an NIH conference on OS was held in 1993; however, a subsequent presentation by Dr. Greenspan before an NIH group was allegedly cancelled because the OS hypothesis was considered "nonmainstream." Dr. Greenspan stated that studies have shown that both an excessive production of reactive forms of oxygen and a loss of primary and secondary antioxidant protective mechanisms result in the mechanisms by which OS is thought to contribute to disease progression: increased viral replication and promotion of T cell death by apoptosis. His testimony provided details about studies of OS and the biochemical and molecular reactions that may be responsible. He also raised the possible protective effects of antioxidants, particularly flavonoids.

3. **Mr. Mark Milano** of the AIDS Cure Coalition said that this group encourages the NIH to explore new pathogenesis theories, seek innovative research proposals, and increase collaborations among researchers/disciplines, perhaps through the creation of AIDS Research Centers. After commenting that the NIH has focused largely on drugs developed by the pharmaceutical industry and that it ignores compounds that lack such sponsors, he urged the NIH to support studies of nonprofitable off-patent, generic, and nonpatentable substances, for example, studies of the use of low-dose prednisone or vitamins to delay disease progression. He also called for the need for full conflict-of-interest disclosure by NIAID ACTG principal investigators.
4. **Ms. Carola Burroughs**, a holistic health educator and consultant, asked NIH to conduct research on alternative therapies in wide use by persons with AIDS. She noted that nutrition, stress reduction, exercise, and other natural therapies cost little. She also suggested that the NIH study the characteristics of long-term survivors, perhaps those associated with the CPCRA program. Dr. Barry Bloom told Ms. Burroughs that he found her statement very impressive and shared with her and the panel his concerns for the research in the basic science of herbal mixtures and the difficulty of setting priorities for choosing which therapies to study.
5. **Dr. Alberto Advendano**, Director of the Health and Treatment Program of the National Association of People with AIDS (NAPWA), was unable to attend the public session and his prepared testimony was read by Mr. Omar Perez, also of NAPWA. Dr. Advendano said that NAPWA supports OAR research and the current NIH evaluation effort but urges NIH to listen to the concerns and needs of the HIV-affected community and to study new research approaches. These approaches should include clinical trials of "realistic" combinations of antiviral agents (because many persons participating in clinical trials do not comply with restrictions) and studies of off-label use of medications. NAPWA urges the NIH to include more minorities and women in clinical trials and to develop a formal scientific methodology to study common alternative therapies, such as the use of thalidomide for wasting syndrome.
6. **Ms. Michelle Lopez**, a black Hispanic lesbian with AIDS, said that NIH should make it a priority to study the relationship between HIV, the human papillomavirus (HPV), and cervical intraepithelial neoplasia (CIN). She noted that antibiotic treatments for CIN are not effective and that hysterectomy, another treatment, is dangerous for immunosuppressed women. She also called for increased research on women of color who are HIV-infected, specifically those afflicted with gynecological abnormalities.

7. **Mr. Martin Delaney**, Founding Director, Project Inform, San Francisco, California, addressed the difference between the processes of program review and assessment. He said that the program review process currently in use at the NIH is backwards-looking, results in a "report card," does not begin with agreed-upon goals, and allows past processes to dominate future planning. By contrast, an assessment is forward-looking and is concerned with broad outcomes (not processes) of past programs. It defines goals and then determines strategies and tactics needed to meet them. Mr. Delaney also addressed some possible objections to his proposal. He criticized the lack of direction given to the Area Review Panels, and he stated that the current evaluation must establish strategies.
8. **Mr. Jamie Gross** of ACT UP New York asked for full public hearings in more cities (including New York) and better publicity about the meetings through AIDS publications and computer bulletin boards. He called for increased research on long-term survivors and treatments actually being used by persons with HIV/AIDS and less research on nucleosides and other drugs with profit potential that already have been studied extensively. He made four specific recommendations: (1) holding a conference on pathogenesis; (2) appointing an expert panel to investigate flaws in ACTG 076 and to review evidence supporting long-term transmission interrupters such as vitamin A; (3) increasing the inclusion of women, minorities, substance users, children, and adolescents in both natural history studies and clinical trials; and (4) rescheduling the NIH presentation by Dr. Greenspan.
9. **Ms. Julie Davids** of ACT UP Philadelphia expressed concern about the attitude of the Working Group/Panels concerning alternative therapies, i.e., they are "pseudoscientific." She said that the NIH should study actual remedies being taken by people living with HIV, many of whom will not take AZT. She supported expansion of the CPCRA network, better observational databases, and more behavioral research about factors that influence a person's treatment decisions.
10. **Mr. Fred Schaich**, Founding Director of the International Foundation for Alternative Research in AIDS (IFARA), asked for basic research on alternative therapies and suggested starting with simple screening trials. He said that, if sufficient interest and expertise is not generated at NIAID to address these questions, the research and the funding for it should be shifted to the NIH Office of Alternative Medicine. He asked NIH leadership to work together with AIDS activists on this issue and to end the adversarial relationship that exists.
11. **Mr. Bob Lederer** read a statement by **Dr. Fred Bingham**, Executive Director of DAAIR. Mr. Bingham called for increased studies of host factors that influence disease progression: nutritional deficiencies, oxidative stress, and dysregulated hyperimmune regulation. Mr. Lederer also listed the joint recommendations of DAAIR, Dr. Greenspan, and ACT UP: (1) immediately constitute a Subpanel to examine pathogenesis and clinical aspects of OS and HIV infection; (2) reschedule the presentation by Dr. Greenspan before the NIH AIDS Executive Committee; (3) plan a larger second conference on OS; and (4) increase funding for pathogenesis research on OS and clinical trials of antioxidants such as nested studies within existing drug trials.

12. **Mr. Lloyd Blake**, a private citizen who has a partner with AIDS, asked NIH to fund more trials of all promising drugs and therapies, to seek input from a wide range of persons, and to increase research on adolescents. He also urged wider availability and Federal approval of protease inhibitor therapy and stated that funding clinical trials of a multitude of drugs and therapies regardless of FDA approval status or potential for market success would keep hope alive for AIDS patients.
13. **Mr. Paul Davis** of ACT UP Philadelphia read some of the recommendations of the Real Treatments for Real People Campaign: (1) quickly fund several dozen short, rapid screening trials of some of the promising but underresearched treatments already in common use by people living with AIDS; (2) include off-label drugs, expired-patent drugs, treatments that do not require FDA approval, alternative therapeutic techniques, and drugs developed outside the United States; (3) utilize outcome markers that can be measured quickly such as viral load for antiviral therapies and CD4/CD8 counts/percentages; (4) incorporate applicants who have mild HIV symptoms unrelated to the agents being tested to study whether the treatment assists the body's regular defenses; (5) examine logical combination therapies for synergistic effects; (5) ensure a diversity of trial subjects in terms of gender, ethnicity, age, and substance use; (8) convene a joint congress of AIDS community representatives, researchers, and clinicians to choose treatments and develop study designs; and (9) give priority to the most promising treatments for inclusion in full-scale clinical trials.
14. **Reverend Brother James E. duPont Wortman** of Homeward Bound, Philadelphia, noted that his deceased partner as well as the vulnerable populations with which he works have repeatedly asked for alternative treatments for HIV/AIDS but receive only AZT. He asked for more clinical trials of nutritional supplements in combination with antiretroviral drugs and studies of vitamins, herbs, and off-label or nonpatentable drugs.
15. **Ms. Kathy DeLeon** noted the lack of representation of Native Americans on the Panels and stated that Native Americans have been ignored in NIH AIDS research. She said there was a need to include more Native Americans in research, especially in: natural history studies and clinical trials; studies linking behavior (alcohol addiction, safe-sex practices, and substance abuse other than IDU) with HIV transmission; studies of the role of the socioeconomic status of Native-American women in negotiation of safe sex; studies of the relationship of low socioeconomic standing and subsequent poor nutrition on the pathogenesis of HIV; studies on how diabetes (which is common among Native Americans) affects disease progression; and studies of genetic differences in Native Americans that might affect resistance to HIV infection. She noted that diabetics like herself are excluded from AIDS clinical trials.
16. **Mr. Chuck Thomas** of the Marijuana Policy Project of Washington, DC, urged the NIH to approve a research protocol developed by Dr. Donald Abrams to study the medicinal use of marijuana to treat the wasting syndrome. This protocol has been approved by the FDA, but the National Institute on Drug Abuse (NIDA) has refused to provide the drug for the study unless the protocol also receives NIH approval. Mr. Thomas stated that thousands of people with AIDS are illegally using marijuana supplied by cannabis buyers' clubs, but this source is threatened and many users have

been arrested. He noted that the Federal Government's Investigational New Drug compassionate access program has been closed to all new applicants since 1992 and that most Americans favor the medicinal use of marijuana. Mr. Kuromiya said he has first-hand knowledge of the effectiveness of marijuana in treating AIDS.

17. **Dr. Arthur Gottlieb**, Professor of Medicine and Chairman of the Department of Microbiology and Immunology at the Tulane University School of Medicine, was unable to attend, but his prepared testimony was read by Ms. DeLeon and Mr. Stettner. Dr. Gottlieb focused on immune system dysfunction and the need to identify drugs that affect cell-mediated immunity (e.g., peptides derived from larger neuropeptides in the promelanocorticotrophin-endorphin-enkephalin pathway) and test them in HIV/AIDS patients. He cited several issues that need study: (1) the interplay of factors related to the effects of HIV on the immune system (is HIV dependent on or does it contribute to other factors capable of affecting the immune system); (2) the ability of leukocytes passed from a blood donor or a sexual partner to mount graft versus host reactions in a recipient and the impact of these reactions result in HIV-infected patients; (3) the genes critical to normal immune function and how they are affected by HIV infection; and (4) the subpopulations of CD4+ cells in both uninfected and HIV-infected persons. Dr. Gottlieb also asked the NIH to keep an open mind to allow investigation of approaches other than antiviral drugs. He also identified the need for more information on the effects of antiviral drugs on immune parameters early in HIV infection.
18. **Mr. Keith Burroughs** stated that he is an HIV-infected teen who works as a peer outreach worker of the Youth Health Empowerment Project. He serves as a role model for young people. He emphasized that persons with HIV/AIDS can function by depending on nutrition, exercise, maintaining a positive attitude, and practicing safe sex. He refuses to take AZT and does not believe it is the answer. He called for more clinical trials of nontoxic drugs and treatments and more attention to the needs of youth.
19. **Ms. Jeanmarie Zippo**, a nurse specialist with ActionAIDS, Philadelphia, decribed the lack of scientific information about alternative therapies such as vitamins, herbs, acupuncture, and stress-management techniques. She stated that NIH has an obligation to study these inexpensive treatments in order to determine whether they are safe and effective and whether they have side effects or interact with prescribed medications.
20. **Ms. Kate Sorenson** of ACT UP Philadelphia noted that she had initially registered as a representative of Health Care for All, but would prefer to present her testimony as a member of ACT UP although the limitation for representation from that organization would then exceed the guidelines of the *Federal Register* notice. Dr. Levine stated that her expressed affiliation would be noted. She asked NIH to test promising alternative treatments that have no profit-making potential; to facilitate the dissemination of clinical results to doctors; to include the public when making AIDS policy decisions; to increase the participation of women, children, and people of color in trials; to expand studies of long-term survivors; and to include more youth on the review panels. She then read a prepared testimony from **Ms. Teresa Chavez**, an HIV-infected mother of two HIV-positive children who asked for more research on children and AIDS.

21. **Mr. Hassan James Gibbs**, representing We the People and the Galaei Project, Philadelphia, introduced himself as an African American who has lived with AIDS for 12 years. He said intravenous gamma globulin treatment had helped to relieve his severe peripheral neuropathy and also raised his CD4 counts. However, doctors will not prescribe this treatment as a preventive measure because research has not been conducted to prove its usefulness. He asked for such studies, as well as for more studies on long-term nonprogressors who are not on antiretroviral therapy, and for trials of multiple-therapy regimens.
22. **Ms. Mary Menendez** read the testimony of **Ms. Mary Lucey**, an HIV-infected activist from California who has served on the ACTG Community Constituency Group (CCG). Ms. Lucey stated that the Working Group had not appointed community activists as Panel members although the Working Group had indicated it would be open to their appointments. She then wrote that separation of the ACTG into the Adult ACTG and the Pediatric ACTG resulted in underfunding of pediatric AIDS, which is overshadowed by perinatal prevention research. She asked that all prevention research be removed from the ACTG system. She also asked NIH to hear from more extensive representation of the AIDS community.
23. **Dr. Maxine Wolfe**, City University of New York, had her prepared testimony read by Ms. Nina Reznick. Dr. Wolfe identified five needs in the area of AIDS clinical and epidemiological research: (1) increased numbers of women and of men of color should be included in clinical research on HIV/AIDS and OIs (inclusion of women will allow statistical analysis of findings by gender); (2) research teams should include persons knowledgeable about the functioning of the female body, and protocols should include a discussion of how the investigators will assess gender-specific effects (women should be included in Phase I trials because hormones affect pharmacokinetics, and women who are not menopausal and not sterilized should be included); (3) the design and results of ACTG 076, a study that indicated that AZT interrupts perinatal transmission should be revised to ensure that problems with this study are not replicated in similar studies; (4) research is needed on the role of vitamin A in interrupting perinatal transmission; and (5) epidemiologic research on women must be adequately funded (e.g., the WIHS study suffered because it only collected small sub-population samples and did not measure viral load).
24. **Dr. Karl Goodkin**, University of Miami School of Medicine, had his prepared testimony read by Mr. John Perrino, who first called for greater availability of protease inhibitors. Dr. Goodkin's testimony focused on his studies of the effect of psychosocial factors on HIV progression. He has found that stressful life events were associated with a decrease in the number of CD4 cells, while active coping style was associated with increases in this immune measure. Results from behavioral intervention studies among AIDS patients suggest that the effects of bereavement may be ameliorated through support groups, aerobic exercise, and so on. Dr. Goodkin called for more support for research on the "psychoneuroendocrine-immunologic hypothesis" of HIV progression.

25. **Mr. Norberto Stuart** asked the Panel to consider ethical questions as part of their scientific inquiry. He labeled as unethical those large long-term trials of a single regimen where the only markers of effectiveness are onset of illness and death. He noted that surrogate markers are needed and patients should not be on placebo. He also noted that AIDS patients want to have medications available once safety is proven, and there is reasonable expectation of success. He called for directed, scientifically valid research that fills the gaps, includes all PWAs, and avoids conflict of interest.
26. **Mr. David Young Allen** was not present; his testimony about peptide T in relation to AIDS dementia was entered into the official record of the meeting.
27. **Mr. Gabriel Guimares**, introduced himself as the Director of an opera company whose proceeds are donated to alternative treatments for AIDS. He read the written testimony of **Mr. Bill Bahlman**, founding member of the ACT UP New York Treatment and Data Committee. He said that clinical trial designs need revamping to respond to the discovery of more potent compounds, the validation of viral burden assays from retrospective studies, and a new understanding of the rapid turnover of HIV and CD4 cells in AIDS patients. These advances have increased the ability to show and measure antiviral activity of new drugs and drug combinations. Mr. Bahlman noted that PWAs will not participate in substandard control arms and that multi-drug combinations rather than monotherapy should be used. He provided an overview of his protocol for rapid screening of promising antiretroviral combination regimens that included details about study design, inclusion/exclusion criteria, length of study, and end points. These studies would be nonrandomized and include no placebos or complicated dosing regimens. Drug combinations would be chosen on the basis of *in vitro* synergy and additive effects and the combinations with which PWAs are experimenting on their own. Those combinations that prove effective then would be studied in larger randomized, controlled Phase III trials that compare different drug combinations in each study arm.
28. **Mr. Orlando Torres**, a Hispanic ex-substance abuser on welfare, said that he was diagnosed as HIV-seropositive in 1992 while in prison and was given no information or assistance, only AZT. Three years later he was released with a very low T cell count; he believes that AZT is a poison that did more harm than good. Mr. Torres asked that prisoners be included in ACTG clinical trials, that protease inhibitors and HIV immunoglobulin be made available to patients with CD4 counts above 300, and that there be greater representation of heterosexuals and the poor in clinical trials.
29. **Mr. George Carter** of ACT UP New York used the metaphor of putting out the fire in a burning house for the fight against AIDS. He said that this requires both fighting the fire (the virus) as well as fireproofing the house. He then stressed the importance of understanding the underlying mechanisms that induce immune dysregulation and understanding the pathogenesis of HIV and AIDS. He noted that many promising drugs (including protease, *tat*, and integrase inhibitors and antiviral substances found in herbs) can be used to help the body fight the virus at various points in the replication cycle. At the same time, the body must be strengthened to keep the virus in check. He noted the need for a multifaceted comprehensive approach, which uses combination drugs in

small screening trials (sole use of double-blind placebo-controlled trials of single agents are not the answer).

30. **Dr. Diana Williamson** said her entire fifteen-year career as a clinician, including work in the prison health system, has been formed by the HIV epidemic. She reflected on the immensity of the problem and asked why there was so much anger in the room. Dr. Williamson noted the relationship of HIV/AIDS to poverty, violence, crime, drug addiction, racism, sexism, lack of access to care, and other social issues. She called for a holistic and unified approach to research as well as efforts to address basic human needs so that disenfranchised populations can obtain messages about HIV prevention and receive treatment.
31. **Dr. Mike Ruff**, Georgetown University School of Medicine, noted that the old paradigm of direct destruction of T cells by HIV is now being questioned; the "revolutionary" paradigm is that inhibition of HIV may not be sufficient to effect a cure. "Indirect mechanisms" deserving study include receptor-mediated actions of the envelope protein gp120 acting at CD4 receptors. Such studies could lead to the development of gp120 receptor antagonists. He also suggested studies of the nature of the CD4/gp120 binding interaction and the development of assays sensitive to gp120 receptor interactions. Dr. Ruff noted that the role of gp120 in pathogenesis has been studied extensively by neuroscientists but should also attract attention from immunologists and virologists.
32. **Ms. Kaiya Montaoceaw** of the Center for Natural and Traditional Medicines discussed the need for alternative therapies for Third World countries, where the majority of people with HIV/AIDS live. She said that people living with HIV are using many alternative therapies (e.g., vitamins, minerals, herbs, acupuncture) and cited instances of successful treatments she saw being used in the Amazon, Tanzania, and Brazil. She urged the Panels to think creatively, to open the door to studying these treatments, and to remember that AZT is not the answer. She noted the bravery of persons with HIV/AIDS who have tried these treatments without help, and she made a plea to enlist the support of American resources for research on these alternative therapies.

Dr. Levine thanked all participants and adjourned the meeting at 5:30 p.m.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

17-Aug-1995 02:46pm

TO: Lynne D. Scheib
FROM: Lynne D. Scheib
 Office of Administration, LISD

SUBJECT: National Plan

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

November 10, 1994

PRESS BRIEFING
BY
PATSY FLEMING, NATIONAL AIDS POLICY DIRECTOR

The Briefing Room

2:15 P.M. EST

MS. FLEMING: Good afternoon. First let me say how grateful I am to the President for this opportunity. The task of directing the federal response to the AIDS epidemic is a demanding one, but it's a challenge I welcome and one I am ready to take on.

Many of you may recall that when I agreed to be interim director, or coordinator it was called at that time, I had said I was not interested in being a candidate for the permanent appointment. However, the last three months have shown me that this is a position that can have enormous impact on the government's response to the AIDS epidemic. I also appreciate the encouragement I received from the AIDS community to take this job.

The demand for action is tremendous. Every day 90 Americans die as a result of AIDS. We estimate that more than 40,000 Americans are becoming infected with HIV every year. And despite our education and prevention efforts, that number has remained fairly constant for the last five years.

As the President noted, AIDS is striking at the core of our collective community. Today AIDS is the number one cause of

death among Americans between the ages of 25 and 44. My mission is clear. We must begin to reduce the number of infections while we vigorously pursue the scientific research that we hope will eventually produce a cure. No stone can or should be left unturned.

The President has asked me to provide him with a report on the spread of HIV among adolescents. We already know that today half of all new infections with HIV occur among Americans under the age of 25. One in four new infections is among people who are younger than 20. These are very troubling trends, and they must be addressed quickly.

I'm also quite concerned about the continued rise in HIV infection among women. Traditional prevention methods do not ensure the safety of women, so we must aggressively seek ways to empower women to protect themselves, including the use of female condoms and microbicides.

Finally, let me say that the gay community has made tremendous progress in reducing the rate of growth in HIV infection in that population. But the fact remains that the largest number of infections are occurring among gay men, particularly those who are in their teens and twenties. Clearly, more must be done.

AIDS remains a critical public health crisis in this country. It's time to roll up our sleeves and get to work.

I'll be happy to take some questions.

Q What about the budget aspect of your job, Ms. Fleming? The AIDS community is very concerned that there won't be enough money to do the things that you've outlined. To what extent -- do you have any kind of a commitment from the President to put more money into AIDS research, treatment and prevention?

MS. FLEMING: The President is committed to fully funding Ryan White. In the '95 budget you've seen increases in all three areas. I will work to try to make sure that such increases are included in the next budget. I'm working with Alice Rivlin and I will be working with the President on the budget. I've also worked with HHS.

Q Any idea what kind of increase might be --

MS. FLEMING: Not at this time.

Q Can you tell us a little more specifically about what the adolescent AIDS initiative is going to include?

MS. FLEMING: Well, the President just asked me to do it today, so I don't really have an answer to your question right now.

Q But from your experience what, maybe, needs to be done in terms of --

MS. FLEMING: Well, certainly, prevention is the area that needs the most work. We need to look at the demographics, see where they are and what they're doing, and then try to find ways to convince them to use safer sex methods and to listen to our prevention messages. We need to find ways of reaching them that we haven't developed.

Q With the Republicans now in control of Congress, how is this going to affect AIDS funding, do you foresee?

MS. FLEMING: Well, I can talk about the last time the Republicans controlled the Senate. Senator Mark Hatfield was chairman of the Appropriations Committee then, and I believe he will be chairman again next year.

At that time the Congress pushed through very large increases in AIDS funding. So I really believe that AIDS is not a partisan issue whatsoever. It's not politics. It's people. And every congressional district, every state in this country is affected by AIDS. So it is my hope that both Houses of Congress will continue to see this as a major priority.

Q Are you satisfied that you're going to have the kind of access to the President that's more than lip service, that will let you be effective?

MS. FLEMING: During the months that I've been interim coordinator I have been very comfortable with my access to the President. I have had opportunities to talk with him about what I see as the important issues related to the AIDS epidemic, and that will continue. The President said, when he made the announcement, that I have access to him. I do.

Q The President said the White House AIDS Office has been newly strengthened. Could you comment on how, if at all, it has been reorganized or strengthened?

MS. FLEMING: The White House AIDS Office has been separated from HHS. Formerly, they were joined at the hip, sort of. But now they're separate and it will be a much more effective way of running the operation. So management-wise, it's very much stronger.

In terms of the other part of that, I think that it has something to do with the way the person in the position operates. I will pursue my duties in this job very vigorously. I feel very passionate about this epidemic. I will do everything that I can to convince Congress, to convince the administration that we must support efforts to prevent AIDS, to develop new drugs and technologies, and to take care of people who are affected by the epidemic, to the greatest extent possible.

Q Congress certainly has been sympathetic to some elements of dealing with AIDS. I was listening to you talk about the

idea of pushing prevention messages to adolescents. And I'm curious about what you anticipate will be the reaction from the new Congress to the idea of pouring money into prevention messages involving safer sex. I mean, we all know in the past, you know, what the sentiments of some of the Republican members of Congress have been, and those are likely to intensify. How do you expect to deal with that when those particular issues come up on the Hill?

MS. FLEMING: We will have to find a way. There have to be approaches that will be acceptable to a wide range of people, and that is something we'll be looking into.

Q Your predecessor, Kristine Gebbie, before she left had laid out some sort of national plan for dealing with AIDS. What is the status of that? Is that now no longer a viable document, and are you going to take that on?

MS. FLEMING: Under my leadership there will be a plan developed. My view of the development of that plan is that it has to come from the bottom up. It has to begin in the agencies. The agencies and departments that are going to have responsibility for implementing have to be involved in the development from the very beginning. There will be an interdepartmental task force. Representatives from each of the departments that have anything to do with AIDS will come together. That group will go back to their agencies and help develop a plan for implementing their aspect to the AIDS agenda. And then we'll put it together.

So we'll have a national plan. But it will grow up from the bottom, rather than be imposed on the agencies from above.

Q When do you think that plan will be finished?

MS. FLEMING: We don't have a timetable yet. We have to convene the task force and we're going to try to do it quickly.

Q What about the report of the Presidential Commission that came out in '92, is that something you can work with? Or why isn't that a good enough --

MS. FLEMING: Yes, we can. We intend to. There are very good recommendations in that report. Some of them have already been implemented. We will look at all the others and see what we can do with them.

END

2:27 P.M.

THE WHITE HOUSE

Office of the Press Secretary
(Minneapolis, Minnesota)

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

November 10, 1994

PRESS BRIEFING

BY

PATSY FLEMING, NATIONAL AIDS POLICY DIRECTOR

The Briefing Room

2:15 P.M. EST

MS. FLEMING: Good afternoon. First let me say how grateful I am to the President for this opportunity. The task of directing the federal response to the AIDS epidemic is a demanding one, but it's a challenge I welcome and one I am ready to take on.

Many of you may recall that when I agreed to be interim director, or coordinator it was called at that time, I had said I was not interested in being a candidate for the permanent appointment. However, the last three months have shown me that this is a position that can have enormous impact on the government's response to the AIDS epidemic. I also appreciate the encouragement I received from the AIDS community to take this job.

The demand for action is tremendous. Every day 90 Americans die as a result of AIDS. We estimate that more than 40,000 Americans are becoming infected with HIV every year. And despite our education and prevention efforts, that number has remained fairly constant for the last five years.

As the President noted, AIDS is striking at the core of our collective community. Today AIDS is the number one cause of death among Americans between the ages of 25 and 44. My mission is clear. We must begin to reduce the number of infections while we vigorously pursue the scientific research that we hope will eventually produce a cure. No stone can or should be left unturned.

The President has asked me to provide him with a report on the spread of HIV among adolescents. We already know that today half of all new infections with HIV occur among Americans under the age of 25. One in four new infections is among people who are younger than 20. These are very troubling trends, and they must be addressed quickly.

I'm also quite concerned about the continued rise in HIV infection among women. Traditional prevention methods do not ensure the safety of women, so we must aggressively seek ways to empower women to protect themselves, including the use of female condoms and microbicides.

Finally, let me say while the House gay community has made tremendous progress in reducing the rate of growth in HIV infection in that population. ~~Office of the President~~ remains set that the largest number of infections are occurring among gay men, particularly those who are in ~~the immediate and~~ basic areas. Clearly, more must be ~~done~~ done February 4, 1993

AIDS remains a critical public health crisis in this country. It's time to ~~make a point~~ make a point ~~the President~~ get to work.

IN LUNCHEON PHOTO WITH THE VICE PRESIDENT

12:30 P.M. EST

Q Mr. President, with productivity soaring and factory orders up, does this mean it's a strong recovery and you might have to adjust your economic plan?

THE PRESIDENT: Well, we haven't -- it could mean that more evidence will come in the deficit will be smaller. But there's no -- it could mean that we'll have more jobs, which is the real issue. But we don't see it yet.

I think the real issue, what appears to be the case is that American productivity is up and that a lot of Americans are

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE / CENTERS FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333 OFFICIAL BUSINESS

Director, Centers for Disease Control
William H. Foege, M.D.
Director, Epidemiology Program Office
Phillip S. Brachman, M.D.
Editor
Michael B. Gregg, M.D.
Managing Editor
Anne D. Mather, M.A.
Mathematical Statistician
Keewhan Choi, Ph.D.

Postage and Fees Paid
U.S. Department of HHS
HHS 396



MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

249	Epidemiologic Notes and Reports
	Dengue Type 4 Infections in U.S. Travelers to the Caribbean
250	<i>Pneumocystis Pneumonia</i> — Los Angeles
	Current Trends
252	Measles — United States, First 20 Weeks
253	Risk Factor Prevalence Survey — Utah
259	Surveillance of Childhood Lead Poisoning — United States
	International Notes
261	Quarantine Measures

Epidemiologic Notes and Reports

Dengue Type 4 Infections in U.S. Travelers to the Caribbean

Dengue type 4 infections have been confirmed in 2 U.S. travelers who recently returned from St. Barthelemy, a small island in the French West Indies. These are the first documentations of dengue type 4 ever reported in the Western Hemisphere.

On April 1, 1981, a Chicago resident had an acute febrile illness typical of classical dengue; symptoms included myalgia, headache, severe retro-orbital pain, and lower back pain. On April 4 he developed a diffuse rash over his torso. When acute- and convalescent-phase serum specimens collected on April 1 and April 14 were tested at CDC, there were diagnostic rises in hemagglutination-inhibition and complement-fixation titers to dengue type 4. The patient recovered completely after a few days.

When the laboratory diagnosis of dengue 4 was made in association with a travel history to the West Indies, the patient was contacted for additional information and a confirmatory serum specimen. This specimen also had dengue antibody titers similar to those of the convalescent-phase specimen.

The patient reported that he had traveled from Chicago to St. Barthelemy, stopping only for brief periods to change planes at the airports in San Juan, Puerto Rico, and St. Martin, West Indies. He stayed on St. Barthelemy from March 13 to March 27 and flew back to Chicago, again with only brief airport stops in St. Martin and San Juan. The patient stated that an outbreak of dengue was thought to be occurring on St. Barthelemy.

Serologic test results for other specimens from U.S. travelers that had recently been evaluated at CDC were reviewed to determine whether any other patients with a history of possible exposure in the Western Hemisphere had findings suggestive of dengue type 4 infection. Another patient, a Virginia resident who had traveled in the French West Indies, had an antibody pattern compatible with 1 or more previous dengue or other flavivirus infections. Results of tests of a second serum specimen obtained from the patient later in convalescence documented secondary dengue type 4 infection. The patient visited St. Barthelemy in April; he developed a typical dengue-like illness on April 17. The patient also recalled that residents of St. Barthelemy believed an outbreak of dengue was occurring.

The Pan American Health Organization and the Caribbean Epidemiology Center (CAREC) have been informed; they in turn have notified health officials throughout the Caribbean.

Reported by: R Merrick, MD, Illinois Masonic Medical Center, Chicago; KT Reddi, MD, Chicago Dept of Health; BJ Francis, MD, State Epidemiologist, Illinois State Dept of Public Health; RS Brown, MD, Gloucester, Va.; JM Owens, MD, GB Miller, Jr, MD, State Epidemiologist, Virginia State Dept of Health; Vector-Borne Diseases Div, Virology Div, San Juan Laboratories, Center for Infectious Diseases, CDC.

Dengue - Continued

Editorial Note: Dengue type 4 frequently occurs in Southeast Asia, the South Pacific, and Africa. How it was introduced onto St. Barthelemy, a small and relatively remote island in the Caribbean, remains unknown. However, French health authorities have reported to CAREC that an outbreak of dengue-like illness has been observed on St. Barthelemy, beginning in February or March, but has since declined. In the absence of reports of an ongoing outbreak of dengue in the Caribbean, the risk that travelers to this area will acquire dengue is probably small.

Dengue types 2 and 3 have been present in the Caribbean at least since the 1960s. Dengue type 1 was first recognized in that area when an outbreak in Jamaica in 1977 was followed by numerous outbreaks on other Caribbean islands and in Central America. All these dengue types, as well as type 4, usually cause an illness that is clinically mild and typically of short duration.

Pneumocystis Pneumonia - Los Angeles

In the period October 1980-May 1981, 5 young men, all active homosexuals, were treated for biopsy-confirmed *Pneumocystis carinii* pneumonia at 3 different hospitals in Los Angeles, California. Two of the patients died. All 5 patients had laboratory-confirmed previous or current cytomegalovirus (CMV) infection and candidal mucosal infection. Case reports of these patients follow.

Patient 1: A previously healthy 33-year-old man developed *P. carinii* pneumonia and oral mucosal candidiasis in March 1981 after a 2-month history of fever associated with elevated liver enzymes, leukopenia, and CMV viremia. The serum complement-fixation CMV titer in October 1980 was 256; in May 1981 it was 32.* The patient's condition deteriorated despite courses of treatment with trimethoprim-sulfamethoxazole (TMP/SMX), pentamidine, and acyclovir. He died May 3, and postmortem examination showed residual *P. carinii* and CMV pneumonia, but no evidence of neoplasia.

Patient 2: A previously healthy 30-year-old man developed *P. carinii* pneumonia in April 1981 after a 5-month history of fever each day and of elevated liver-function tests, CMV viremia, and documented seroconversion to CMV, i.e., an acute-phase titer of 16 and a convalescent-phase titer of 28* in anticomplement immunofluorescence tests. Other features of his illness included leukopenia and mucosal candidiasis. His pneumonia responded to a course of intravenous TMP/SMX, but, as of the latest reports, he continues to have a fever each day.

Patient 3: A 30-year-old man was well until January 1981 when he developed esophageal and oral candidiasis that responded to Amphotericin B treatment. He was hospitalized in February 1981 for *P. carinii* pneumonia that responded to oral TMP/SMX. His esophageal candidiasis recurred after the pneumonia was diagnosed, and he was again given Amphotericin B. The CMV complement-fixation titer in March 1981 was 8. Material from an esophageal biopsy was positive for CMV.

Patient 4: A 29-year-old man developed *P. carinii* pneumonia in February 1981. He had had Hodgkins disease 3 years earlier, but had been successfully treated with radiation therapy alone. He did not improve after being given intravenous TMP/SMX and corticosteroids and died in March. Postmortem examination showed no evidence of Hodgkins disease, but *P. carinii* and CMV were found in lung tissue.

*Paired specimens not run in parallel.

Pneumonia - Continued

Patient 5: A previously healthy 36-year-old man with a clinically diagnosed CMV infection in September 1980 was seen in April 1981 because of a 4-month history of fever, dyspnea, and cough. On admission he was found to have *P. carinii* pneumonia, oral candidiasis, and CMV retinitis. A complement-fixation CMV titer in April 1981 was 128. The patient has been treated with 2 short courses of TMP/SMX that have been limited because of a sulfa-induced neutropenia. He is being treated for candidiasis with topical nystatin.

The diagnosis of *Pneumocystis* pneumonia was confirmed for all 5 patients antemortem by closed or open lung biopsy. The patients did not know each other and had no known common contacts or knowledge of sexual partners who had had similar illnesses. The 5 did not have comparable histories of sexually transmitted disease. Four had serologic evidence of past hepatitis B infection but had no evidence of current hepatitis B surface antigen. Two of the 5 reported having frequent homosexual contacts with various partners. All 5 reported using inhalant drugs, and 1 reported parenteral drug abuse. Three patients had profoundly depressed numbers of thymus-dependent lymphocyte cells and profoundly depressed *in vitro* proliferative responses to mitogens and antigens. Lymphocyte studies were not performed on the other 2 patients.

Reported by MS Gottlieb, MD, HM Schanker, MD, PT Fan, MD, A Saxon, MD; JD Weisman, DO, Div of Clinical Immunology-Allergy, Dept of Medicine, UCLA School of Medicine; I Pozalski, MD, Cedars-Mt. Sinai Hospital, Los Angeles; Field Services Div, Epidemiology Program Office, CDC.

Editorial Note: *Pneumocystis* pneumonia in the United States is almost exclusively limited to severely immunosuppressed patients (7). The occurrence of pneumocystosis in these 5 previously healthy individuals without a clinically apparent underlying immunodeficiency is unusual. The fact that these patients were all homosexuals suggests an association between some aspect of a homosexual lifestyle or disease acquired through sexual contact and *Pneumocystis* pneumonia in this population. All 5 patients described in this report had laboratory-confirmed CMV disease or virus shedding within 5 months of the diagnosis of *Pneumocystis* pneumonia. CMV infection has been shown to induce transient abnormalities of *in vitro* cellular-immune function in otherwise healthy human hosts (2,3). Although all 3 patients tested had abnormal cellular-immune function, no definitive conclusion regarding the role of CMV infection in these 5 cases can be reached because of the lack of published data on cellular-immune function in healthy homosexual males with and without CMV antibody. In 1 report, 7 (3.6%) of 194 patients with pneumocystosis also had CMV infection; 40 (21%) of the same group had at least 1 other major concurrent infection (7). A high prevalence of CMV infections among homosexual males was recently reported: 179 (94%) of 190 males reported to be exclusively homosexual had serum antibody to CMV, and 14 (7.4%) had CMV viremia; rates for 101 controls of similar age who were reported to be exclusively heterosexual were 54% for seropositivity and zero for viremia (4). In another study of 64 males, 4 (6.3%) had positive tests for CMV in semen, but none had CMV recovered from urine. Two of the 4 reported recent homosexual contacts. These findings suggest not only that virus shedding may be more readily detected in seminal fluid than in urine, but also that seminal fluid may be an important vehicle of CMV transmission (5).

All the above observations suggest the possibility of a cellular-immune dysfunction related to a common exposure that predisposes individuals to opportunistic infections such as pneumocystosis and candidiasis. Although the role of CMV infection in the pathogenesis of pneumocystosis remains unknown, the possibility of *P. carinii* infection must be carefully considered in a differential diagnosis for previously healthy homosexual males with dyspnea and pneumonia.

Pneumonia — Continued

References

1. Walzer PD, Perl DP, Krogstad DJ, Rawson PG, Schultz MG. *Pneumocystis carinii* pneumonia in the United States. Epidemiologic, diagnostic, and clinical features. *Ann Intern Med* 1974; 80:83-93.
2. Rinaldo CR, Jr, Black PH, Hirsch MS. Interaction of cytomegalovirus with leukocytes from patients with mononucleosis due to cytomegalovirus. *J Infect Dis* 1977;136:667-78.
3. Rinaldo CR, Jr, Carney WP, Richter BS, Black PH, Hirsch MS. Mechanisms of immunosuppression in cytomegaloviral mononucleosis. *J Infect Dis* 1980;141:488-95.
4. Drew WL, Mintz L, Miner RC, Sands M, Ketterer B. Prevalence of cytomegalovirus infection in homosexual men. *J Infect Dis* 1981;143:188-92.
5. Lang DJ, Kummer JF. Cytomegalovirus in semen: observations in selected populations. *J Infect Dis* 1975;132:472-3.

Current Trends

Measles — United States, First 20 Weeks

During the first 20 weeks (through May 23) of 1981, a total of 1,532 cases of measles were reported in the United States (Table 1). This represents an 82% decrease from the 8,519 cases reported during this same period in 1980. If this trend continued throughout the year, fewer than 2,500 cases would be reported in 1981. The previous record low incidence for an entire calendar year was 13,430 cases (provisional total) reported in 1980.

TABLE 1. Measles — United States, May 23, 1981

Year	Week 20	Weeks 1-20
1981	135	1,532
1980	816	8,519
1970	1,950	27,955
1960	18,833	286,097

More than 100 measles cases have been reported each week since week 17 (May 2), ending 37 consecutive weeks during which fewer than 100 cases per week were reported. Nevertheless, the number of cases reported in the last 4 weeks are still record lows. The seasonal upswing in reported cases, which usually occurs in late winter and spring, has not yet occurred (Figure 1).

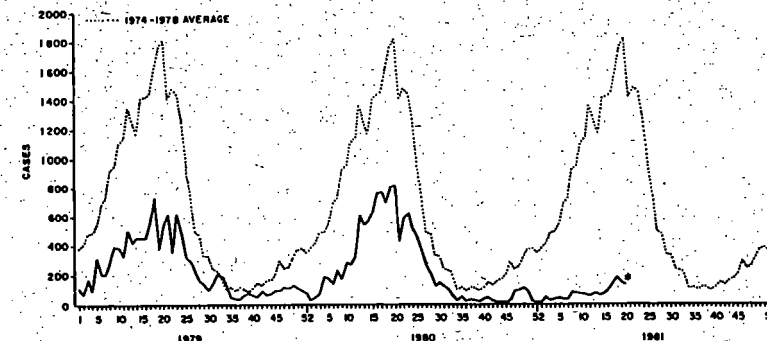
Seventeen states have not reported any measles cases in 1981. In contrast, only 5 states did not report any measles cases for the same period in 1980.

Reported by Surveillance and Assessment Br, Immunization Div, Center for Prevention Services, CDC.

Editorial Note: The reported incidence of measles in 1981 continues at record low levels, indicating that measles transmission has been interrupted in most areas of the United States. The goal of elimination of indigenous measles from the United States by October 1, 1982, is within reach, provided intensive control efforts are continued.

Measles — Continued

FIGURE 1. Measles incidence, United States, 1979-1981, and 1974-1978 average



*First 20 weeks.

Risk-Factor-Prevalence Survey — Utah

In September 1980, a survey of adults in Utah showed that levels of smoking and alcohol use were each >40% below the national level. Specifically, 19% of respondents in Utah reported smoking cigarettes, and 37% reported drinking alcohol, with 9% reporting that they had 5 or more drinks of alcohol more than once each month. This compares with an overall level for U.S. adults of 33% for smoking and 67% for alcohol use (Table 2) (1-3).

These data were obtained from a random sample of 500 adult Utah residents contacted through random-digit dialing.* Trained interviewers described to each person reached by telephone the purpose of the survey and asked if he/she would participate.

*Mountain Bell Telephone Company estimates that 95% of Utah households have a telephone.

TABLE 2. Risk prevalence for adults in Utah and entire United States, 1980

Risk factor	Percent reporting	
	Utah	United States
Tobacco use	18.5	33.0
Alcohol use	37.3	67.0
Lack of regular fitness program	69.9	65.0
Failure to use seat belts regularly	82.0	89.3
Excess weight	46.0	19.0

THE WHITE HOUSE

Office of the Press Secretary
(Galesburg, Illinois)

For Immediate Release

January 10, 1995

PRESS BRIEFING

BY

SECRETARY OF LABOR ROBERT REICH
AND SECRETARY OF EDUCATION RICHARD RILEY

Carl Sandburg Community College
Galesburg, Illinois

1:47 P.M. CST

MS. TERZANO: Secretary Reich and Riley will be available here to answer questions. There's no opening statements; they're here to answer questions on the record and for camera for you. And Secretary Reich has a 2:00 p.m. meeting that he needs to go to, so this will be fairly brief.

SECRETARY REICH: So any questions anybody has, we will dispense with any introductory statements, but please fire away.

Q The skills program being announced today -- I should remember this -- is there new money being asked for in that, or is it essentially old money? The President talked about it just in telescoping a lot of existing --

SECRETARY REICH: The President's budget, as you know, comes out on February 6th. I can only say at this point that the President will be asking for some additional funds, in addition to the job training, the consolidation of jobs that are -- job-training funds that are already there.

Q This morning a number in the realm of -- was it \$3.5 billion was talked about. Does that include the --

SECRETARY REICH: I'm sorry, just because I'm not able to talk about the budget that's going to be presented on the 6th, but let me just say that the bulk of the funds obviously come from consolidating job-training programs. And the President will be asking for somewhat more, simply because of the scale of the problem is so great. We want to make sure that the delivery system is efficient. We want to empower individuals to get the

skills they need. But the universe of people who need those kinds of skills is extraordinarily great.

Q Secretary Reich, the size of that program now -- the aggregate size of the 60 programs would be what in dollar terms?

SECRETARY REICH: I don't have the figure right in front of me. The aggregate size is in the order of \$12 billion. But let me -- I want to check back with you, because the GAO estimate included a lot of programs like vocational rehabilitation programs, veterans programs, small business programs -- training programs -- that have nothing to do with job training. So I want to make sure that we have the right figure for it.

Q Secretary Reich, is this program being proposed as an alternative to the Republican program, or is it a signal that the President is seeking a compromise in terms of job growth -- the same positions that are currently being espoused by Mr. Gingrich and his colleagues in the House and Senate?

SECRETARY REICH: There's a fundamental difference between the President's approach to raising the incomes of hardworking American families and the Republicans' approach. The Republicans are talking about capital gains tax reductions, including capital gains tax reductions on assets already owned. They are pushing what they call a neutral cost recovery tax break, which is a very rich depreciation allowance which will cost upwards of \$160 billion over the next 10 years. Those and a few other proposals form the core of their efforts to build jobs.

The President's approach is very different. The President is saying, in effect, look, the best way of rebuilding America's middle class, given that there has been a profound shift of demand in favor of skilled workers and against people who don't have the education and skills necessary for this new economy, is to give people the wherewithal to get the skills; to empower people directly. Not empower the masters of physical and financial capital, but empower individuals to be their own masters in the next economy.

Q Mr. Secretary, using the scenario the President described in his speech today, and also in the meeting earlier, with Maytag, needing skilled workers and not finding them in the work force, would get them by having the federal government provide vouchers so the workers can buy the training -- why should the taxpayers pay for the training that Maytag needs to give its workers?

SECRETARY REICH: There's a very substantial difference between the kind of training that individual companies give their workers and the kind of training that workers need to

get for themselves. Individual companies provide very company-specific training. Companies do not want to train their workers in skills that are applicable to their competitors, for the simple reason that anybody who gets those skills can walk down the street and get a good job with a competitor. There is no incentive for an individual company --

Q the kind of training the company would give would not be good enough, and therefore, the taxpayer should foot the bill?

SECRETARY REICH: No, they're completely different. The kind of training that companies provide -- let me just repeat this because it's a very important point -- the kind of training that companies typically provide their workers is company-specific training that is not applicable to their competitors for the very and simple and logical reason that there's no incentive for a company to train workers in general skills that those workers can take anywhere. The kind of training that workers need to get better jobs, and often to have the kind of flexibility they need in this new economy is more general training -- the kind that they can get at a community college, like this.

This is what -- not to get too highfalutin about it -- this is what economists would call a market failure. If the companies could all get together in industry, if we didn't have to worry about antitrust collusion -- which we do -- if companies could get together in industry and the companies altogether in industry could say, yes, we need trained workers in this industry and let's all chip in to buy the training for this industry -- yes, maybe then you'd have industry-specific, as opposed to firm-specific training going on.

But for a variety of appropriate reasons, we don't allow companies to get together and collude -- we don't want companies to get together and collude. So these are complementary policies. We want companies to train their workers. Companies need to do more firm-specific training. They're not doing much -- as much as they need to do. Only 35 percent of American workers are getting any formal company training at all, and most of them are college educated. But in addition, American workers need to be empowered themselves -- to get training that no company has an incentive to provide.

Q Mr. Secretary, I thought that former Treasury Secretary Bentsen had distanced himself from your remarks on corporate welfare before, and I noticed that you repeated some of them today. I wondered if this is an administration proposal you're talking about, or is it something you're pursuing on your own?

SECRETARY REICH: Let me just say that there is a profound difference between the approach that the President is

taking and the approach that the Republicans are taking toward rebuilding incomes. We already have got the great American job machine started. We spent two years getting the budget deficit under control; getting more than five million jobs. And those are, on average, good jobs, paying well. The problem is that the 110 million old jobs are splitting between a few that are very good, but a majority that are not so good.

The Republicans want to provide tax breaks to companies. We want to provide tax breaks to individuals and also skill grants to individuals to get the skills they need to flourish in the new economy. That is the difference.

Q Does the administration oppose a capital gains tax then?

Q Can you go over the examples of the programs that are being folded in -- the more significant programs that are being folded in to pay for the vouchers? I also want to be clear on what happens to those programs? Are their old functions -- they no longer exist?

SECRETARY REICH: Our proposal would be to take a lot of the -- many of these individual programs -- there's a Clean Air Act program, retraining program, for workers that may lose their jobs because of environmental regulations. There's a defense diversification program, another defense downsizing program. There is the JTPA Title 2 A program for adults. There is the JTPA Title 3 program, which is basically your general dislocated worker program. There are several programs in the Education Department. And I could go through a long list of programs, and I don't have the entire list in front of me.

The point is, it doesn't matter why you lost your job. If you lost your job, you should be able to get skills necessary for the next job.

Q over, or simply won't exist anymore? I just want to be clear on that. Under the old format --

SECRETARY REICH: Yes, our proposal is to consolidate all of these and provide the resources in terms of skill grants.

Q Secretary Riley, under the individual education account, sir, how much can people -- how much can students borrow from these low-cost loans? What's the cap on it? What kind of interest rate are you talking about?

SECRETARY RILEY: I don't think that that's been identified. You're talking about how the -- you're talking about the --

Q Individual education accounts -- student loans.

SECRETARY RILEY: Yes. Well, in the direct student loans, you can -- it depends on the cost of the school and the number of children in the family that gives the level that you can borrow up to. In other words, if the school is a lot more expensive, under the current formula, you can borrow more money. So those two factors really control the amount that you can borrow.

Q So this is not a new program, this is just the same programs that are --

SECRETARY RILEY: Yes, the direct student loan is the same program.

Q Secretary Reich, do you support the idea being floated in Washington today by Gephardt for a flatter income tax code?

SECRETARY REICH: I would have to know more about the program. I don't think that there is any administration position on that yet. We would just have to look at it very carefully.

Q Secretary Reich, I've heard many reasons why you guys came to Central Illinois to announce this Bill of Rights, but one other thing that hasn't been addressed and that is, in Central Illinois there are many labor disputes going on. Is it the government's intent to intervene in any of those disputes, and if not, why?

SECRETARY REICH: I'm going to meeting with several labor leaders very shortly. Let me say a few things about that. The federal government provides mediation services and we encourage collective bargaining. The President, the Executive Branch, should not, in my view, ever get directly involved in a labor dispute. But we do want to encourage all sides to a dispute to use peaceful collective bargaining as the means of settling their dispute.

I'm encouraged that Caterpillar seems to be, once again, on that road. I am distressed about Bridgestone-Firestone. In fact, Bridgestone-Firestone's decision to bring in striking replacement workers is the largest decision of its kind since the 1980s, since Eastern Airlines, Greyhound, International Paper, many of the major problems we had during the 1980s.

Now, I have personally asked that the president of Bridgestone-Firestone come in to visit with me to talk about the issue. I have talked with rubber workers, and the President of Bridgestone-Firestone, I regret to say, has denied my request -- will not meet with me. I consider this outrageous, quite frankly.

Japanese countries in this country have a sterling record of social responsibility, in general. Japanese companies in this country, like most foreign companies working in the United States, have gone out of their way to abide by our laws, our rules, to give every impression, both in appearance and reality, of cooperating with American citizens and American institutions. I do not for the life of me understand why this company is such an outlayer. We have had problems in other areas as well.

THE PRESS: Thank you.

END 2:02 P.M. CST

✓

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

September 30, 1993

September 30, 1993

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: AIDS at Work

Halting the spread of HIV/AIDS and caring for those already touched by the disease is our common responsibility. Sadly, if you do not know someone with HIV/AIDS, you soon will. Every 17 minutes an American dies of AIDS; one of every five Americans knows someone who has died of AIDS; over one million Americans are already infected with HIV.

HIV/AIDS affects everyone in this Nation. Preventing the spread of HIV/AIDS and its associated human and economic costs is crucial to the success of health care reform. Likewise, enlightened, nondiscriminatory workplace policies are essential to both our efforts at reinventing government and at lowering health costs. This Administration and this Nation must do all within our power to prevent discrimination against those infected with HIV. I am committed to facing the difficult issues raised by HIV/AIDS.

This is an Administration of action and leadership by example. Today's Cabinet meeting discussion of HIV/AIDS is the beginning. All of you are asked to develop and fully implement comprehensive HIV/AIDS workplace policies and employee education and prevention programs by World AIDS Day, 1994, beginning with your Senior Staff.

To begin this process:

- * Each Cabinet Secretary shall designate a member of his/her Senior Staff to implement ongoing HIV/AIDS education and prevention programs and to develop nondiscriminatory workplace policies for employees with HIV/AIDS.
- * These designees, with the Office of the National AIDS Policy Coordinator (ONAPC), shall form a working group to implement this directive.

- * The Office of Personnel Management (OPM) shall review its current HIV/AIDS workplace guidelines and assist in the development of workplace policies in the departments and agencies, as directed by ONAPC. OPM should pay particular attention to ensuring that the administrative burden on the departments and agencies is minimized.
- * The National AIDS Policy Coordinator shall report to me quarterly on the progress of each department and agency, beginning January 1, 1994.
- * The White House Staff and the Staff of the Executive Office of the President (EOP) will participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1993.

HIV/AIDS is the health crisis of this century; it cannot be allowed to extend into the next. Only through education and prevention can we stop its spread. Only through aggressive and coordinated efforts at medical research can we find a cure. Join me on World AIDS Day, 1993, to remember the hundreds of thousands of American dead and the millions of Americans infected or suffering because of this disease; help me to vividly demonstrate this Administration's commitment to end the HIV/AIDS epidemic.

WILLIAM J. CLINTON

#

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

November 30, 1994

WORLD AIDS DAY, 1994

- - - - -

BY THE PRESIDENT OF THE UNITED STATES OF AMERICA

A PROCLAMATION

On this World AIDS Day, we recognize the countless determined individuals who have provided assistance to those affected by HIV and AIDS, and we redouble our efforts to work with our international partners and to confront the enormous challenges that remain. Here and around the world, people are reaching out to those who are living with HIV and AIDS and are joining the fight to stop this epidemic. The theme of this year's commemoration, "Families and AIDS," is especially fitting. When one person suffers, the entire global family is affected. Today, we pledge to keep faith with the thousands of people living with HIV and AIDS and their families -- their mothers and fathers, brothers and sisters, their friends, neighbors, and loved ones.

In slightly more than 13 years, AIDS has claimed the lives of more than 250,000 Americans -- nearly five times as many men and women as were killed in the Korean War. If current trends continue, by the end of this decade we will have lost half a million people to this insidious disease, more than our Nation's total losses in World War II. The World Health Organization estimates that 30 to 40 million people worldwide will have been infected with HIV by the end of the decade. The problem of HIV and AIDS is global, and it is one of staggering proportions. The United States will continue to work with our global partners in the worldwide battle against HIV and AIDS.

Here at home in response to the epidemic, hundreds of community-based organizations have devoted themselves to provide medical care, social and support services, respite care, meal delivery, and education and prevention programs to persons with HIV or AIDS. Together with those they serve, the men and women of these organizations -- most of whom are volunteers -- are the heroes of our common struggle.

In the past two years, our Nation has reenergized its response to HIV and AIDS. At a time of zero budget growth, funding for AIDS programs has been increased by 30 percent. AIDS research funding has risen by 25 percent, and money going to grants under the Ryan White CARE Act has been increased by 82 percent, bringing vital services to thousands of men, women, and children in need. Our research efforts have been

reorganized and refocused, and they have already begun to produce results. When scientists discovered that treatment with AZT could sharply reduce the risk of HIV transmission from mothers to their unborn children, the Government acted quickly both to provide women and their health care professionals with new guidelines and to change the labeling on that drug. Already, we are saving lives.

On World AIDS Day, we rededicate ourselves to the battle against HIV and AIDS. Our Government must continue to do its part, including reauthorizing the Ryan White CARE Act and continuing to enforce the Americans with Disabilities Act. Business and community leaders must push forward in their remarkable efforts to educate people everywhere. And every one of us must strive to reach out to those who are living with HIV and AIDS to make their paths a little smoother, to make their hearts a little lighter, and to make their lives a little richer.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim December 1, 1994, as "World AIDS Day." I invite the Governors of the States, the Commonwealth of Puerto Rico, officials of other territories subject to the jurisdiction of the United States, and the American people to join me in reaffirming our commitment to combat HIV and AIDS and to reach out with compassion to those living with this disease.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of November, in the year of our Lord nineteen hundred and nine

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

July 28, 1995

REMARKS BY THE PRESIDENT
IN PHOTO OP WITH THE AIDS ADVISORY COUNCIL

The Roosevelt Room

11:26 A.M. EDT

THE PRESIDENT: Good morning, and welcome. I'd like to begin by thanking Patsy Fleming for the work that she's done with me and with you and for our country on this issue; and by thanking all of you for your service on this Advisory Council. We need your advice, your wisdom, your enthusiasm, your energy, and America needs your service. And I thank you for it very much.

As you know, I have been strongly committed to an increasing federal response to the AIDS crisis. In spite of the fact that we have cut and eliminated hundreds and hundreds of programs since I have been President, we've increased overall AIDS funding by 40 percent, and funding for the Ryan White Care Act by 80 percent since I've been President.

I was very, very pleased to see yesterday how overwhelmingly the Senate voted to reauthorize the Ryan White Care Act. I've got a budget before them which would increase our funding considerably more. I hope that will pass. But the United States Senate made an important statement yesterday, almost unanimously. And I think we should all appreciate that and be grateful for it.

This terrible plague has cost our country 270,000 American lives, and over 100 every day. There are some encouraging signs on the research front, as all of you know. Scientists have discovered ways to block the transmission of HIV from mothers to children. New classes of drugs are being developed to actually repair damaged immune systems, which is very, very hopeful. These scientific advances give us all reason to hope, and should redouble our determination, even in this season of balanced budget to reinvest even more and more of our nation's wealth into medical research in AIDS and medical research of all kinds.

This is not the time to slow down and retreat. This is not the time to give in. AIDS is a challenge which all of us face. That's what the United States Senate said yesterday. It really is a part of our common ground. I think we can attack this disease without attacking each other. And apparently, sensible, good, farsighted Americans in both parties agree.

When we begin to pit one disease against another, or one group of people against another in this country, we all wind up behind. And I felt much better about the future of our country, at least on this point, when I saw how the United States Senate conducted itself yesterday. Now, our task is to continue to marshal all the forces we've got to lift the visibility of this issue.

When I spoke about this matter in my speech at Georgetown just a few weeks ago I said that this was one area where we had to find common ground. This morning, I think we got a chance to do it. And with your help, we'll continue to make progress on it. Thank you very much. (Applause.)

Q Is the United States orchestrating the transfer of arms to the Bosnian Muslims through Arab or Middle Eastern countries or anywhere else?

THE PRESIDENT: No.

Q Mr. President, have you managed to achieve the economic soft landing?

THE PRESIDENT: Well, I think the economy is coming back up, if that's what you mean. We had a slow second quarter, we knew we did. But the general thrust of the economy looks strong again. The fundamental problem is now that we had a slow second quarter -- if you're going to have a long, long period of growth, you're going to have uneven periods within that.

The fundamental problem is, we've created 7 million jobs and most Americans haven't gotten a raise. Most Americans still feel economically insecure in their own circumstances because their incomes haven't gone up, because they don't think their jobs are secure, because they're worried about their family's health care. And we need an agenda in this country that I have been pushing for two years now that not only creates jobs, but also raises incomes and increases the security of families.

That is the fundamental problem. But it starts with having a good economic policy. So we wouldn't even be where we are if we didn't have the 7 million jobs and a lower unemployment rate with low inflation. So I'm proud of what we've accomplished. But it's only half the job.

Thank you.

THE PRESS: Thank you.

END

11:31 A.M. EDT

<HTML>
<HEAD>
<TITLE>Pharmaco-economics v clinical economics</TITLE>
<H2></H2>
</HEAD>
<BODY>
<HR>
<H1>Pharmaco-economics versus clinical economics:</H1>
<H2>What is the best approach?</H2>
Reprinted from Pharmacy Cost Control News, Volume 2, Issue 6, June 1995

<HR>
<BLOCKQUOTE>
<I>Pharmacy Cost Control News</I> has featured frequent articles on the subject of pharmaco-economics. This rapidly growing and maturing discipline is one of extreme importance to our readers. Since few have had the opportunity to study this field formally, we interviewed two leaders in this field to gain information on ways of studying pharmaco-economics.

</BLOCKQUOTE>

<P>

Our first interview was with Lee C. Vermeulen, Jr., M.S., Director, Center for Drug Policy and Clinical Economics, the Department of Pharmacy Services at the University of Wisconsin Hospital and Clinics, Madison, WI. We then interviewed Lisa Sanchez, Pharm.D., Director of Pharmaco-economics, Department of Pharmacy Services, Brigham and Women's Hospital in Boston.

<P>

PCCN: Mr. Vermeulen, we note that the name for your center includes the term, "clinical economics". How does this term differ from the more widely-used term, "pharmaco-economics?"

<P>

Vermeulen: The field of pharmaco-economics has quickly evolved into a more sophisticated science in which outcomes rather than cost is of primary interest. Pharmaco-economics also implies a study of the economics of drugs. However, I believe that is a too narrow view of what needs to be examined. Today, we not only need comparisons of drug versus drug, but also drug versus procedure with an emphasis on the societal-based outcomes of these comparisons. I prefer the term "clinical economics" as indicative of a new, more encompassing approach to the study of economics in health care.

<P>

PCCN: Where can our readers turn for educational and training programs in

maybe you can call them?!

pharmacoeconomics or clinical economics?

<P>

Vermeulen: I see three possibilities for these types of programs. The first is a formal academic program leading to a degree, the second is a formal fellowship program, and the third is in the form of short symposia.

<P>Sanchez: Yes, I agree. Unfortunately, there are not as many resources on pharmacoeconomics as we might like. The literature contains an increasing number of reviews and studies, however for the beginner, these publications do not serve as tutorials to learn the language and the science. There are a few landmark articles that can be found in

the medical and pharmaceutical literature. In my opinion, however, there is no single good

source for information to improve the pharmacist's skills in pharmacoeconomics.

<P>PCCN: How sophisticated are most pharmacy practitioners in this field?

<P>Sanchez: I find varying degrees of expertise. Quite frankly, I believe some pharmacists hoped that the whole notion of pharmacoeconomics would simply go away, and therefore the discipline was ignored by some. Now however, these doubters are beginning to take the subject seriously, and realize that they must acquire skills to incorporate into their practice. Some pharmacists have begun to "dabble," yet others have begun to move to greater levels of sophistication. I still find much misuse of terminology and lack of understanding of many of the principles of pharmacoeconomics.

<P>

PCCN: Can you describe the current environment for degree-granting programs?

<P>

Vermeulen: A small number of universities are developing graduate coursework in pharmacoeconomics or clinical economics. Generally, these programs are being developed to educate the student at the M.S. level. While a Master's Degree may be most appropriate for those interested in remaining in practice, Ph.D. level education may be required for those who wish to pursue academic careers. Quite honestly, I don't see formal graduate education meeting the needs of or being practical for large numbers of pharmacists.

<P>Sanchez: Most academic programs of this type are very focused in pharmacy administration. Formal graduate study probably should be of interest only to those interested in pursuing academic careers.

<P>PCCN: What can you tell us about fellowship programs?

<P>Sanchez: In addition to the formal graduate fellowship already mentioned, we now see fellowships that are jointly sponsored between a pharmaceutical company and an academic center. We also see the emergence of hospital-sponsored residencies in pharmacoeconomics. This latter type of fellowship is springing up frequently.

<P>

Vermeulen: I would agree. Several types of organizations have begun to develop fellowship programs. The pharmaceutical industry, health care provider organizations and pharmacy benefits manager organizations have all expressed an interest in developing fellowships built around clinical economics. In some cases, two or more of these organizations have developed partnerships to cosponsor the fellowship. In that situation, the fellow spends part of the fellowship working in each environment.

In most cases, fellowships are designed as post-doctoral experiences, usually two years in length. At the present time, there are no accreditation standards for these fellowships, nor is it clear who an appropriate accrediting body might be.

<P>

PCCN: What advice would you give to someone considering a fellowship program?

What are the hallmarks of a good program?

<P>Sanchez: The choice of a program should be made primarily upon the needs of the potential fellow. In general, industrial fellowships will provide an environment to learn the industrial perspective of pharmacoeconomics and the marketing and sales applications of these principles. Hospital-sponsored fellowships are able to provide a patient perspective, lead to the development of policies and interventions at the patient level, and allow for the development of a theoretical area for clinical application.

<P>

PCCN: Since some of the parties involved in these fellowships would have an obvious economic interest in clinical economics, do you have any concern regarding possible conflict of interest or biases built into fellowships or other educational programs tied to industry?

<P>

Vermeulen: Of course, one must be careful that such conflicts of interest do not arise.

In my opinion however, there have been no problems of this type to date. I believe that partnerships between organizations such as the pharmaceutical industry and an academic health center will provide appropriate balance and built-in assurances against bias. Quite

frankly, funding for fellowship programs is most likely going to come from the industrial sector. Cooperation with our industrial partners will lead to academically sound and unbiased fellowship training. Should we ever evolve into a system of accreditation, there will be additional safeguards against conflicts of interest. I think we should actually give credit to the industry for coming forth with support for fellowship programs.

<P>Sanchez: I find much of the industry-distributed pharmacoeconomic materials to be variable in their inherent bias. In general, if an educational tool is not product specific, it is likely to be free of bias in favor of the company. I have noted that some items that are product specific may contain pharmacoeconomic assumptions that may not necessarily be appropriate to a given institution. Data that are presented may be derived from a controlled environment such as a protocol-driven clinical trial. Conclusions from such data may not be transferrable to a different setting, and may not be reflective of actual practice.

<P>

PCCN: What about symposia on the subject of pharmacoeconomics or clinical economics?

<P>

Vermeulen: We are all familiar with the one to three hour programs offered in conjunction with national meetings such as ASHP's Midyear Clinical Meeting. These programs tend to be introductory and help large numbers of participants get introduced to some of the principles of clinical economics. In my opinion, the practitioner interested in getting to another level should explore more intensive programs.

One of the best experiences I have had to study the field was an intensive program offered at McMaster University in Hamilton, Ontario. This program is a two to three day in-depth examination of the evaluation of clinical and economic research. Stand-alone programs such as this should be considered by the person interested in moving beyond the basics.

I, too, would like to add a word about educational materials now being distributed by the pharmaceutical industry. These are in the form of computer software, CD-ROM, videos and audiotapes. I advise your readers to be very careful and critical. In my opinion, much of this material reflects the views of marketing rather than science. While these programs often address cost analysis, they often do not contain outcome analysis. In all fairness however, I need to say that I believe industrial economists are moving away from marketing and toward a more scientific outcome approach.

<P>

PCCN: Thank you for your information and advice. Do you have any final thoughts?

<P>Sanchez: I often recommend three strategies to help pharmacists to incorporate pharmacoeconomics into everyday practice. To solve a pharmacoeconomic problem, take

the following approach. First, go to the literature. Critique and evaluate previously published work to determine whether someone else's work can be applied to the present problem. Second, consider building an economic model to forecast the impact of the needed decision. Test the assumptions you put into your model. Third, if necessary, conduct your own study. Before you design a study, look for published guidelines on how to conduct this type of research. Remember that prospective economic studies have a cost of their own. So make sure that your studies are well-designed to answer the question you really need answered.

<P>

Vermeulen: The challenge for pharmacists is to find ways to use pharmacoeconomics, or clinical economics, in the practice setting. Identifying cost is not enough. We must move to outcomes.

<HR>

For more information on subscribing to <I>Pharmacy Cost Control News</I>, please call 1-800-638-8437.

<HR>

<P> Pharmacy Cost Control News Contents</P>

<P>PharmInfoNet Homepage

</BODY>

</HTML>