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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service



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ROUTING AND TRANSMITTAL SLIP

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REMARKS:

Attached are camera ready copies of dot maps -- we don't have one for 1981 data -- the five maps are all that the Division has developed.

I've also included Leading Causes of Death Table for Persons 25-44 & Death rate for HIV Infection for Persons 25-44 by sex & race. Stay Warm!
+ latest Recent Trends "Reported U.S. AIDS Cases"

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U.S. GPO 1993-0-733-276 86004



Recent Trends in Reported U.S. AIDS Cases*

Through December 1995, more than one-half million persons with AIDS had been reported to CDC by state and territorial health departments.

These 513,486 cumulative reported cases included:

- 438,294 cases among males
- 75,191 cases among females
- 506,538 cases among adolescents and adults
- 6,948 cases among children less than 13 years of age

Surveillance for AIDS began in 1981, following recognition of the first cases of unexplained severe immunosuppression and the resulting opportunistic illnesses. The AIDS surveillance case definition for adolescents and adults was substantially expanded in 1987 and again in 1993 to reflect increased knowledge of the natural history of HIV infection and to remain consistent with the clinical management of HIV disease. Approximately half of the 513,486 cumulative AIDS cases have been reported since 1993, reflecting both the expanded definition as well as the magnitude of the epidemic.

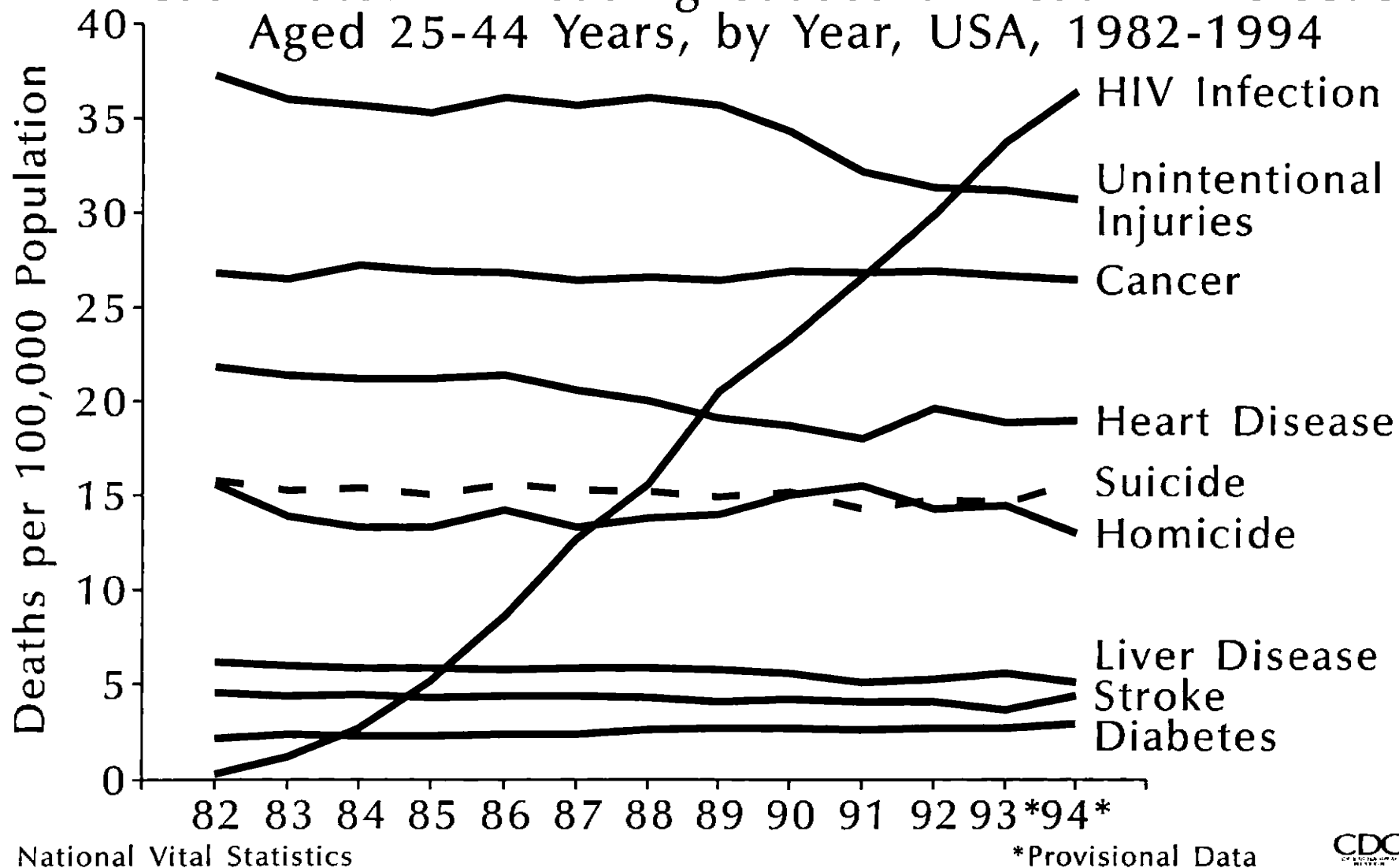
During 1995 the following characteristics of persons reported with AIDS have been observed:

by exposure category among adults/adolescents, 42% of cases were reported among men who have sex with men; 26% were attributed to injecting drug use; 11% were attributed to heterosexual contact; 5% were reported among men who have sex with men and inject drugs; 1% were attributed to receipt of blood transfusion, blood components, or tissue; 1% occurred in persons with hemophilia or other coagulation disorder; and 15% occurred among persons whose risk has not yet been reported or identified. (Many are currently under investigation and will be reclassified).

by exposure category among children, 91% occurred in children infected through perinatal transmission; 3% were attributed to receipt of blood transfusion, blood components, or tissue; 1% occurred in children with hemophilia or other coagulation disorder; and 5% occurred among children whose risk has not yet been reported or identified.

by race, whites accounted for 40% of cases, blacks 40%, and Hispanics 19%. Asian/Pacific Islanders and American Indian/Alaska Natives each accounted for less than 1% of reported cases.

Death Rates for Leading Causes of Death in Persons Aged 25-44 Years, by Year, USA, 1982-1994



During 1995, 74,180 people were reported to have AIDS; the AIDS case rate per 100,000 population was 27.8. For blacks and Hispanics, the rates (120 and 62, respectively) were substantially higher than rates for whites (19), American Indians/Alaskan Natives (17) and Asian Pacific Islanders (8).

Although men who have sex with men continue to account for the largest proportion of cases, recent trends have indicated that the epidemic is increasing more rapidly among injecting drug users and persons infected through heterosexual contact. The increase in AIDS cases resulting from heterosexual transmission is also reflected in the increase in cases reported among women. Geographic patterns have also changed, with the greatest proportionate increases in the epidemic occurring in the South and Midwest. Regardless of transmission mode or region, blacks and Hispanics continue to be disproportionately affected by the epidemic.

*Provisional AIDS case data. Publication of the *HIV/AIDS Surveillance Report* (Vol. 7, No. 2) is expected during the first quarter of 1996.

For more information:

CDC National AIDS Hotline: 1-800-342-AIDS (2437)

Spanish: 1-800-344-SIDA (7432)

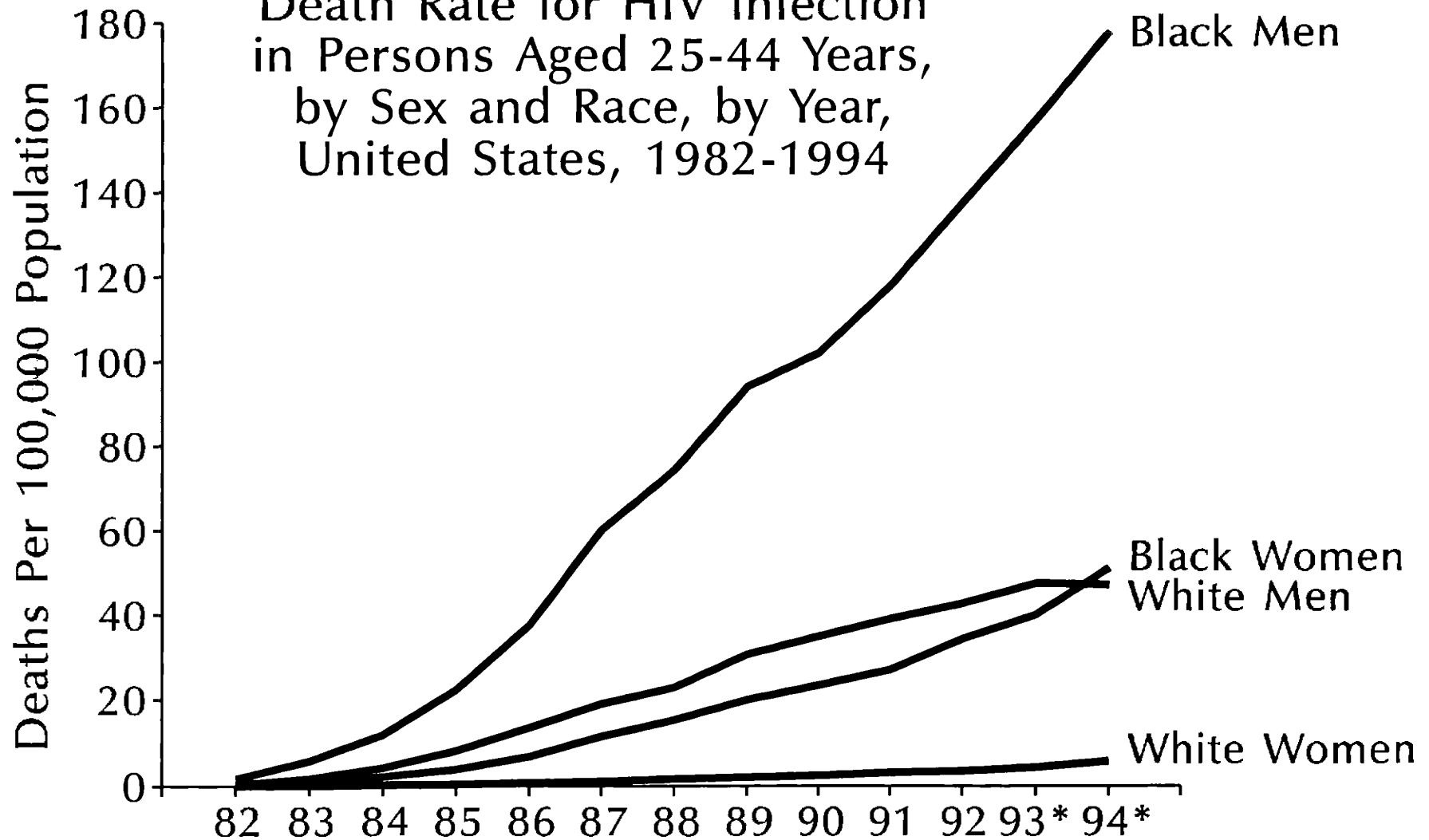
Deaf: 1-800-243-7889

CDC National AIDS Clearinghouse

P.O. Box 6003

Rockville, MD 20849-6003

Death Rate for HIV Infection
in Persons Aged 25-44 Years,
by Sex and Race, by Year,
United States, 1982-1994

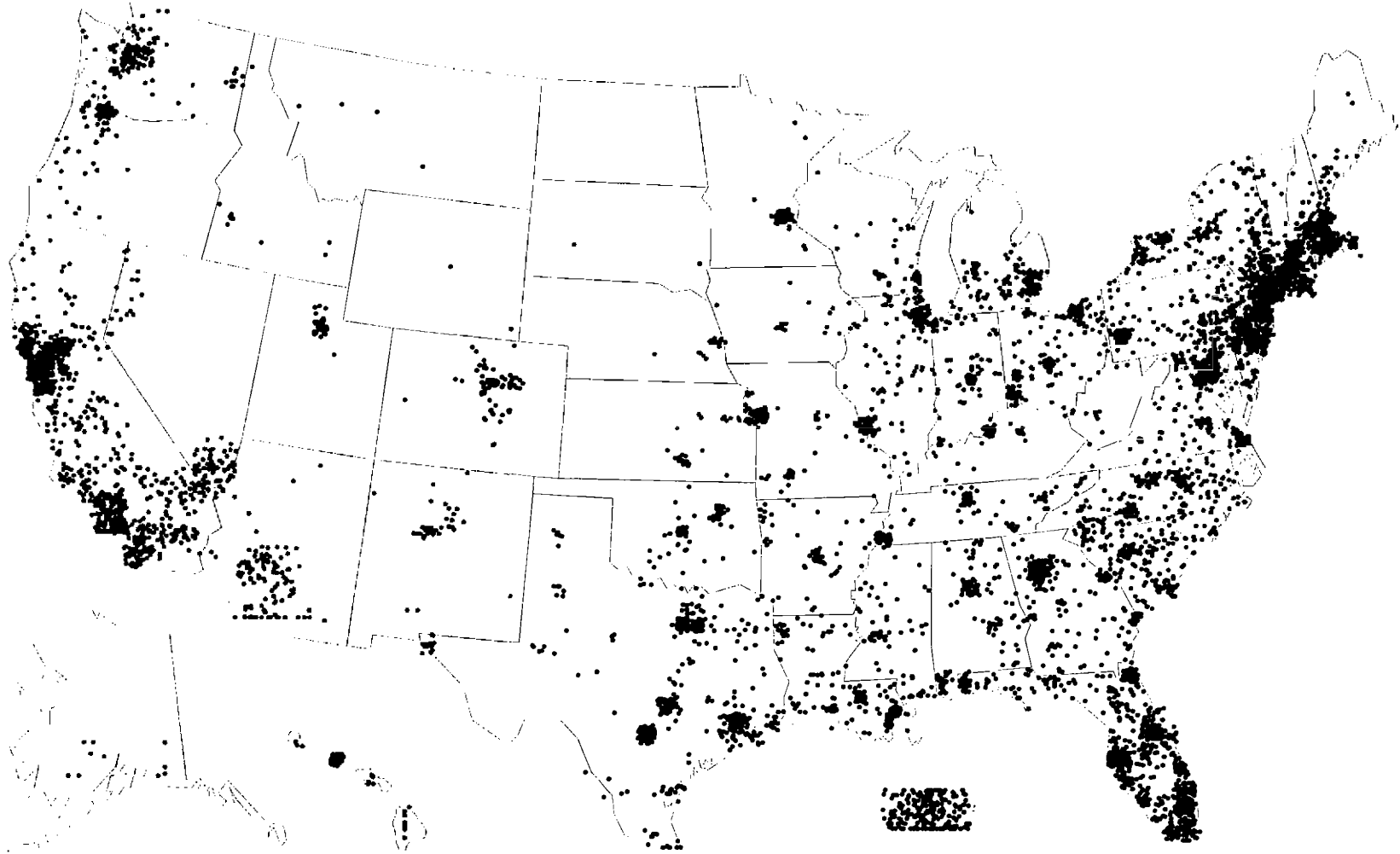


National Vital Statistics

*Provisional data

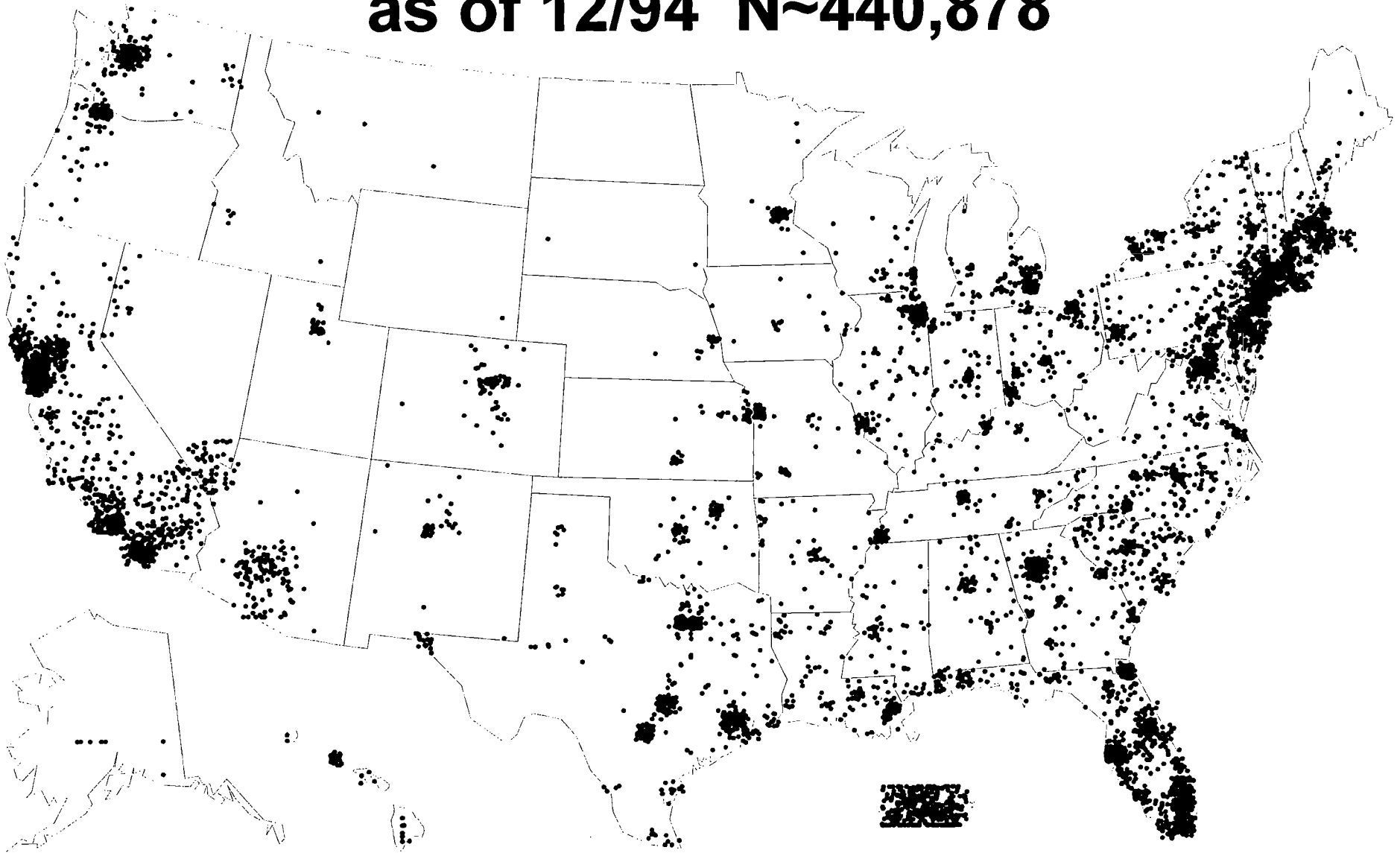


Cumulative U.S. AIDS Cases as of December 31, 1995



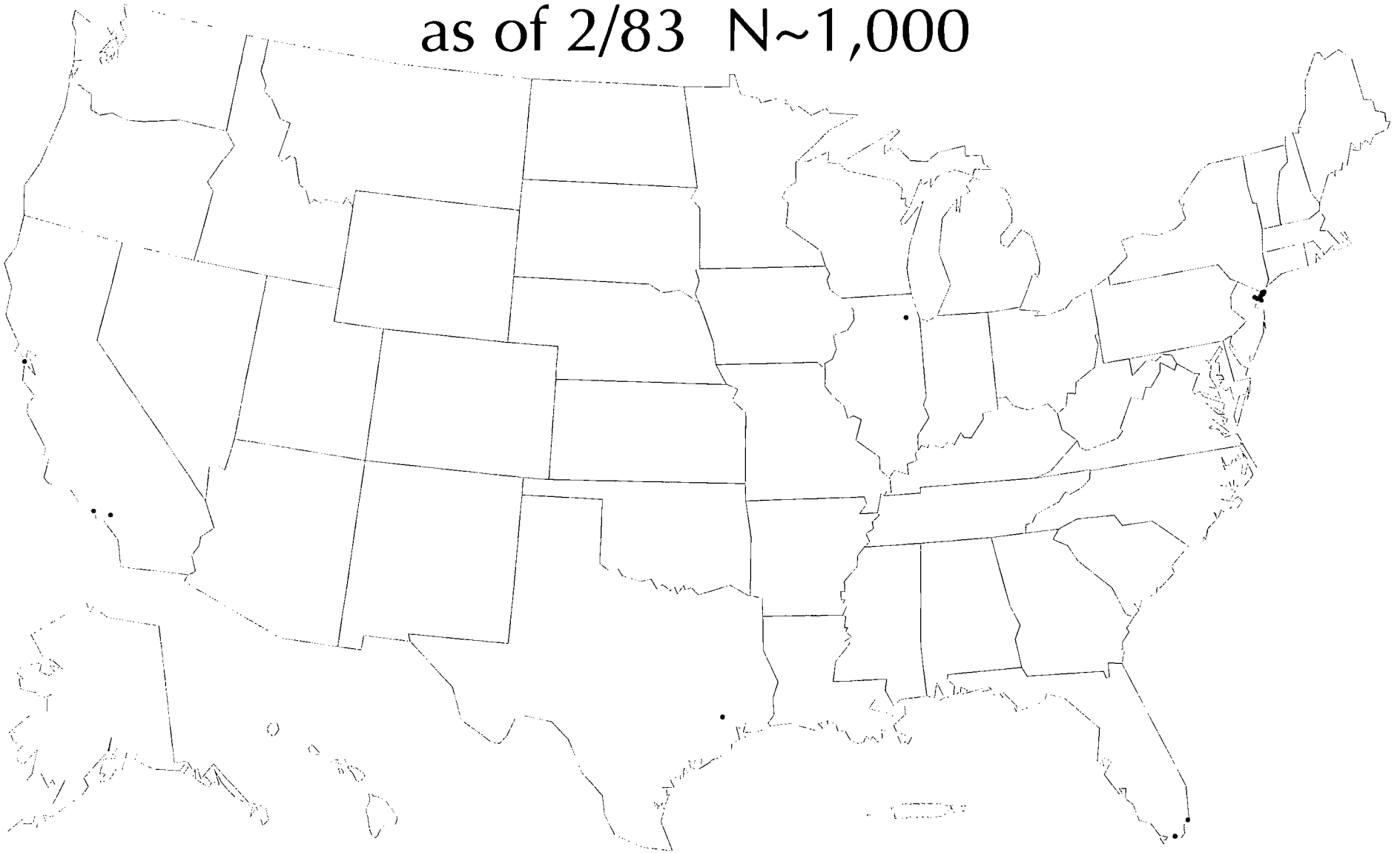
Each point = 30 cases

Cumulative U. S. AIDS Cases as of 12/94 N~440,878



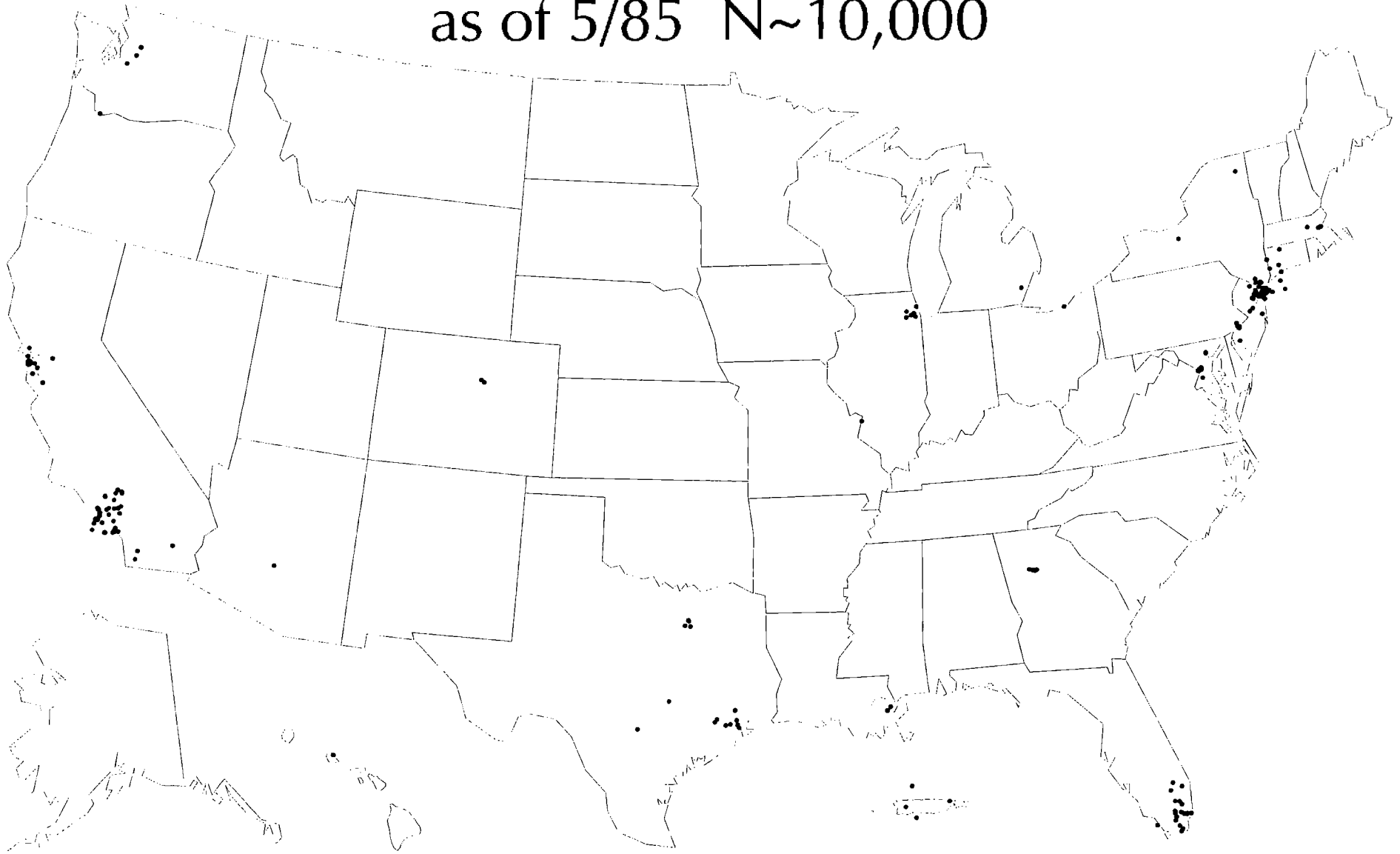
Each point = 30 cases

Cumulative U.S. AIDS Cases as of 2/83 N~1,000



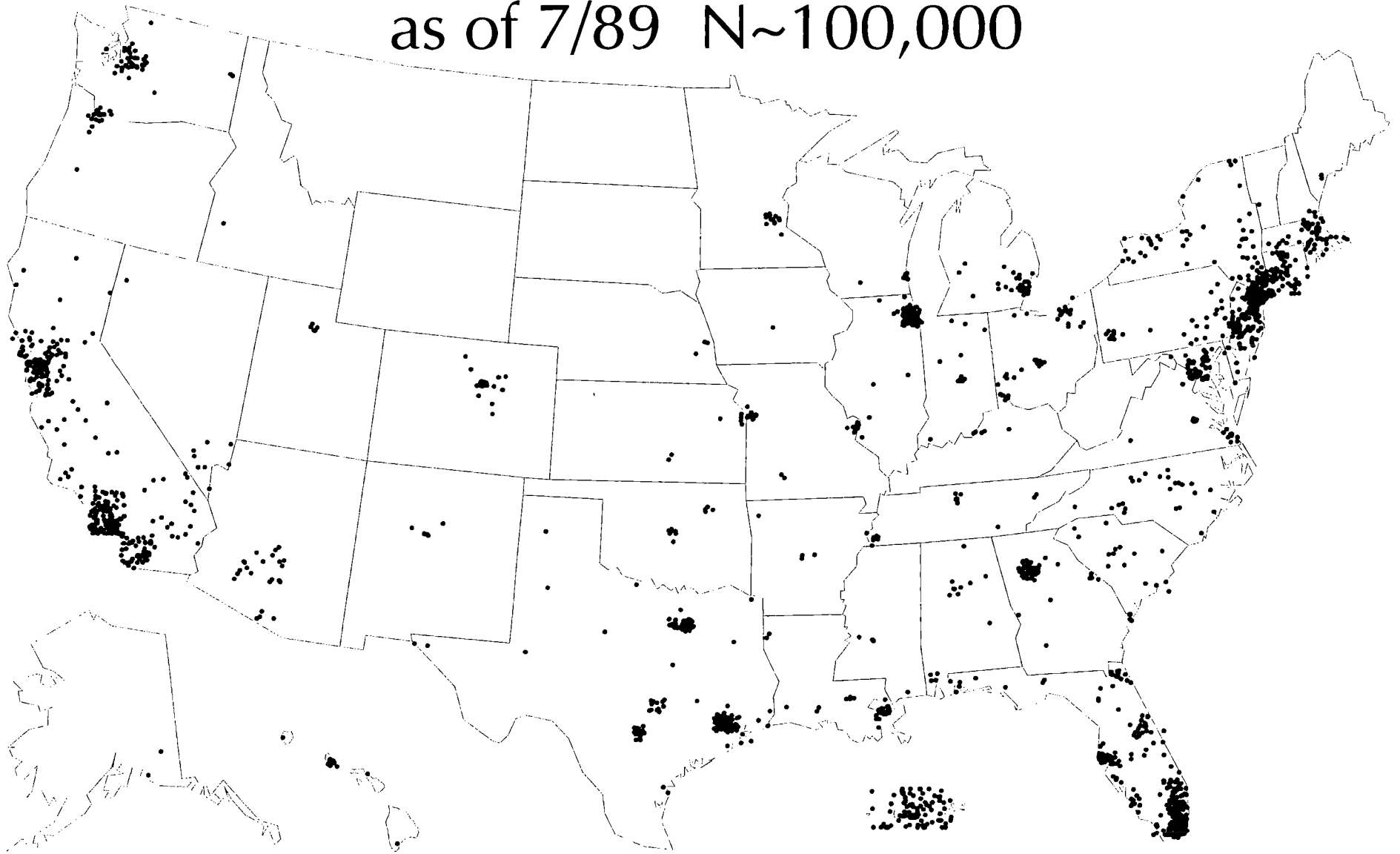
Each point = 30 cases

Cumulative U. S. AIDS Cases as of 5/85 N~10,000



Each point = 30 cases

Cumulative U.S. AIDS Cases as of 7/89 N~100,000



Each point = 30 cases



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892**

OFFICE OF COMMUNICATIONS
National Institute of Allergy and Infectious Diseases

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NO. OF PAGES INCLUDING COVER SHEET: 4

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NIAID NEWS

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EMBARGOED FOR RELEASE
Wednesday, Oct. 25, 1995
5:00 p.m., Eastern Time

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HIV Trapped in Lymph Nodes Infectious Despite Antibodies

Even when coated with antibodies, HIV trapped by specialized lymph node cells remains infectious, according to researchers supported by the National Institute of Allergy and Infectious Diseases (NIAID). Ensnared viruses may ambush critical immune cells that migrate through the lymph node, a scenario that provides a possible explanation for the large quantities of HIV and HIV-infected cells found in the lymph nodes of people with HIV disease, many of whom have abundant anti-HIV antibodies.

As reported in the Oct. 26, 1995 *Nature*, Gregory F. Burton, Ph.D., and colleagues at Virginia Commonwealth University in Richmond found that HIV, when attached to the external surface of lymph node cells called follicular dendritic cells, infected CD4+ T cells even in the presence of a vast excess of neutralizing antibodies. In the absence of follicular dendritic cells, similar quantities of neutralizing antibodies blocked the infectivity of the virus.

Although the precise mechanisms remain unclear, Dr. Burton and his colleagues observed the ability of follicular dendritic cells to facilitate HIV infection in the presence of neutralizing antibodies in a laboratory model based on human cells, and in mice.

"These important findings build on previous data that demonstrate that the lymphoid organs are central to the pathogenesis of HIV disease," says Anthony S. Fauci, M.D., NIAID director.

(more)

A commentary on the paper by the Virginia Commonwealth group, written by Dr. Fauci and Lewis K. Schrager, M.D., of NIAID's Division of AIDS, appears in the same issue of *Nature*.

Follicular dendritic cells have thread-like tentacles and are found in lymph nodes and related organs such as the tonsils and spleen, within hot spots of immune activity called germinal centers. These cells act as flypaper, trapping invading pathogens (including HIV) and holding them in the germinal centers until B cells come along and initiate an immune response. Close on the heels of B cells are CD4+ T cells, which rush into the germinal centers to help the B cells fight the invaders.

"CD4+ T cells are the primary targets of HIV," explains Dr. Fauci. "These cells may become infected as they enter the germinal center and encounter HIV trapped on follicular dendritic cells." Once infected, CD4+ T cells may leave the germinal center and infect many other CD4+ T cells that congregate in the region of the lymph node surrounding the germinal center.

"Paradoxically, the networks of follicular dendritic cells in the germinal centers, by doing their normal job of trapping pathogens and initiating an immune response, may be an important reason why HIV is so effective at destroying the immune system," says Dr. Schrager. "By trapping HIV, the follicular dendritic cells expose a steady stream of CD4+ T cells to the virus, which, as Dr. Burton's work tells us, appears to be infectious even in the presence of neutralizing antibodies."

In previous studies, NIAID scientists have studied the lymph nodes of HIV-infected individuals and found large amounts of HIV in germinal centers in the early stages of disease, both in infected cells and as "free" virus bound to follicular dendritic cells. Over time, large quantities of HIV accumulate in the lymph nodes, ultimately overwhelming the germinal centers,

(more)

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leading to the destruction of the follicular dendritic cells and their trapping function, as well as the rest of the lymph node. This may preclude a successful immune response against other pathogens as well as HIV.

"Taken together, recent studies of the interactions between HIV and follicular dendritic cells in lymph node germinal centers may have important therapeutic implications," says Dr. Schragar. "It may be possible, for instance, to prevent the virus from becoming trapped in the first place or to remove the entangled virus from the follicular dendritic cells. These and other related questions need to be explored further in animal models."

Dr. Burton's co-authors, all from Virginia Commonwealth University, include Sonya L. Heath, M.S., J. Grant Tew, B.S., John G. Tew, Ph.D., and Andras K. Szakal, Ph.D.

NIAID, a component of the National Institutes of Health, supports investigators and scientific studies at universities, medical schools, hospitals and research institutions in the United States and abroad. NIH is an agency of the U.S. Public Health Service, part of the Department of Health and Human Services.

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A Randomized Controlled Trial of an HIV Sexual Risk-Reduction Intervention for Young African-American Women

Ralph J. DiClemente, PhD, Gina M. Wingood, ScD, MPH

Objective.—To evaluate the efficacy of a community-based social skills human immunodeficiency virus (HIV) prevention intervention to enhance consistent condom use.

Design.—A randomized, single-blind controlled trial.

Setting.—Bayview-Hunter's Point neighborhood of San Francisco, Calif, a predominantly African-American community that is economically disadvantaged.

Participants.—A sample of 128 sexually active, heterosexual, African-American women 18 through 29 years of age was recruited using street outreach techniques. Participants completed a structured baseline interview; 100 women (78.1%) completed 3-month follow-up interviews.

Intervention.—Women randomized to the social skills intervention completed five sessions that emphasized ethnic and gender pride, HIV risk-reduction information, sexual self-control, sexual assertiveness and communication skills, proper condom use skills, and developing partner norms supportive of consistent condom use. Women randomized to the HIV education condition participated in a single session that provided HIV risk-reduction information. Women randomized to the delayed HIV education control condition received no HIV risk-reduction information until all follow-up interviews were completed.

Main Outcome Measures.—Consistent condom use, HIV risk-reduction knowledge, sexual self-control, sexual assertiveness, sexual communication, and partner norms supportive of consistent condom use.

Results.—Compared with the delayed HIV education control condition, women in the social skills intervention demonstrated increased consistent condom use (adjusted odds ratio [OR], 2.1; 95% confidence interval [CI], 1.03 to 4.15; $P=.04$), greater sexual self-control (adjusted OR, 1.9; 95% CI, 1.00 to 3.60; $P=.05$), greater sexual communication (adjusted OR, 4.1; 95% CI, 1.67 to 10.01; $P=.002$), greater sexual assertiveness (adjusted OR, 1.8; 95% CI, 1.01 to 3.27; $P=.05$), and increased partners' adoption of norms supporting consistent condom use (adjusted OR, 2.1; 95% CI, 1.08 to 3.87; $P=.03$). No statistically significant differences in outcome variables were observed between the HIV education condition relative to the delayed HIV education control condition.

Conclusion.—Community-based HIV risk-reduction programs that are gender relevant and culturally sensitive and provide social skills training can effectively enhance consistent condom use.

(JAMA. 1995;274:1271-1276)

From the School of Public Health, Department of Health Behavior (Drs DiClemente and Wingood); School of Medicine, Department of Pediatrics, Division of Adolescent Medicine (Dr DiClemente); Center for AIDS Research (Drs DiClemente and Wingood); and the Center for Health Promotion (Drs DiClemente and Wingood), University of Alabama, Birmingham.

Reprint requests to the School of Public Health, Department of Health Behavior, 1825 University Blvd, Suite 121, Birmingham, AL 35294-2010 (Dr DiClemente).

AFRICAN-AMERICAN women are disproportionately affected by the acquired immunodeficiency syndrome (AIDS) epidemic.¹ Surveillance data for 1994 indicate that African-American women were approximately 16 times more likely to be diagnosed with AIDS than white women (63 per 100 000 vs four per 100 000). More

over, seroepidemiological surveys from various populations indicate that, relative to other ethnic groups, African-American women have markedly higher human immunodeficiency virus (HIV) prevalence rates. In a study of childbearing women, seroprevalence rates for African-American women were six to 15 times higher than for white women.² Similarly, HIV prevalence rates among African-American women applicants to the Job Corps training program more than doubled between 1988 and 1992, not only exceeding rates for white and Hispanic women, but also exceeding rates for African-American men.³

Reducing the risk for HIV among sexually active African-American women requires the use of prevention strategies that effectively inhibit viral transmission.^{4,5} A primary HIV prevention strategy is to use a condom during each episode of sexual intercourse.⁶ When used correctly and consistently, condoms effectively prohibit the transmission of viral pathogens, including HIV.⁷⁻¹⁰ For economically disadvantaged African-American women, numerous behavioral, sociocultural, and gender-related factors may reduce their compliance with consistent condom use and increase their risk for HIV infection. These factors include competing socioeconomic stressors and power imbalances experienced by many African-American women in heterosexual relationships.¹¹⁻¹⁴ Unfortunately, the development and implementation of culturally sensitive, gender-relevant HIV prevention programs designed to promote the adoption and maintenance of consistent condom use among African-American women lags behind prevention efforts for other risk populations.^{15,16}

The present study used a randomized, single-blind controlled design to evaluate the efficacy of a community-based HIV sexual risk-reduction intervention to enhance the adoption and maintenance of consistent condom use

among economically disadvantaged young adult African-American women.

METHODS

Participants

A total of 128 women were recruited from the Bayview-Hunter's Point community of San Francisco, Calif. The Bayview-Hunter's Point neighborhood is 84% African American. Twenty-four percent of the total households are below the poverty line, and the median family income is 34% lower than the median family income for the rest of San Francisco.¹⁷

Women were recruited over an 11-month period from February 1993 through December 1993, using street outreach and media advertisements placed throughout the community. Indigenous African-American women field recruiters, familiar with the Bayview-Hunter's Point neighborhood, approached and screened women for eligibility at the local unemployment office, the Social Security office, public laundry facilities, beauty salons, grocery stores, health clinics, and the local Aid to Families With Dependent Children (AFDC) office. Inclusion criteria consisted of being a sexually active, heterosexual African-American woman 18 through 29 years of age residing in the Bayview-Hunter's Point neighborhood. Exclusion criteria included use of crack cocaine in the previous 3 months or a history of injection drug use. After assessing a woman's willingness and eligibility for study participation, field recruiters recorded the woman's name and telephone number on a recruitment list.

Study Procedures

Recruitment lists were given to the project director, and the project director contacted each potential participant, reconfirmed her eligibility and willingness to participate in the study, and scheduled a baseline interview for the following week. Interviews were conducted at the Bayview-Hunter's Point Foundation, an African-American, community-based organization with a long history of providing social and medical services in this community. Prior to the interview, each participant completed a tracking form that included her name, address, and telephone number as well as the address and phone number of a close confidant. After being informed of the purpose of the investigation and procedures to protect confidentiality and after providing written informed consent, a trained African-American woman interviewer administered a face-to-face, 45-minute private interview. After completing the baseline interview, women were compensated \$10 for their time. Following the baseline interview, the

project director entered each participant's name, address, telephone number, and assigned case number into a log book. The project director, using a random numbers table, generated a listing that identified the treatment assignment for each participant and entered the treatment allocation into the log book. One week prior to implementation of the treatment conditions, the project director telephoned all participants to inform them of the start date for their treatment condition. To encourage compliance, the project director also telephoned participants the day prior to implementation of their treatment condition.

Three months after the intervention, the project director contacted and scheduled all participants to return for follow-up interviews, using a modified version of the baseline interview to assess changes in consistent condom use and theoretically important constructs thought to mediate condom use. Each participant completed a follow-up interview administered by an interviewer who was blinded to the participant's treatment assignment. A reimbursement of \$20 was provided to all participants after completion of the 3-month follow-up interview. The study was approved by the Committee on Human Subjects at the Bayview-Hunter's Point Foundation and the University of California San Francisco Committee on Human Research.

Study Design

The study was a randomized, single-blind controlled trial. After completing baseline interviews, women were randomly assigned to one of three study conditions: a five-session social skills intervention condition ($n=53$), a single-session HIV education condition ($n=35$), or a delayed HIV education control condition ($n=40$).

Intervention Methods

The social skills intervention was developed by the research team in collaboration with several young adult African-American women from the Bayview-Hunter's Point community. Intervention content was both theoretically and empirically based. Social cognitive theory (SCT) and the theory of gender and power were used as theoretical models to guide the development of the social skills intervention. According to SCT, participants need the appropriate information, social skills, and norms to avoid high-risk sexual behaviors.¹⁸

While current models of behavior change have provided useful guidance for understanding HIV risk-reduction practices, these models have failed to consider a host of contextual social factors that

shape the reality of risk and potential for risk-reduction among women.^{19,20} Therefore, we also used the theory of gender and power,²⁰ a social structural theory that examines the sexual division of labor, the sexual distribution of power and authority, affective influences, and gender-specified norms about what constitutes appropriate sexual conduct within heterosexual relationships, to guide intervention development. Applying this gender-specific theory to HIV prevention takes into account how a woman's lack of power, commitment to a relationship, and role in heterosexual relationships can affect her willingness to use sexual risk-reduction strategies. Additionally, the social skills intervention was based on the results of focus groups that explored the psychosocial and cultural influences on sexual decision making among young adult African-American women.²¹

Women in the social skills intervention received five 2-hour weekly group sessions implemented by two African-American women peer health educators.

The first session emphasized gender and ethnic pride. This was accomplished by discussing the positive attributes of being an African-American woman, identifying personal African-American women role models, and engaging in values clarification exercises.

The second session emphasized HIV risk-reduction information by increasing participants' knowledge about HIV-associated risk behaviors and preventive strategies. Participants viewed and discussed an HIV educational video that encouraged women to take responsibility for sexual decision making.

The third session emphasized sexual assertiveness and communication training. Participants were first taught how to differentiate assertive, passive, and aggressive communication styles. Participants were then taught assertiveness strategies to assist them in managing risky sexual situations, such as when having sex with a noncompliant partner or when a partner has been drinking. All exercises modeled by the peer health educators were role-played by participants in several practice situations with the peer health educators providing corrective feedback.

The fourth session emphasized enhancing proper condom use skills and fostering positive norms toward consistent condom use. Condom use demonstrations with phallic replicas were modeled by peer health educators and subsequently role-played by participants. Norm-setting exercises focused on reinforcing the perception of consistent condom use as normative.

The fifth session emphasized development of cognitive coping skills, such

as sexual self-control, through cognitive rehearsal.^{22,23} During cognitive rehearsal, the peer health educators would describe a sexual scenario, often with a noncompliant sexual partner, and the women would apply the newly learned assertiveness strategies to solve the problem.

Participants in the HIV education condition received a single 2-hour HIV risk-reduction information session similar to that provided in the social skills intervention.

Participants in the delayed HIV education control condition did not receive any HIV information until they completed follow-up interviews. At that time, they received gender-based and culturally appropriate HIV education.

Monitoring the Intervention

The monitoring procedure consisted of two elements: logging the number and type of sessions participants received and obtaining anonymous participant ratings assessing the value of each social skills intervention session. Participants attended a median of four social skills intervention sessions. At the end of each session, participants completed a 10-item scale. Each scale item was rated using a 10-point Likert response format ranging from 1 (little value) to 10 (very valuable). The mean scale score was 96.0. Participant ratings did not differ significantly across the five intervention sessions.

Main Outcome Measures

Measures included in the baseline and 3-month follow-up interview were selected based on their relevance to previously identified constructs associated with the adoption and maintenance of consistent condom use, from the results of focus groups conducted among women in the target population, and from the theoretical models underlying the social skills intervention.

HIV Risk Behavior Knowledge.—A knowledge score was developed by summing correct responses to six binary response (true-false) items, with higher scores indicative of greater HIV risk-reduction knowledge. "High" and "low" HIV knowledge categories were determined based on a median split of scale scores. Internal consistency for the scale was 0.65.

Sexual Self-Control.—Sexual self-control was measured by a single item: "If a condom is not handy, I will have sex anyway." Participants disagreeing with the statement were categorized as having high sexual self-control, those agreeing were categorized as having low sexual self-control.

Sexual Assertiveness.—Sexual assertiveness was measured by a single item:

"Have you ever demanded that your regular sex partner use a condom?" Participants answering yes to the statement were categorized as having high sexual assertiveness, those answering no were categorized as having low sexual assertiveness.

Sexual Communication.—Sexual communication was measured by a single item: "Have you ever asked your regular sex partner to use a condom?" Participants answering yes to the statement were categorized as having high sexual communication, those answering no were categorized as having low sexual communication.

Partner Norms.—Partner norms were measured using the Interpersonal Impact subscale of the Condom Attitude Scale.²⁴ Each item was scored using a 4-point Likert scale ranging from strongly disagree (1) to strongly agree (4), with higher scores indicating greater impact on sex partners' adoption of safer sex norms. High and low interpersonal impact categories were determined based on a median split of scale scores. Cronbach's α for the scale was .76.

Condom Use Skills Scale.—Condom use skills were measured by an 11-item scale that assessed participants' ability to use condoms during sexual intercourse. Each item was scored using a 5-point Likert-scale, with higher scores indicative of poorer skills in using condoms. High and low condom use skills categories were determined based on a median split of scale scores. Cronbach's α for the scale was .84.

Consistent Condom Use.—Consistent condom use, the primary outcome, was defined as use of a condom during every episode of vaginal intercourse. Consistent condom use was calculated by dividing the number of occasions condoms were used during vaginal intercourse by the total number of episodes of vaginal intercourse reported in the 3-month follow-up period.

Statistical Analyses

Analyses were performed only on pre-specified hypotheses using an intention-to-treat protocol in which participants were analyzed in their original randomized conditions regardless of number of sessions attended.²⁵ Baseline differences between the three treatment conditions for continuous variables were assessed using analysis of variance (ANOVA), and differences for categorical variables were assessed using contingency tables analyses.²⁶ Intervention effects were evaluated using logistic regression models adjusting for corresponding baseline outcome variables.²⁷ Logistic regression was used because of the dichotomous nature of several outcome variables and the

markedly skewed distribution underlying scale scores. Consistent condom use was the primary outcome variable. Secondary outcome variables included HIV knowledge, sexual self-control, sexual assertiveness and communication, partner norms, and condom use skills. The primary predictor variable was treatment condition. Variables identified at baseline that approached statistical significance ($P \leq .10$) between treatment conditions and were theoretically important potential confounders were included in logistic regression models as covariates.²⁸ Model statistics computed included adjusted odds ratios (ORs) and corresponding 95% confidence intervals (CIs) to assess the significance and magnitude of the association between the treatment conditions and outcome variables.

Sample Size Determination

Sample size calculations were conducted based on our previous research with this population identifying approximately 25% of women as consistent condom users over a 3-month period. We projected an effect size for women randomized to the social skills intervention that would be meaningful in terms of reducing the risk for HIV acquisition (OR, 2.0). Setting α at .05 using a one-tail test (with power=0.80) required 46 participants in each treatment condition to detect the specified effect size.

RESULTS

A total of 128 African-American women 18 through 29 years of age (mean, 23.2 years; SD, 3.8 years) completed baseline interviews. The equivalence of sociodemographic variables (age, education, income, children, residence, and relationship length), sexual behavior in the past 3 months (frequency of vaginal intercourse, number of sex partners, and sexually transmitted disease history), alcohol use prior to sexual intercourse, and outcome variables (HIV knowledge, sexual self-control, condom use skills, communication skills, assertiveness skills, partner norms supportive of safer sex, and consistent condom use in the past 3 months) across the three treatment conditions was assessed at baseline and at follow-up. At baseline, participants in the social skills intervention condition were significantly more likely to be in a long-term relationship; 44.8 months compared with 21.4 months for the HIV education condition and 32.7 months for the delayed HIV education control condition ($F[2, 76]=2.98$; $P=.06$). Differences were also observed between treatment conditions with respect to income, with a larger proportion of the delayed HIV education control condition participants reporting incomes less than \$400 per month (82.5%) compared

Table 1.—Evaluation of Program Effects on Knowledge of the Human Immunodeficiency Virus (HIV), Coping Skills, Interpersonal Skills, Partner Norms, and Consistent Condom Use at 3-Month Follow-Up for the Social Skills Intervention Compared With the Delayed HIV Education Control Condition

Variable	Social Skills Intervention Condition		Delayed HIV Education Condition*		Adjusted Odds Ratio†	95% Confidence Interval	P
	Baseline	3-mo Follow-up	Baseline	3-mo Follow-up‡			
HIV knowledge, %							
High HIV knowledge	41.7	56.6	26.1	40.0	1.4	0.82-2.36	.22
Cognitive coping skills, %							
High sexual self-control	60.4	61.2	52.2	41.7	1.9	1.00-3.60	.05
Interpersonal skills, %							
High communication skills	80.4	89.4	86.4	65.2	4.1	1.67-10.0	.002
High assertiveness skills	56.3	61.2	39.1	37.5	1.8	1.01-3.27	.05
High condom use skills	47.9	51.2	43.5	35.0	1.3	0.63-2.51	.52
Partner norms, %							
Perceived partner norms supportive of safer sex	33.3	53.1	38.1	25.0	2.1	1.08-3.87	.03
Condom use behavior, %							
Consistent condom use	35.4	46.9	21.7	29.2	2.1	1.03-4.15	.04

*Delayed HIV education control condition is the referent for calculation of odds ratios.

†Baseline and follow-up percentages are unadjusted by covariates.

‡Adjusted by corresponding baseline variable, length of current relationship, and income level.

with participants in the social skills intervention (71.7%) and HIV education condition (60.0%) (χ^2 [df=2]=4.68; $P=.10$). At follow-up, length of relationship and income remained different across treatment conditions. Therefore, relationship length and income level were entered as covariates in logistic regression analyses.

Of the 128 participants completing baseline interviews, 100 (78.1%) completed 3-month follow-up interviews. Follow-up rates differed by treatment condition, with 48 (90.6%) of the 53 participants in the social skills intervention, 29 (82.9%) of the 35 participants in the HIV education condition, and 23 (57.5%) of the 40 participants in the delayed HIV education control condition completing 3-month follow-up interviews (χ^2 [df=2]=15.2; $P<.001$). Unavailability for follow-up ($n=28$) was attributable to relocation outside the Bayview-Hunter's Point community ($n=23$), incarceration/drug rehabilitation ($n=3$), and refusal to complete the follow-up interview ($n=2$). Additional analyses assessing attrition bias identified no differences on baseline variables across treatment conditions for participants unavailable for follow-up.

Table 1 summarizes the results of logistic regression analyses examining changes in outcome variables for the social skills intervention compared with the delayed HIV education control condition. Participants in the social skills intervention demonstrated increased consistent condom use (adjusted OR, 2.1; 95% CI, 1.03 to 4.15; $P=.04$), greater sexual self-control (adjusted OR, 1.9; 95% CI, 1.00 to 3.6; $P=.05$), greater sexual communication (adjusted OR, 4.1; 95% CI, 1.67 to 10.01; $P=.002$), greater sexual assertiveness (adjusted OR, 1.8; 95% CI, 1.01 to 3.27; $P=.05$), and increased partners' adoption of norms supporting consistent condom use (ad-

justed OR, 2.1; 95% CI, 1.08 to 3.87; $P=.03$). Dose-response effects within the social skills intervention were difficult to assess because of the high participation rate, as 80% of women completed four or more of the intervention sessions.

No statistically significant differences in outcome variables were observed between the HIV education condition relative to the delayed HIV education control condition (Table 2).

COMMENT

This study is the first randomized controlled trial of a community-based HIV sexual risk-reduction intervention for economically disadvantaged young adult African-American women. Women's self-reports indicate that significant changes were made in theoretically important areas of HIV prevention; interpersonal skills, cognitive coping skills such as sexual self-control, partner norms, and, most importantly, consistent condom use. The inference that the increase in consistent condom use is attributable to the social skills intervention is strengthened by concomitant favorable changes in theoretically important HIV preventive skills and norms.

One methodological characteristic of the present study that differentiates it from other randomized controlled behavior change interventions designed to enhance condom use is the classification of the outcome variable. Consistent condom use was selected as the primary outcome measure based on findings from prospective studies indicating that condoms, when used consistently, can provide a 70% to 100% reduction in the risk of HIV transmission.⁶ In particular, the most recent findings, from the European Study Group on Heterosexual Transmission of HIV,¹⁰ observed no seroconversions among couples who used condoms

consistently, while the seroconversion rate among inconsistent condom users was significantly higher (4.8 per 100 person-years). Moreover, predictions based on mathematical modeling suggest that, irrespective of the number of sexual partners and the prevalence of HIV among potential sex partners, consistent condom use can substantially reduce the risk of sexually transmitted HIV infection relative to no or half-time condom use.²⁸ Thus, as empirical evidence supports the clinical and public health significance of consistent condom use for preventing HIV infection, future behavior change interventions should assess consistent condom use as a primary outcome measure for evaluating program efficacy.

The effectiveness of this intervention may be attributed, in large part, to the focus on gender relations in which HIV sexual risk behaviors occur. In managing safer sex, women have to exercise influence over themselves as well as their sexual partners.¹⁸ However, few HIV prevention interventions have been based on theoretical models that address gender relations.^{16,19} The theory of gender and power, a gender-appropriate model useful for understanding relationship dynamics, provided a framework for developing and implementing the social skills intervention. In particular, the social skills intervention addressed how to successfully negotiate safer sex and foster favorable partner norms supportive of consistent condom use within the context of a heterosexual relationship where women are often in unequal positions of power relative to men.

This intervention's effectiveness may also have been the result of using African-American women peer health educators to implement the HIV social skills intervention. Peer health educators were used to implement the social skills in-

Table 2.—Evaluation of Program Effects on Knowledge of the Human Immunodeficiency Virus (HIV), Coping Skills, Interpersonal Skills, Partner Norms, and Consistent Condom Use at 3-Month Follow-up for the HIV Education Only Treatment Condition Compared With the Delayed HIV Education Control Condition

Variable	HIV Education Condition		Delayed HIV Education Condition*		Adjusted Odds Ratio†	95% Confidence Interval	P
	Baseline	3-mo Follow-up	Baseline	3-mo Follow-up‡			
HIV knowledge, %							
High HIV knowledge	48.3	48.6	26.1	40.0	0.9	0.54-1.76	.94
Cognitive coping skills, %							
High sexual self-control	55.2	48.3	52.2	41.7	0.9	0.42-1.74	.67
Interpersonal skills, %							
High communication skills	75.0	62.1	66.4	65.2	0.5	0.25-1.13	.10
High assertiveness skills	51.7	44.8	39.1	37.5	0.8	0.43-1.61	.58
High condom use skills	55.2	46.2	43.5	35.0	1.5	0.66-3.52	.28
Partner norms, %							
Perceived partner norms supportive of safer sex	39.3	48.3	38.1	25.0	1.1	0.56-2.28	.73
Condom use behavior, %							
Consistent condom use	20.7	37.9	21.7	29.2	1.1	0.55-2.40	.71

*Delayed HIV education control condition is the referent for calculation of odds ratios.

†Baseline and follow-up percentages are unadjusted by covariates.

‡Adjusted by corresponding baseline variable, length of current relationship, and income level.

intervention because they are perceived as a credible source of information, communicate in a manner that is easily understood, and serve as positive role models. Peer health educators are also more effective at facilitating the acquisition of social skills through modeling exercises that emphasized skills mastery, such as sexual communication and assertiveness, and fostering perceptions of consistent condom use as normative.

While demonstrating that young adult women can be taught skills to encourage their sex partners' consistent use of condoms and that several theoretically important mediators associated with the adoption of this HIV prevention strategy can be enhanced, no differences were observed for two other important mediators (condom use skills and HIV risk-reduction knowledge). Condom use skills may take longer for women to acquire and to feel confident in using. With respect to HIV risk-reduction knowledge, both the social skills intervention and the delayed HIV education control condition demonstrated high baseline HIV knowledge scores, suggesting that efforts to disseminate HIV information have been effective. Although differences were observed between the social skills intervention and delayed HIV education control condition, achieving statistical significance was difficult because of a ceiling effect.

A subsidiary analysis evaluating the efficacy of the HIV education condition relative to the delayed HIV education control condition identified no statistically significant differences in consistent condom use or theoretically important mediators of HIV preventive behavior. These findings corroborate previous research that suggests that providing HIV risk-reduction information, in and of itself, is not sufficient to motivate the adoption of preventive behaviors.⁴ In general, inter-

ventions that are theory driven, emphasize intrapersonal and interpersonal factors, provide skills training, and attempt to modify social norms have been more effective at promoting use of HIV prevention behaviors.²⁹⁻³¹

The present study is not without limitations. The external validity of the findings may be affected by the unavailability of participants for follow-up. However, neither participants unavailable for follow-up nor those remaining in the study cohort differed across treatment conditions on sociodemographic, psychosocial, or behavioral variables. This suggests that the study findings may be generalized to low socioeconomic, young adult African-American women residing in urban environments. However, the findings may not be applicable to African-American women with different sociodemographic or behavioral risk profiles, for example, women who are injection drug users. Evaluating this intervention with African-American women with different risk profiles may help establish its generalizability across risk groups.

One potential limitation is the lack of a placebo attention control condition. It is plausible that at least part of the observed intervention effect is attributable to the nonspecific special attention received by women assigned to the social skills intervention. Future interventions should include a placebo attention group in the study design to control for the effects of differential attention as a result of treatment assignment.

A further methodological concern is the reliability of self-reported outcome measures, particularly condom use. Since direct observation of sexual behavior is impractical, HIV prevention interventions have typically relied on participants' self-reports. Recent findings suggest that self-reported sexual behavior among African-

American women may be reliable. Young adult African-American women attending family planning clinics reported 2-month test-retest reliability for a variety of sexual behaviors, including condom use, as relatively high, ranging from 0.80 to 0.98.³² Similarly, findings from a study of predominantly African-American couples attending an inner-city sexually transmitted disease clinic indicate that women's self-reports of condom use were highly correlated with their sexual partners' reports of condom use.³³ However, as a method of validating self-reported condom use, future studies may consider monitoring biological changes that can be measured objectively, such as incident sexually transmitted diseases and pregnancy, that are specific for the occurrence of unprotected sexual intercourse.

An additional methodological concern is the limited sample size. In most randomized clinical trials of limited size there is often some imbalance, even when stratifying for primary variables. In the present study, women in the social skills intervention reported being in longer relationships and having higher income levels. Though the analyses were adjusted for these variables, it is conceivable that statistical adjustment may not adequately control for these variables. Thus, the favorable treatment effects observed could be explained by these differences. However, the longer duration of relationships for women in the social skills intervention condition may mitigate against identifying a significant intervention effect. Recent findings from the present study and other studies indicate that length of relationship is inversely related to condom use. Specifically, the longer a woman is in a relationship, the less likely her partner is to use condoms and the more difficult it is to change condom use behavior.³⁴ Differences in income level between the so-

cial skills intervention and the delayed-HIV education control group, though less pronounced, conceivably could affect differences in treatment effects. Further studies may need to enroll larger samples sizes to assure equivalence across treatment conditions.

Finally, while not specifically a methodological limitation, the length of the study follow-up period (3 months), while useful for reducing attrition and obtaining more reliable self-report information,³⁵ limits inferences regarding maintenance of treatment effects. Long-term follow-up is essential since newly adopted HIV preventive behaviors must be enduring if they are to be meaningful. However, the high relocation rate observed in this study poses a formidable methodological obstacle to conducting long-term follow-up assessment.³⁶

CONCLUSION

Human immunodeficiency sexual risk-reduction interventions have been evaluated for a variety of populations^{15,37};

however, only a few studies have focused exclusively on women.³⁸⁻⁴¹ Of the studies evaluating changes in condom use, both are clinic based.^{42,43} Clinic-based studies may have limited relevance for women not seeking clinical services.

The present study represents the first evaluation of an intervention designed to increase consistent condom use among a community-recruited sample of women. The findings suggest that a culturally appropriate, gender-tailored intervention that emphasizes social skills training and attempts to modify partner norms may be effective at enhancing consistent condom use and psychosocial mediators associated with this HIV preventive behavior.

In the absence of an effective prophylactic vaccine or cure, interventions designed to enhance the use of HIV prevention behaviors are needed to avert further escalation of new infections, particularly among African-American women at high risk for sexually acquired HIV infection. Given the epidemiological significance of consistent condom use as an

effective strategy in preventing HIV infection, relative to any use of condoms during sexual intercourse,^{6,28} interventions that emphasize and assess the adoption of consistent condom use may have a greater public health impact on reducing HIV incidence. Ultimately, however, controlling the HIV epidemic among inner-city women is dependent not only on the development and evaluation of gender-tailored prevention interventions but also on how effectively these interventions can be translated into existing community prevention activities and how rapidly they can be disseminated to high-risk urban centers.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 9, 1995

Note to: The Secretary

This note is to provide you with background on selected FDA issues and activities.

NEW ITEMS

1. Biotechnology Announcement - Today at 1:30 p.m., Vice-President Gore announced the Administration's changes in the drug approval process for most biotechnology drugs. The changes will cut drug development times by months and save companies millions of dollars. Among other things, FDA will implement the following changes relating to biotech drugs: eliminate the existing requirement that manufacturing facilities be separately licensed; eliminate the existing policy whereby individual lots of products are evaluated and released after the drugs have been approved; replace with one form the 21 different approval application forms for biotech drugs, blood, vaccines, and other drugs; eliminate the requirement that promotional labeling be approved prior to the marketing of a biologic; and permit a corporation to designate more than one person to act as a "responsible head" in dealings with the Agency.

The Vice President also announced the release of a report by the National Science and Technology Council, entitled "Biotechnology for the 21st Century: New Horizons," which describes the Federal investment in biotechnology and identifies research priorities and opportunities for the future.

2. Two New AIDS Drugs Recommended for Accelerated Approval - On November 6 and 7, 1995, FDA's Antiviral Drugs Advisory Committee recommended accelerated approval for Glaxo Wellcome's Efavir® or 3TC (for use in combination with AZT) and Hoffmann-LaRoche's Invirase®. Accelerated approval is a mechanism by which FDA expedites marketing of promising new therapies for serious and life-threatening diseases based on improvement in laboratory measures, rather than on clinical endpoints such as increased survival. In these two cases, the primary measure of improvement was the CD4 cell count (a reflection of immune system strength).

3TC belongs to the same class of drugs as AZT, but in combination with AZT, shows immune system improvement over

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AZT used alone. Invirase® is the first "protease inhibitor" to be brought to an FDA advisory panel. Protease inhibitors are a promising new class of anti-AIDS drugs that block an enzyme necessary for HIV to reproduce and, in essence, "stall" the virus. Although there are a number of protease inhibitors under development, none has yet been approved for marketing in the U.S. or elsewhere. Following advisory committee recommendations, FDA works with the sponsor to finalize labeling and ensure availability of the drug, sometimes granting approval within weeks of a recommendation.

On November 8, 1995, the advisory committee reviewed the results of post-marketing trials required as part of a June 1994 accelerated approval of Bristol-Myers Squibb's Zerit®, also known as d4T. The committee concluded that these trials confirm that the drug does provide clinical evidence of effectiveness. Committee members did recommend, however, that the labeled indication be limited to patients who had been on prolonged prior use of AZT. Zerit® has been available since 1992 under FDA's expanded access program.

3. Bottled Water - On Monday, November 13, 1995, FDA will publish in the Federal Register final regulations on bottled water that will promote honesty and fair dealing in the marketplace by providing standard definitions for the terms "artesian water," "ground water," "mineral water," "purified water," "sparkling bottled water," "spring water," and "well water." The regulations would also bring mineral water under existing quality standards for bottled water. In addition, the regulation addresses various other labeling concerns. For example, water bottled from municipal water supplies must clearly be labeled as such unless it is processed sufficiently to be labeled as "distilled" or "purified" water. Bottled water marketed for infants are also addressed by labeling requirements. Products labeled as "sterile" must meet FDA's requirements for commercial sterility. The rules were originally published in January 1993. The new rule will become effective in mid-May 1996.
4. Identity Standard for Milk Products - In today's Federal Register, FDA is proposing to remove the standards of identity for sweetened condensed skimmed milk, lowfat milk, skim or nonfat milk, sour half-and-half, lowfat and nonfat yogurt, and lowfat cottage cheese. The action is based in part on petitions filed jointly by the Milk Industry Foundation and the Center for Science in the Public Interest. The Agency is also proposing to remove the standards of identity for evaporated skimmed milk and lowfat dry milk, based on a petition filed by the American Dairy products Institute.

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Removal of these food standards would permit the products covered by these regulations to be manufactured and labeled in accordance with the general definition and standard of identity in the regulations for foods named by use of a nutrient content claim and a standardized term. These products would then be named in a manner that is consistent with FDA's definition of the terms "lowfat" and "nonfat" established pursuant to the Nutrition Labeling and Education Act of 1990.

5. Reconstruction Products Made from Living Cells - On November 16 and 17, 1995, FDA will hold a hearing to gather information on an emerging field of tissue repair products. Autologous (self) cell products involve a system whereby a patient's own cells are grown in tissue culture. The tissues are then implanted in the patient's body to aid in repair or reconstruction. Autologous systems may help prevent implant rejection by the body's immune system. Examples are cartilage used to repair defects in the knee and skin used for burns and wound healing. FDA has been working closely with health professionals, industry, and other interested groups to develop appropriate measures to ensure quality control and patient protection without over regulating these important new therapies.

ADVISORY COMMITTEES

6. Biological Response Modifiers - The Biological Response Modifiers Advisory Committee will meet on November 13, 1995, to discuss product license application supplements for GM-CSF (granulocyte-macrophage colony stimulating factor) and G-CSF. Both supplements are for peripheral blood stem cell mobilization for transplantation in the reconstitution of bone marrow following chemotherapy. GM-CSF is made by Immunex Corporation, and G-CSF is made by Amgen, Inc.
7. Food - The Food Advisory Committee and Working Groups will meet November 14-17, 1995, to discuss a safety review of the fat substitute olestra, which would be used in savory snacks such as potato chips. The review will cover nutrient effects, gastrointestinal tract effects, and labeling. The committee will also discuss adverse events associated with the consumption of food products containing a source of ephedrine alkaloids, including ephedrine, pseudoephedrine, and norpseudoephedrine from Ephedra sinica and other related species (e.g., Ma huang and Chinese ephedra).
8. Pulmonary-Allergy Drugs - The Pulmonary-Allergy Drugs Advisory Committee will meet on November 17, 1995, to be briefed on the Pediatric Labeling Rule and the data necessary to support pediatric labeling of drugs. The

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committee will also discuss an NDA for Astelin nasal spray (azelastine, Carter-Wallace, Inc.) for seasonal allergic rhinitis.



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AIDS Daily Summary

August 9, 1995

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"Vitamin A and Infants with H.I.V."

"Robbers with AIDS Evade Jail in Italy"

"Across the USA: Tennessee"

"Show of Support"

"Rock for Research"

"Blocked in U.S., AIDS Kit Goes Overseas"

"Eastern Arctic Puzzle: Why HIV Is Still So Rare"

"Fighting AIDS, Getty 'Not Afraid of Death'"

"Justices Ask Clinton Administration's View of AZT Patent Issue"

"Agen Biomedical to Make AIDS Test Kits in China"

"Vitamin A and Infants with H.I.V."

New York Times (08/09/95) P. C8

A new study by researchers at Natal University in South Africa indicates that vitamin A could be a low-cost way to reduce some of the illnesses that HIV-infected babies contract. The study,

published in The American Journal of Public Health, found that moderately large doses of vitamin A helped infants fight off AIDS-related illnesses, particularly dangerous diarrhea. A total of 118 babies born to HIV-infected women were given either vitamin A or placebos. Regardless of HIV status, all the children who received supplementation had fewer illnesses. Among HIV-infected infants, the vitamin supplements reduced diarrhea cases by nearly 50 percent, and reduced diarrhea cases that last more than one week by 56 percent. In addition, diarrhea-related hospital stays were more than 75 percent shorter among the HIV-positive babies who received vitamin A. Anna Coutoudis, an author of the study, noted that the study followed the infants for just 18 months, so it could not be determined whether vitamin A helped them live longer.

"Robbers with AIDS Evade Jail in Italy"

New York Times (08/09/95) P. A9

In Turin, Italy, a group of robbers--called the "AIDS gang" by newspapers--has been released again after their fourth bank hold-up in three weeks. The members, who are secure in the knowledge that they will not be imprisoned because they have AIDS, rob the banks in full view of security cameras and without covering their faces. "They know they can't be imprisoned, so they take no precautions to hide their identities," a police spokesman said. Under Italian law, full-blown AIDS patients cannot be jailed. In the most recent robbery, the "AIDS gang" stole \$12,000 and hid the money prior to their arrest.

"Across the USA: Tennessee"

USA Today (08/09/95) P. 5A

An HIV-infected man in Gallatin, Tenn., may go to prison for spitting in a police officer's face. Ronnie Todd was charged under a 1994 Tennessee law that makes it illegal to expose another person to AIDS.

"Show of Support"

USA Today (08/09/95) P. 3D; Zimmerman, David

Radio personality Chuck "Hoss" Burns this week became the first well-known person in the country-music industry to reveal that he has AIDS. Country music stars were quick to offer Burns their support. "Garth [Brooks]'s people were the first to call," said Nashville's WSIX-FM general manager John King, after the station announced it will hold a day-long radiothon next week to support Burns and to raise money for the pediatric AIDS unit of St. Jude Children's Hospital. Burns, who tested HIV-positive 10 years ago, said he made the announcement because he had "told my friends, told my family, told my work, and told my mother. It was time to tell everybody else." Although he is leaving the station, Burns will continue to host the weekly radio show "Country Hitmakers," which boasts more than 2 million listeners.

"Rock for Research"

USA Today (08/09/95) P. 4D; Peterson, Karen S.; Hellmich, Nanci

This week's 13th Annual Rock 'N Roll Charity Celebration in Los Angeles will benefit research funds for AIDS, cancer, and other diseases. The three-day affair--to which such stars as Glenn Frey, Little Richard, and Luke Perry are expected to attend--includes a silent auction, golf tournament, and bowling. Proceeds of the fundraiser will go to the T.J. Martell Foundation and the Neil Bogart Memorial Fund, which finance research for

cancer, AIDS, and leukemia.

"Blocked in U.S., AIDS Kit Goes Overseas"

St. Louis Post-Dispatch (08/07/95) P. 1E; Nolin, Robert

According to Dr. Joseph D'Angelo, the U.S. Food and Drug Administration (FDA) is too strict when it comes to over-the-counter home test kits. The Miami physician has developed a saliva-based HIV test kit that costs \$9.23, compared to professionally administered ones that can cost as much as \$200. D'Angelo is marketing the Ana-Sal kit to foreign governments because the FDA makes "it very difficult to do something like this." San Francisco's E.Y. Laboratories tested the product and found that in two out of 10 cases, Ana-Sal was more accurate than standard blood tests. A study at Jackson Memorial Hospital in Miami confirmed the validity of the process for detecting HIV. A major problem for the kit, however, is its lack of counseling. U.S. public health policy dictates that a person being tested for HIV must be counseled before and after the screening by a trained practitioner. The kit only includes a paragraph telling those who test HIV-positive to obtain a confirmatory test and medical treatment.

"Eastern Arctic Puzzle: Why HIV Is Still So Rare"

Toronto Globe and Mail (08/07/95) P. A1; Feschuk, Scott

Although Broughton Island in Canada's Northwest Territory has a population of just 530, the health center's nurse says that not one month has gone by in five years in which a youth has not tested positive for a sexually transmitted disease. Infection rates in the region are as many as seven times higher than in Canada's southern communities. No one on Broughton Island, however, has been infected with HIV, says nurse Theresa Joseph. To explain the lack of HIV in the Eastern Arctic region, some health workers have suggested that the resident Inuit population may have a kind of physiological factor that reduces their chances of becoming infected, although there is no scientific proof of this. Others argue that HIV may be much more prevalent than is currently thought. It is also possible that some Inuit who doubt the true anonymity of HIV testing in their closely-knit community have gone to southern cities for testing, and that their statistics would be reflected there. The majority of health care professionals, however, believe that it is just luck that has guarded the region against AIDS--luck that is bound to come to an end in the face of data that reflects a very sexually active population.

"Fighting AIDS, Getty 'Not Afraid of Death'"

USA Today (08/08/95) P. 2D

Aileen Getty--granddaughter of J. Paul Getty--says that after living with HIV for a decade and AIDS for six years, she believes she is prepared to die. In the September issue of Ladies' Home Journal, Getty states, "When I'm no longer capable of giving my children anything more, I intend to take my own life. I'm not afraid of death." The former daughter-in-law of actress Elizabeth Taylor says she became infected with HIV in 1985 "through unprotected sex during a brief, reckless affair." According to Getty, the man lied about his HIV status when he knew he was infected.

"Justices Ask Clinton Administration's View of AZT Patent Issue"

American Medical News (07/31/95) Vol. 38, No. 28, P. 8

The Supreme Court has asked lawyers from the Justice Department to comment on an appeal by two generic-drug makers from a ruling that found Burroughs Wellcome Co. entitled to five patents for AZT. The two companies said that Burroughs should not receive exclusive patents because some of the testing was performed at the National Institutes of Health (NIH). Burroughs, which received six patents after NIH found AZT to be effective against HIV, sued Barr Laboratories and Novopharm for alleged patent infringement after each company sought permission to sell generic forms of the drug. Barr said that two NIH researchers should be added to the patent. The manufacturing of a generic product would then be possible because NIH awarded the company nonexclusive rights to do so. Novopharm, however, claimed that the patents were not valid because the NIH researchers were not named. After a series of appeals, attorneys for the two companies said that an invention must demonstrate its effectiveness before it can become eligible for a patent. The NIH scientists, therefore, would be entitled to share the patent.

"Agen Biomedical to Make AIDS Test Kits in China"

Nikkei Weekly (07/24/95) Vol. 33, No. 1681, P. 20

Australian medical-testing equipment producer Agen Biomedical Ltd. will establish a joint venture in Beijing to produce and market an HIV test kit that can provide results in a half an hour. According to sources, the company will provide the necessary clinical data and production technology for the kit. Agen, which will be joined by partners Beijing Hua Yi Biotechnology Co. and Diagnotech Co., will have a 25 percent interest in the endeavor.

[209] From: GREG_FOLKERS (NIH.GREGFOLK) at SOFTSWITCH 8/25/95 1:21PM (10464 bytes: 185 ln)

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Subject: 8/25/95 AIDS Daily Summary

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Subject: 8/25/95 AIDS Daily Summary

AIDS Daily Summary

August 25, 1995

The Centers for Disease Control and Prevention (CDC) National AIDS Clearinghouse makes available the following information as a public service only. Providing this information does not constitute endorsement by the CDC, the CDC Clearinghouse, or any other organization. Reproduction of this text is encouraged; however, copies may not be sold, and the CDC Clearinghouse should be cited as the source of this information.

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"Treating STDs and Reducing AIDS Risk"

"Ex-Convict Fights Time to Clear Name"

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"Treating STDs and Reducing AIDS Risk"

Washington Post (08/25/95) P. A8

Researchers working in Tanzania report that treating individuals for sexually transmitted diseases (STDs) such as gonorrhea significantly reduces their risk of becoming infected with HIV. Villagers who were treated for STDs were approximately 40 percent

less likely to contract HIV than villagers whose STDs were not treated, the physicians report in the current issue of The Lancet. Professor David Mabey of the London School of Hygiene and Tropical Medicine noted that because they were not using the most effective drugs, "there might have been an even bigger effect if we had." Mabey warned, however, that the \$7.50 to \$15 cost per treatment could exclude many countries if aid agencies did not help out.

"Ex-Convict Fights Time to Clear Name"

Miami Herald (08/24/95) P. 2B; Greene, Ronnie

Twelve years ago, after three trials, a jury found Christopher Clugston guilty of murder, and he was sentenced to life in prison. Last year, however, Fla. Gov. Lawton Chiles commuted Clugston's sentence, noting the inconsistent statements of an eyewitness, the recantations by Clugston's co-defendant and that person's wife, and no physical evidence linking him to the murder, among other factors. However, Clugston remains a convicted felon, unable to enter the state of Florida without the express permission of the clemency board. Clugston, who is HIV-positive, is now trying to clear his name. Coughing frequently, he recently told reporters that he contracted the virus when other inmates gang-raped him at the Union Correctional Institution in Raiford. Clugston explained that he just wants to have his good name back, to own a cabin in the woods, and to take walks with his dog.

"Procept Begins Phase I/II Clinical Trial for PRO 2000 in HIV-Positive Patients; Company-Sponsored Trial Will Evaluate Activity of Lead HIV Therapeutic"

Business Wire (08/24/95)

Procept, Inc. has launched a Phase I/II clinical trial for its drug PRO 2000, a potential treatment for HIV-1 infection which specifically targets the CD4 protein on the surface of the human cell. The dose-escalating trial will assess the safety, tolerability, and antiviral activity of PRO 2000. In vitro preclinical studies indicate that the drug blocked the binding of the glycoprotein gp120, which is found on HIV-1's surface, to the CD4 protein. Procept theorizes that PRO 2000 may act as a molecular barrier to keep HIV from infecting vital immune system cells, such as T cells and macrophages.

"French Holidaymakers Take to Carrying Condoms"

Reuters (08/24/95)

A new survey reveals that one in four French holidaymakers always carries a condom for fear of contracting HIV from casual sex. "Fear has not killed off love on holidays," the weekly Paris Match said regarding the poll that it published. This year's total is more than two times the number found in a similar poll four years ago. The most likely vacationers to have condoms were between the ages of 18 and 24, with more than 40 percent always having one, compared to 23 percent in 1991. A total of 83 percent of the women polled said they required one-time sexual partners to use a condom, up from 62 percent four years ago. Despite an aggressive information campaign about the risks of AIDS and HIV, France has the greatest number of AIDS cases in Europe. Paris authorities have hung posters across the city telling tourists in a number of languages how to ask for a box of condoms in French.

"Interferon Sciences Completes Public Offering"
Business Wire (08/24/95)

Interferon Sciences Inc. has sold 10,706,480 shares of common stock for more than \$12.8 million, excluding expenses and fees. The sales were made pursuant to a best efforts public offering of between 6,500,000 and 12,000,000 shares of common stock at \$1.20 per share. The remaining shares may be purchased until the offering ends on Sept. 13. The biopharmaceutical company is involved in the manufacture and sale of ALFERON N Injection, which is approved for the treatment of certain kinds of genital warts and is being developed for the possible treatment of HIV and hepatitis C.

"Should the FDA Approve the Home HIV Test?"

Health (09/95) Vol. 9, No. 5, P. 20; Bayer, Ronald; Portelli, Christopher

The U.S. Food and Drug Administration (FDA) is deliberating approval of a home HIV test, in which people would draw a sample of blood from a finger, send it to a laboratory for analysis, and then call in about a week later for the results. Columbia University professor Ronald Bayer feels that the FDA should approve the test. He argues that because nearly "60 percent of those at high risk for HIV have not been tested,...the home kit is our best alternative." Bayer acknowledges that the opportunity for in-person counseling is lost with the home test, but he reasons that not everyone receives extensive counseling anyway. Christopher Portelli of the National Lesbian and Gay Health Association counters that home HIV test kits should not receive FDA approval because it is not a good idea for anyone to receive their HIV status over the phone. Even if the person tests negative, he "could hang up before hearing how to avoid HIV." Although Bayer claims that low-income, high-risk individuals would use the test, Portelli says the \$30-\$40 price tag is geared toward middle- and upper-class, low-risk persons. He concludes that selling the test to persons of all ages, such as teenagers, is "irresponsible," although Bayer contends that "if you're old enough to have sex, you're old enough to know your HIV status."

"Guidelines for Management of HIV Infection with Computer-Based Patient's Record"

Lancet (08/05/95) Vol. 346, No. 8971, P. 341; Safran, Charles; Rind, David M.; Davis, Roger B. et al.

Safran et al. studied more than 100 physicians and nurse practitioners to determine the efficacy of electronic medical records when used for HIV patients. The scientists examined the clinicians' response times to the situations that caused alerts and reminders, the number of ambulatory visits, and hospitalization. They found that the average response time to the 388 alerts in the control group was 52 days, while the intervention group's median response time to 303 alerts was 11 days. The average response times to 432 reminders in the intervention group and 360 reminders in the control group were 114 days and more than 500 days, respectively. Although the system had no effect or difference on visits to the primary care practice; admission rates; admissions for pneumocystosis; visits to the emergency room; or survival, there was a dramatic increase in the number of visits outside of the primary care practice--which is due to an increased rate of ophthalmology visits. Overall, the researchers concluded that computer medical

records helped clinicians treating HIV patients adopt new practice guidelines more rapidly and more thoroughly.

"Depression in Low HIV Prevalence Areas"

Focus (08/95) Vol. 10, No. 9, P. 8

A new study by Perkins et al. reveals that serious depression is common among both seronegative and asymptomatic homosexual men in a region of low HIV prevalence. The researchers in the Coping in Health and Illness Project in North Carolina found that 8 percent of the HIV-infected subjects experienced major depression at the time of the study, while 3 percent of the uninfected subjects were depressed. The overall lifetime prevalence of such depression was 29 percent for the infected group and 45 percent for the uninfected group. In addition, there was a 2 percent prevalence of major depression in the general population, with a lifetime total of 3 percent.

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Subject: AIDS Treatment News #234

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AIDS TREATMENT NEWS #234, November 3, 1995

phone 800/TREAT-1-2, or 415/255-0588

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***** Project Inform's THE HIV DRUG BOOK Now Available

THE HIV DRUG BOOK, a well-organized guide to what patients should know about the major drugs used to treat HIV and opportunistic infections, has just been published and is now reaching bookstores. We believe that everyone interested in AIDS treatment should have a copy of this important reference, published by Pocket Books at a cost of only \$16 for the 688-page book. The contents have been reviewed by an advisory board of eleven well-know HIV physicians.

Most of the book consists of drug profiles; the profiles are listed alphabetically, within the following categories: Antibiotics; Anticancer drugs; Antidiarrheal drugs; Antifungal drugs; Antihistamines; Antinausea/Antivomiting drugs; Antiprotozoal drugs; Antiseizure drugs; Antiulcer drugs; Antiviral drugs; Antiwasting treatments; Corticosteroids; Immune-based therapy; Neuropathy drugs; Pain relievers; Psychoactive drugs; Vaccines, and Miscellaneous drugs. All the drug profiles are organized in the same way, with the following sections always in the same order: Brand names/Manufacturers; Type of drug; Used for; General information; Treatment; Cautions and warnings; Side effects; Pregnancy/Breast feeding; Use in children; Use in the elderly; Drug interactions; Food interactions; and Other drugs used for similar conditions. In addition, each drug class has a short overview of the class as a whole.

A number of experimental drugs are described, usually without full profiles but in a separate annotated list at the end of the section for their drug class.

The book also includes an introduction by Martin Delaney, a preface by Donald Abrams, M.D., a forward by Joel Thomas, a glossary, and various practical articles -- from nutrition, to alternative treatments, to managing opportunistic infections, to communicating with your physician, to understanding clinical trials, to avoiding AIDS fraud and exploitation. There is also an extensive resource guide, including national hotlines, a state-by-state and city-by-city listing of major AIDS service organizations, Canadian resources, national AIDS publications, mail order pharmacies, buyers' clubs, state AIDS drug assistance programs (ADAP), and pharmaceutical company payment assistance programs. A 16-page drug identification guide provides color photographs of the various drug preparations available, and an extensive drug interaction chart warns of known problems of using certain drugs together.

***** Thalidomide for Wasting Syndrome: Progress Toward

Compromise

by John S. James

The outline of a compromise to an intense dispute about access to thalidomide as a potential treatment for wasting syndrome -- a dispute that could have led to FDA raids on the largest AIDS buyers' clubs -- appears to have been reached at an October 24 meeting of the buyers' clubs, thalidomide developer Celgene Corporation, and the FDA. Under this compromise, physicians will be able to choose a dose of 50, 100, or 200 mg per day (the most common dose has been 100 mg), under an open-label safety study; patients will have to pay for the drug, with the price not yet worked out. (An earlier plan, which would have had patients pay for the drug without controlling which dose they got, raised concerns that it would set a dangerous precedent of allowing companies to charge volunteers for entering a randomized clinical trial.)

The buyers' clubs -- the PWA Health Group in New York, and Healing Alternatives in San Francisco -- have worked for over two years so that people with AIDS-related wasting could get thalidomide under some form of official compassionate-access system. When the drug remained unavailable outside of a restrictive clinical trial, they organized a special Thalidomide Underground Compassionate Use Program, in order to force the creation of an official program. This goal now seems to have been reached. When the new open-label safety protocol is functioning, the underground program will end.

Background: Wasting Syndrome

Wasting syndrome -- extreme loss of lean body mass -- kills many people with AIDS. It has many different causes, and there is no single treatment for everyone. The first step in prevention or treatment is diagnosis and correction of a specific cause, such as an intestinal infection, or an obstacle to sufficient food intake. Nutritional and life-style counseling can also be important, especially for early intervention and prevention. But there are many cases that do not respond to these approaches.

The FDA has approved treatments for wasting syndrome: megestrol acetate (Megace(TM)), and dronabinol (Marinol(TM), which uses the active ingredient of marijuana to stimulate appetite). For some people these are helpful; for others they are not. Both are expensive. Smoked marijuana appears to work better than the dronabinol pills for some people (for others, the pills are better), but marijuana is illegal. TPN (total parenteral nutrition, a very expensive intravenous feeding) can help in certain specific cases. Other possibilities are mentioned below.

When other treatments have failed, some of the best results

seem to have come from human growth hormone -- a very expensive prescription drug which has been FDA-approved in the U.S. for years for treating short stature in children, but has been tightly controlled to prevent abuse by athletes. Human growth hormone is now available to treat wasting syndrome in certain cases under a "treatment IND" -- a special FDA program which is intended to allow compassionate use of a drug when urgently needed by a group of patients, and which can allow companies to charge for "cost recovery" in supplying these drugs. The problem is that human growth hormone costs about \$1,000 per week under the treatment IND, and will probably need to be used indefinitely. Some people can get coverage under insurance, Medi-Cal in California, or an indigent-patient program.

The prescription versions of this drug are even more expensive. Incidentally, a similar hormone for cattle costs over a thousand times less. It cannot be used by people; we mention it to show that investigation is needed into how the price of human growth hormone has stayed so uniformly high for so long all over the world, despite the fact this drug is manufactured by a number of different and supposedly competing companies, and manufacturing cost is apparently not an issue. There are patents, but they have not effectively provided a monopoly; something other than the patents must be keeping the price very high.

Because no single treatment for wasting syndrome works for everyone, and because several of the major treatments are economically out of reach for most people, there is urgent interest in low-cost options. The main ones now being examined are (1) anabolic steroids and/or testosterone, and (2) thalidomide. [In addition, thalidomide might also have other uses in AIDS; see "Thalidomide and Kaposi's Sarcoma -- Call for Information," below.]

Background: The Thalidomide Controversy

For some time thalidomide has been available through an FDA-approved program for compassionate use in treating certain AIDS-related aphthous ulcers which have not responded to other therapies. Until recently this program was not open to persons with wasting syndrome. Such persons had no way to get thalidomide in the U.S., despite a small placebo-controlled trial in which eight of nine patients with AIDS-related wasting gained weight when treated with thalidomide, vs. only two of nine in the placebo group, a statistically significant difference. (1) Another placebo-controlled study reported statistically significant weight gain with thalidomide treatment in tuberculosis patients, many of whom also had HIV. (2) There have also been anecdotal reports of weight gain in persons with AIDS-related wasting.

AIDS buyers' clubs, after much thought and investigation,

responded and obtained thalidomide for persons with wasting syndrome. (Thalidomide has long been used in Brazil and other countries -- including the U.S. -- in the treatment of leprosy.) The FDA was upset, and sent the clubs increasingly threatening demands that they stop supplying the drug. The buyers' clubs have made it clear that they are willing to do so -- but not until there is an FDA-approved program which is effectively supplying the drug to the people who desperately need it.

The reason for the FDA's concern, of course, is that thalidomide can cause birth defects if taken by pregnant women. About 35 years ago, before this was known, thalidomide caused thousands of deformities in Europe, where it was prescribed for morning sickness. In the U.S., this disaster was prevented because the FDA had fortunately not approved thalidomide due to other safety concerns. This U.S. disaster which was averted by the FDA became a proud, defining historical moment for the organization.

What is happening now is that the FDA is temporarily accepting persons with AIDS-related wasting into its small compassionate-use program for persons with aphthous ulcers. This will end when Celgene Corporation of Warren, New Jersey, the company which is developing thalidomide for treatment of wasting, is ready with a program for wider use of the drug. [Note: While thalidomide is being developed for wasting syndrome by Celgene, it is being developed for aphthous ulcers by another company, Andrulis Pharmaceutical Corporation.]

All three parties gain from the apparent compromise, and all give something up. The FDA has been most anxious to shut down unofficial access to thalidomide through the buyers' clubs; the compromise will probably accomplish that. But the FDA has also been reluctant to allow a "treatment IND" compassionate access program with cost recovery, until more data is available than it now has about thalidomide and wasting. (A controlled trial for wasting is now ongoing, but it has had serious problems recruiting volunteers, because of exclusion conditions, and because it is placebo controlled when there is a standard of care (Megace or Marinol); persons with wasting syndrome severe enough to qualify for the trial are unwilling to risk getting no treatment.) Something had to be done to justify shutting down the buyers' club supply -- hence the pressure to speed up plans for a second Celgene randomized trial, to provide alternative access. But at the October 24 meeting, it became clear that the resulting trial would not produce the kind of efficacy information the FDA wanted in any case, so there was no need for it to be randomized.

The company had to give up its hope for randomized data. But it can charge for the program, and will get safety

information from it.

The buyers' clubs are convinced that they have given better service to patients than the official program will -- and at a much lower cost. They had to give this up, but they did achieve their central goal -- the creation of an official program to distribute the drug for persons with wasting syndrome.

Thalidomide for Aphthous Ulcers: New NIAID Results

On October 31, as this issue went to press, the U.S. National Institute of Allergy and Infectious Diseases announced that thalidomide had worked well enough in treating severe mouth ulcers (oral aphthous ulcers) that a major ongoing government study (ACTG 251) was being changed to no longer require persons with that condition to take a chance of receiving a placebo. Instead, the trial will continue, in order to collect data on maintenance use of thalidomide for this purpose; but all current and new volunteers with mouth ulcers will get the active drug. In the trial so far, the ulcers healed in 14 of 23 patients receiving thalidomide, but only one of 22 who received the placebo.

Volunteers with aphthous ulcers of the esophagus will still be randomly assigned to thalidomide or placebo, however, because there has not yet been enough enrollment in the study to prove that the drug works for these ulcers as well.

This study is still open for enrollment in about 20 U.S. cities; it is seeking a total of 164 volunteers. For more information, call the AIDS Clinical Trials Information Service, 800/TRIALS-A.

Comment: This result is no surprise. The medical literature has been full of successful reports of thalidomide use in aphthous ulcer treatment for the last five years.

Other AIDS-Related Uses: Kaposi's Sarcoma? Microsporidiosis?

If anyone using thalidomide also has Kaposi's sarcoma (KS), we would like to hear if the drug seemed to have any effect on that disease. An animal study published last year found that oral thalidomide inhibited angiogenesis (the growth of new blood vessels), and concluded that the drug had promise as a possible treatment "of many diverse diseases dependent on angiogenesis." (3) (The abstract did not mention Kaposi's sarcoma specifically, and is not included on the AIDSLINE computer database.)

A small study (17 volunteers) in England, reported at the recent AIDS conference in Copenhagen, found improvement in diarrhea due to microsporidiosis after treatment with thalidomide, in patients who had failed to respond to

previous treatment with albendazole.(4) This trial was organized after earlier research found that persons with AIDS-related microsporidiosis had abnormally high levels of TNF (tumor necrosis factor, which has many effects on the body) in their feces. Thalidomide reduces TNF levels.

In addition, there is interest in thalidomide as a possible treatment for other illnesses which are not AIDS related, including lupus, and some cancers.

We are concerned that removal of thalidomide from the buyers' clubs will make it more difficult to explore new possible uses for the drug. Official clinical research is usually years behind the leading front-line scientists, physicians, and patients.

FDA Compassionate Access Program

The FDA program for compassionate access to thalidomide -- originally set up for persons with aphthous ulcers, then temporarily used for persons with AIDS-related wasting syndrome -- is still open for wasting syndrome. This program is free; but its use for wasting will be ended when the Celgene open-label safety protocol is ready. For information about the FDA compassionate-access program, contact Matthew Tarofsky or Brenda Atkins, 301/443-9553.

Comment - Charging for Trials

The entire issue of charging patients for the costs of research -- research undertaken not for their benefit, but for the benefit of the pharmaceutical company which owns the rights to the drug -- needs much more attention.

This problem must be seen in the larger context of pharmaceutical companies big and small shedding costs of developing their own proprietary drugs. Insurance companies and government programs alike are usually adamant that they will not pay for the pharmaceutical companies' research -- and strong enough to avoid having to do so. The bills, then, go to desperate patients who have to pay out of their own pockets if they can pay at all, and give up the treatment they need if they cannot. The PWA Health Group was concerned that the earlier, randomized thalidomide trial-for-sale would set a new, dangerous precedent in this direction. There is widespread fear that many pharmaceutical companies will happily make patients pay for research if they can get away with it -- a "Republican wet dream," one activist called it. [It has long been noted that people are cheaper than monkeys for some clinical trials; they will be cheaper still if they have to pay their own way as guinea pigs.]

Already it has become a widespread practice to force volunteers to pay for laboratory tests required by research

protocols.

Note that charging for COMPASSIONATE ACCESS (including "treatment IND" and other programs set up primarily for treatment, not for research) is also an issue, but a different one than charging clinical-trial volunteers for DRUG RESEARCH AND DEVELOPMENT. Compassionate access is for the patient's benefit, not the pharmaceutical company's; it should be reimbursed as part of medical care. The problem is that insurance companies and other third-party payers, public and private, have control of the rules, and have abused their power by extending their understandable refusal to pay for other companies' drug development to also refusing to pay for treatment on the grounds that it is "experimental" -- even when the clear purpose of the medication is treating the patient, not drug development. These compassionate access programs provide some of the most important medical treatment, simply because they are seldom set up except in cases of desperate need. To single out this most urgent medical expense for refusal of coverage is unconscionable.

This issue has been obscured because pharmaceutical companies have been expected to pay for compassionate access out of their research and development budgets; patients and payers alike did not see the bill. It has been argued that it is inherently immoral to charge for a drug which has not been proven safe and effective. We believe this whole area needs more attention. Sometimes the drugs are not available at all unless companies can charge for them. And requiring that research funding cover these programs might slow development of new drugs. These problems would be greatly reduced if, when an unapproved drug is the best option for a patient's therapy, it could be reimbursed like any other medical care. (In addition, pharmaceutical companies need to continue to help patients obtain reimbursement for which they are qualified, and to set aside some proportion of the drug for an indigent program for patients who cannot be reimbursed.)

Research and medical costs which should legitimately be paid by others must not be dumped onto the individual patient, just because powerful institutions are fighting among themselves over who should pay. Patients, physicians, and the general public are in an excellent position to organize politically against this.

References

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***** NIH Research Evaluation: Last Meeting on Clinical Trials November 13, Public Comment Allowed

The Office of AIDS Research (OAR) -- which recently was given budgetary authority over the U.S. National Institutes of Health (NIH) AIDS research program, which is by far the world's largest -- is finishing up a one-year process of evaluating AIDS research at NIH. Due to a closed, secretive atmosphere around this evaluation process, most of the AIDS community has not been informed of what is going on, or able to give input. Protests by ACT UP/New York and ACT UP/Philadelphia against the closed process -- including three arrests -- led to some increase in openness, including the appointment of two community representatives. (Two other community representatives, both active in Treatment Action Group (TAG), were on the panel from the beginning.) The final report is due in January.

The last meeting of the Area Review Panel on Clinical Trials (one of six Area Review Panels of the NIH AIDS Research Program Evaluation Working Group) will be held November 13 and 14 at the Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, Maryland. Only the morning of November 13, from 8:00 a.m. to noon, will be open to the public. Individuals and organizational representatives (no more than one from each organization) may be able to speak for five minutes; however, the deadline for making prior arrangements to speak has passed. Written statements will be accepted; but the deadline for having them distributed in advance to the panelists has passed. Since both deadlines were October 30 and the meeting was announced in the FEDERAL REGISTER (page 53793) on October 17, there was little time to get the word out. Not surprisingly, few people signed up.

To submit written comments, send three typewritten copies, including a brief description of your organization, to the attention of Dr. Judith Feinberg, Office of AIDS Research, NIH, 31 Center Drive, MSC 2340, Building 31, Room 5C08, Bethesda, MD 20892-2340, phone 301/496-0358, fax 301/402-

8638. "Comments should be confined to statements related to the current status of NIH AIDS research in the areas of therapeutic clinical trials and recommendations for consideration by the panel in assessing and reviewing the relevant research in these areas."

If you want to speak at the meeting, those who have not made any advance arrangements may be permitted to do so at the end of the meeting, if there is time and the chairperson agrees. We suggest contacting OAR in advance, even though the deadline has passed, as preferable to just showing up. To do so, send a letter of intent and three typewritten copies of the presentation, along with a brief description of the organization represented, to Dr. Feinberg at the above address.

***** NIH Role in Clinical Research

by John S. James

[This is our statement to the Office of AIDS Research NIH AIDS Research Program Evaluation Working Group Area Review Panel on Clinical Trials, November 13-14 (see notice above).

[Do not rely on us to get this message across. We cannot attend the meeting, and we missed the deadline for advance distribution of this statement. Nor do we know what issues are being addressed in the evaluation process, as that is not public information; sometimes it has not been available even to Working Group members themselves.]

We are hearing widespread concern that OAR may go overboard in the shift to basic research, and seriously limit the NIH role in AIDS trials. Granted, previous AIDS clinical-trial research often lacked focus, and as a result was unproductive. But some AIDS trials clearly belong at NIH.

Here are four kinds of AIDS trials (not a complete list) that NIH must do:

(1) Pathogenesis-intensive trials. For example, one ACTG trial now being designed will suppress viral replication as completely as possible with multiple drugs, in a small number of patients, to allow intensive study of the changes in CD4 and other blood cells as the CD4 counts increase. Clearly this clinical trial is basic science as well -- basic science which is especially relevant, as it is done in people. Industry is unlikely to do such work, and community organizations are seldom equipped for it.

Note that pathogenesis-intensive trials -- the most scientific of all trials -- do not always need to be

controlled.

(2) Small, rapid, proof-of-principle trials of treatment leads, including "alternative" treatments. The history of medicine is full of surprises; treatment progress seldom moves in predictable straight lines. Testing the dozens of treatment leads which have known safety information and some credible rationale will almost certainly find no measurable benefit from most of them. But a few probably will prove unexpectedly interesting -- producing incalculable SCIENTIFIC benefit by opening new research avenues, in addition to any immediate value the potential treatments may have to patients and physicians. (Other benefits at no extra cost include the public-health importance of showing that many popular treatments fail to work as intended -- as well as the economic value of any positive discovery in reducing the cost of medical care, since most of the treatment leads in this class are non-proprietary and readily available at negligible cost.)

The primary outcome could be viral load, immunological markers, or other credible measurements. The aim of this research would be to find some measurable, reproducible effect indicating drug activity. Once activity is known, further research could be planned from there.

The National Cancer Institute has traditionally done such early testing in cancer; but in AIDS, no one has done much of it so far. Community organizations could conduct these trials, but usually they have not. Part of the problem may be regulatory cost, as many treatment leads in common human use do not exist in forms that meet FDA requirements for research -- prepared under GMP (Good Manufacturing Practices) rules, and with the active ingredient properly standardized from batch to batch (which is probably impossible if the active ingredient(s) are unknown). Running a trial legally in the U.S. could require the major expense of setting up a new production facility -- in addition to laboratory research to identify, test for, and perhaps synthesize active ingredient(s). Because of these barriers, nothing happens -- when a safe, simple trial could quickly identify the few valuable leads, which then could easily find the support required for further research. NIH could deal with this problem more effectively than community organizations can.

Another problem for community research is that only organizations with a highly "respectable" face can raise the money required, and those groups tend to follow the same scientific fashions as NIH and others, reducing their potential contribution to that of a small drop in the big bucket of research already being done. Technically these trials would be easy to run; but it is hard to find the required money, expertise, good judgment, and also openness to new ideas, all in the same organization.

(3) Development and standardization of "markers" and other tests. NIH is already the leader here. Industry can develop specific tests, but there are major gaps that industry will not fill.

NIH should do more to develop new immunological markers -- especially those which can be measured by flow cytometry or related methods, since this technology is well suited to standardization and quality control.

(4) Confirmatory trials -- or rather, a single master protocol for clinical confirmation of antiretrovirals which have received accelerated approval. When new treatments are likely to become part of the standard of care and be administered to hundreds of thousands of people, many researchers, physicians, and patients want long-term clinical data, to confirm that treatments approved based on short-term trials really are ultimately beneficial, and do not have detrimental surprises later.

There is no way that every new treatment and promising combination can continue to have its own confirmatory trial, with its own control group, etc. We need a master protocol to compare the most important possibilities; and government must be involved in the administration and data management, instead of leaving this to the competing companies. Government should pay for and control the aspects of this research which are not drug-specific.

Confirmatory trials will become much more feasible if we can accept a certain philosophical shift. We need to realize that these trials -- although they are randomized and controlled -- do not need to produce a winner and a loser. Therefore, this master protocol does not need to have a loser arm (traditionally provided by an obsolescent standard of care, such as AZT monotherapy before the ACTG 175 and Delta results were reported), and can avoid all the ethical, recruitment, and compliance problems that requiring a loser entails.

And these trials do not need to prove equivalence either; they do not need to reject any null hypothesis. Instead, their purpose should be to monitor the major therapeutic options likely to become part of the standard of care, looking for any unexpected problems (or unexpected benefits as well). If the master protocol we propose never proves that anything is better than anything else, and also never proves that anything is equivalent to anything else, it will still have been a complete success. It will have safeguarded the public from unexpected toxicities or treatment failures in all of the treatments tested. (All these treatments will already have proven superiority or at least equivalence to standard of care -- in the surrogate-marker trials required to gain accelerated approval -- before being eligible to enter the confirmatory master protocol.)

Such a master-protocol trial will also produce a treasure chest of associated information, such as which patients are likely to do well on which treatments -- information not as readily available from separate confirmatory trials which are not designed to be comparable. And additional substudies can be nested to address specific questions.

To illustrate with specific drugs, such a protocol could randomize volunteers to the Roche, Merck, Abbott, or other protease inhibitor -- or any other drug combination with equally good safety and surrogate-marker results -- after those drugs have received accelerated approval. Each developer would recommend other drugs (for example, AZT plus 3TC) designed to make the combination with their product work as well as possible; and volunteers would not have to pay for these recommended drugs. (Volunteers would be allowed to use other, non-recommended drugs on their own; therefore, they would have no reason to conceal anything from the researchers, but could fully report what they did.)

NIH, as administrator of the master protocol, would decide which combination treatments were good enough to become an arm in the trial -- meaning that participation would be a major marketing advantage for a company (not an unavoidable burden like confirmatory trials today) because it would imply official recognition that, based on all current knowledge, the company's treatment was as good as any treatment known. And participation would of course fulfill the accelerated approval confirmatory trial requirements -- almost regardless of the result of the trial, as there would be no loser arm, and therefore no winner/loser relationship expected. Only the discovery of a serious toxicity or other drug failure would be held against a drug, greatly reducing the developer's risk from the head-to-head comparison with competitors. With these incentives, industry will compete to get into these trials, greatly facilitating inter-company cooperation (since a winning combination will usually require products of more than one company), and helping to finance the project as well.

But this whole structure requires government management of the master protocol, requires an outside party which answers to the public interest. Competing companies probably cannot organize such a program on their own. NIH has already shown that it can fulfill this kind of management role, for example in ACTG 175. No one else could do so.

***** CMV: Oral Ganciclovir for Prevention

On October 31 Hoffmann-La Roche announced that it had received FDA approval to market oral ganciclovir (Cytovene(TM)) for prevention of CMV disease in persons with advanced HIV infection. Oral ganciclovir had previously been FDA approved, but only for maintenance treatment of CMV

retinitis (after the disease had already developed, and been stabilized with intravenous treatment). A Roche Biosciences (formerly Syntex) clinical trial in 725 volunteers with CD4 count less than 100 found a 49% reduction of risk of CMV disease in those randomly assigned to preventive treatment with oral ganciclovir, compared to those who received the placebo. Side effects of the treatment included anemia, neutropenia, and elevated serum creatinine.

***** CMV: New Screening Program

Hoffmann-La Roche also recently started a CMV Retinitis Screening Program, to teach patients at risk for CMV retinitis to recognize symptoms of the disease between doctor visits, so that they can get rapid treatment. Patients can obtain a kit -- including a videotape "Recognizing CMV Retinitis," a brochure, and an Amsler grid, which is used to help diagnose CMV retinitis -- by calling the voicemail number 800/624-CHECK. AIDS service organizations can request a physician-led seminar about CMV retinitis and the screening program; call 800/293-7428 or 212/698-1662.

***** Cryptosporidiosis Information Phone/Fax Line

The U.S. Centers for Disease Control has started a phone and fax service for information about cryptosporidiosis. Callers can listen to recorded messages, or receive printed information by fax. The phone number is 404/330-1242.

***** Protease Inhibitor Trial Drops AZT-Only Arm

Hoffmann-La Roche has changed its trial of the protease inhibitor saquinavir, due to new information from the ACTG 175 trial and the Delta trial showing that AZT alone was inferior to combination therapy (for background on ACTG 175, see AIDS TREATMENT NEWS #231, September 23, 1995; for background on Delta, see AIDS TREATMENT NEWS # 232, October 6, 1995).

Those in the saquinavir trial (named SV 1406) who were randomized to AZT will be offered a chance to switch to the triple combination of saquinavir plus AZT plus ddC. New volunteers entering the trial will be randomized to one of the three combination therapy arms (saquinavir plus AZT, AZT plus ddC, or the triple combination).

***** Help Wanted: AIDS Treatment Activist, Atlanta

The AIDS Survival Project, an Atlanta, Georgia coalition of people affected by HIV, is seeking a full-time treatment resource specialist. This program-management position involves treatment activism as well as supervising and maintaining a large treatment resource library. Applicants need the ability to work with a wide variety of people,

strong writing skills, strong knowledge of HIV treatments and treatment issues, and the desire and ability to advocate for treatment reform both locally and nationally. Salary range \$24,000-26,000 plus benefits.

If interested, send resume, cover letter, and references to: Jeff Graham, Executive Director, AIDS Survival Project, 828 W. Peachtree St., Suite 208, Atlanta, GA 30308. People of color and HIV positive individuals encouraged to apply.

[Note: AIDS TREATMENT NEWS does not usually publish help-wanted announcements, but we do consider them for TREATMENT SPECIALIST positions.]

***** Peptide T: Negative Trial Result

by John S. James

A government study of 215 volunteers with AIDS-related cognitive impairment found no proof that peptide T was helpful for treating this condition.

The volunteers were randomly assigned to receive either peptide T (intranasally, up to six mg/day) or placebo for six months; for the next six months, everyone was given peptide T, and they could continue the medication beyond one year if they wanted. Cognitive impairment (which includes difficulties with memory, attention, language, problem solving, spatial ability, and visual-motor coordination) was measured by standard neuropsychological tests. The treatment group showed no statistically significant improvement compared to the control group.

The study also found no toxicity from peptide T.

Recruiting for this study began in March 1991. It took a long time to find volunteers -- probably because AIDS-related cognitive impairment is less common than had been expected, and because it can often be treated effectively with AZT.

This clinical trial was conducted by the U.S. National Institute of Mental Health, with additional funding from the U.S. National Institute of Allergy and Infectious Diseases (NIAID).

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AIDS TREATMENT NEWS reports on experimental and standard treatments, especially those available now. We interview physicians, scientists, other health professionals, and persons with AIDS or HIV; we also collect information from meetings and conferences, medical journals, and computer databases. Long-term survivors have usually tried many different treatments, and found combinations which work for them. AIDS Treatment News does not recommend particular therapies, but seeks to increase the options available.

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Subject: AIDS Daily Summary 10/20/95

AIDS Daily Summary

October 20, 1995

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"Scientists Report First Success of 'Gene Therapy'"

"France Tests Thousands Treated by Doctor With AIDS"

"HIV-Positive Man Sues Dental Clinic"

"Amgen Announces 27 Percent Increase in Earnings per Share"

"ChemTrak Inc. Announces Quarterly Results and Completion of Repositioning"

"Nine-Year-Old Child with Falling CD4 Count after Neonatal HIV"

"Current Corporate Reports: The Immune Response Corporation"

"HIV Coverage Rules Set"

"Keeping a Lid on Marijuana Research"

"Pump Up the Volume"

"HIV Risk Practices of Male Injecting Drug Users Who Have Sex with Men -- Dallas, Denver, Long Beach"

"Scientists Report First Success of 'Gene Therapy'"

Washington Post (10/20/95) P. A1; Weiss, Rick

Friday's issue of the journal Science contains the first published summary of a landmark experiment in genetic therapy. The report shows that two children with adenosine deaminase (ADA) deficiency who received transplanted genes are healthy five years

after beginning the treatment. R. Michael Blaese of the National Center for Human Genome Research, a senior author on the paper, was enthusiastic about the results, but critics point out that the girls' health could also be attributed to the drug PEG-ADA from Enzon Inc. However, gene therapists hope to apply similar strategies to diseases such as diabetes, cancer, and AIDS.
Related Story: New York Times (10/20) P. A22

"France Tests Thousands Treated by Doctor With AIDS"
Business Wire (10/19/95)

The Saint-Germain-en-Laye Hospital Center in Paris said on Thursday that it would test more than 5,000 former patients for HIV after finding out that one of its surgeons had been infected with the virus for 13 years, according to hospital official Michel Pencard. Health officials said that it was very unlikely that the doctor had infected any of his patients.

"HIV-Positive Man Sues Dental Clinic"

Houston Chronicle (10/19/95) P. 33A; Tedford, Deborah

David Keith Slater, an HIV-positive Houston resident, has filed suit against a local dental clinic, two dentists, and his dental insurance carrier, citing Title III of the Americans With Disabilities Act, which prohibits discrimination against the disabled in places of public accommodation. Slater alleges that he arrived for an appointment at Westfield Dental Center and was examined by dentist Linda Newsome instead of David Ashmore, with whom he had the appointment. Newsome allegedly told him that he needed a root canal or tooth extraction and referred him to the Bering Clinic, which provides dental services to individuals with HIV. However, Slater claims that the Bering Clinic refused to perform the root canal, so he was forced to have the tooth extracted.

"Amgen Announces 27 Percent Increase in Earnings per Share"
Business Wire (10/19/95)

Amgen reported a third-quarter increase in earnings per share of 27 percent on Thursday, up from \$0.41 a year ago to \$0.52. Net income rose 28 percent from \$114 million to \$145 million, and revenues jumped 16 percent from \$426 million to \$493 million. The company has boosted its research and development spending to 23 percent of sales, or \$106 million. Worldwide sales of Neupogen increased by 7 percent from \$215 million in the third quarter a year ago to \$230 million in the quarter ended Sept. 30. "We continue to invest heavily in defining both Neupogen's benefits in oncology as well as its future role in a variety of new clinical settings and market opportunities, including HIV and other infectious diseases," said CEO Gordon Binder. Amgen has filed for regulatory approval in Europe for use of the drug in treatment of neutropenia due to myelosuppressive medications in HIV-positive patients.

"ChemTrak Inc. Announces Quarterly Results and Completion of Repositioning"
Business Wire (10/19/95)

ChemTrak Inc. has announced revenues of \$486,000, product sales of \$271,000, and a net loss of \$1,241,000 for the third quarter. CEO Prithipal Singh said the company is preparing to introduce a home testing system for HIV. The company's Pre-Market Approval Application has been accepted by the Food and Drug Administration; approval is expected in 1996.

"Nine-Year-Old Child with Falling CD4 Count after Neonatal HIV"
Lancet (10/07/95) Vol. 346, No. 8980, P. 963; Giaquinto, Carlo;
De Rossi, Anita

Giaquinto and De Rossi present follow-up data on a nine-year-old child, in whom HIV was isolated from peripheral blood mononuclear cells (PBMCs) but who subsequently lost antibodies to HIV. Although blood collected at three and seven months was positive by viral culture in PBMCs, and borderline three months later, polymerase chain reaction was negative for HIV at seven months, positive for ENV and LTR primers at 10 months, but only LTR at 24 and 47 months. The child tested negative for HIV by ELISA and western blot at 16 months. Currently, he is symptom free and his growth and development are normal. One negative point, however, is that the child's CD4 cell level has dropped significantly. The researchers suggest that uninfected children born to HIV-infected mothers may have HIV-specific cytotoxic T-lymphocyte activity, which indicates possible viral exposure. In this case, although testing for T-lymphocyte activity was conducted, the researchers believe that viral exposure was unlikely due to the negative results of in-vitro antibody-production tests. It is therefore necessary to determine whether seemingly HIV-free children are truly uninfected and unable to transmit the virus that causes AIDS, the researchers conclude.

"Current Corporate Reports: The Immune Response Corporation"
Barron's: Market Week (10/02/95) Vol. 75, No. 40, P. MW13

Immune Response Corp. will collaborate with Trinity Medical Group Co. Ltd. of Thailand to develop and test the Salk Immunogen in up to 10,000 HIV patients in Thailand. Trinity will fund the endeavor in return for the rights to market the Salk Immunogen in Thailand and selected Asian countries. Immunogen will supply the product for the clinical trials and receive royalties on Asian sales. The clinical trials in Thailand will determine how effective the Salk Immunogen is in delaying the progression of HIV infection to AIDS and complement U.S. clinical trials currently under review by the FDA.

"HIV Coverage Rules Set"

Business Insurance (10/16/95) Vol. 29, No. 42, P. 2; Hofmann, Mark A.

A proposed New Jersey regulation would allow commercial health insurance companies--not health maintenance organizations or self-insured companies--to test new applicants for group policies covering 50 or more people for HIV. The law would allow the companies to deny coverage for applicants who refuse to be tested or for those who test positive, and are later confirmed positive, in FDA approved tests. The New Jersey Department of Insurance said the proposal would have a minimal impact on most employers in the state. Although the proposal would allow group health insurers to directly ask applicants whether they have tested positive for HIV or have experienced symptoms of HIV, they would not be allowed to ask subjective questions or those concerning lifestyle.

"Keeping a Lid on Marijuana Research"

Nature Medicine (09/95) Vol. 1, No. 9, P. 853; Steele, Fintan R.

AIDS activists, researchers, and government officials are going head-to-head in a controversy over a proposed study to examine the effects and usefulness of marijuana on AIDS-related wasting

syndrome. Despite receiving the go ahead from the FDA and both state and university review boards, Donald Abrams and his colleagues are finding it impossible to actually obtain the drug because the National Institute of Drug Abuse (NIDA) and the Drug Enforcement Agency (DEA) will not allow them to have any. When confronted by AIDS-activists, NIDA officials said the drug would be made available if the research was approved through "normal" National Institutes of Health (NIH) peer review although the study is privately funded and does not require an NIH grant. Abrams and his fellow researchers will submit their proposal to NIH but do not expect a favorable outcome.

"Pump Up the Volume"

POZ (10/95-11/95) No. 10, P. 22

ProScan-A, a new procedure based on cancer diagnostic technology, could change the way in which doctors diagnose HIV progression. The process uses a protein that binds to HIV and a non-toxic radioisotope that sends out signals detectable with a special camera. The radioisotope--which is injected into HIV-infected persons--clings to infected cells and HIV itself, allowing physicians to see the volume and concentration of HIV in the body, according to Joel Sendek, spokesman for Progenics Pharmaceuticals. The Memorial Sloan-Kettering Cancer Center in New York City is currently conducting a phase I safety trial of ProScan-A. Progenics ultimately hopes to create a database of thousands of different readings to help physicians in diagnosing the health of HIV-infected persons based on the ProScan-A picture.

"HIV Risk Practices of Male Injecting Drug Users Who Have Sex with Men -- Dallas, Denver, Long Beach" MMWR Summary, Centers for Disease Control and Prevention (10/20/95) Vol.44, No.41

Men who report both intravenous drug use and sex with other men (MSM IDU) now account for 7% of AIDS cases in the United States and 21% of cases among IDU. For communities to design effective programs to prevent the spread of HIV to IDU, their sexual partners, and their children, a great deal must be understood about the characteristics, practices, and motivations of this subgroup of men. Findings from three cities --Dallas, Denver, and Long Beach--demonstrate an urgent need for local prevention efforts to reach to reach MSM-IDU. Interviews with MSM IDU in these areas indicate that these men are at extremely high risk of acquiring and transmitting HIV. The majority had shared injection equipment, traded sex for money or drugs, and had unprotected sex with multiple male and female partners. The findings also illustrate that sexual self-identification as heterosexual or homosexual may not correspond with sexual practices. One third of MSM IDU in this study described themselves as heterosexual.

[342] From: GREG_FOLKERS (NIH.GREGFOLK) at SOFTSWITCH 10/23/95 2:34PM (10622 bytes: 186 ln)

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"Drug Company Did Not Act on AIDS Virus Warning"
Philadelphia Inquirer (10/23/95) P. A1; Shaw, Donna

In October of 1985, executives of Armour Pharmaceutical Co. agreed to ignore a warning from researcher Alfred M. Prince that the company's heating procedure was insufficient to kill the AIDS virus in Armour's blood clotting medicine Factorate. "Confronted with the facts at the time, Armour had no scientific reason to believe that there was anything wrong with its heat-treatment methods, and every good reason to suspect that the Prince results

were flawed." The company did switch to a more rigorous heating process in 1987, but it continued to sell the remainder of the medicine that was heat treated by the old method. By this point, the medicine had already infected several hemophiliacs in Britain, Canada, and the United States with HIV.

"Safeguarding US Drug Patents"

Journal of Commerce (10/23/95) P. 10A; Brock, William E.

William E. Brock, a former U.S. trade representative who now represents Glaxo Pharmaceuticals, applauds Congress's recent decision to uphold its commitment to intellectual property rights under the General Agreement on Tariffs and Trade (GATT). Generic drug companies have been lobbying for immunity from the GATT agreement, and Sen. David Pryor (D-Ark.) has argued that such a provision was erroneously left out of the GATT terms due to "bureaucratic oversight." Brock contends that the United States' policy of protecting intellectual property rights has made it a world leader in innovation, adding, "It is no coincidence that the pharmaceutical industry is one of the few sectors of the U.S. economy enjoying a balance of trade surplus with the rest of the world." He concludes, "Eroding the incentives that reward pioneering drug companies will mean less research devoted to cures for cancer, heart disease, AIDS and Alzheimer's."

"100,000 Zimbabweans Face AIDS Deaths in 18 Months"

Reuters (10/22/95)

According to a statement made to the independent Sunday Gazette newspaper by Zimbabwe Health Minister Timothy Stamps, at least 100,000 Zimbabweans will die of AIDS-related diseases over the next 18 months. "I am not trying to be alarmist," he said, "but this is the reality we are facing." Stamps added, "At present ... 25 to 30 bodies of victims of AIDS are put [daily] into mortuaries of Harare and Mpilo hospitals where authorities are now failing to cope with the congestion." Stamp noted that Zimbabwe is now one of the world's top countries in terms of new HIV infections.

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Reuters (10/22/95); Zabarenko, Deborah

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"Pros and Cons: Carrington Laboratories"

Barron's (10/02/95) Vol. 75, No. 40, P. 5; Welling, Kathryn M.

Carrington Laboratories suffered a decline in the late 1980s when several of its aloe vera extracts, touted as remedies for everything from AIDS to cancer, did not pan out. The company is back now, performing better on the stock market and planning trials of aloe-based capsules to treat ulcerative colitis as well as a possible aloe-based cancer treatment. Its FDA-approved OTC canker-sore remedy is in test marketing. The company claims to

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POZ (10/95-11/95) No. 10, P. 36; Murphy, Robert

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Journal of the Association of Nurses in AIDS Care (09/95-10/95) Vol. 6, No. 5, P. 37; Eccles, Elizabeth; Ptak, Judy

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"Chicago Hope"

Multi-Housing News (09/95-10/95) Vol. 30, No. 6, P. 37; Foong,

L. Keat

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[343] From: GREG_FOLKERS (NIH.GREGFOLK) at SOFTSWITCH 10/24/95 11:02AM (10142 bytes: 180 ln)
To: Jane Sanville at ~ONAPC, *hauslerh@who.ch at SOFTSWITCH,
*htaylor@phnet.sph.jhu.edu at SOFTSWITCH, *llanier@cpcra.niaid.nih.gov at SOFTSWITCH, *rkaslow@epi.soph.uab.edu at SOFTSWITCH, *sgs@hivnet.fhcrc.org at SOFTSWITCH, STEN (INTERNET.STEN1) at SOFTSWITCH, *yann@aol.com at SOFTSWITCH, *jkovacs@nih.gov at SOFTSWITCH, *michael_polis@nih.gov at SOFTSWITCH
Subject: AIDS Daily Summary 10/24/95

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(Soft*Switch Central V4L380P7);
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Date: Tue, 24 Oct 95 11:08:05 EST
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From: Greg Folkers <Greg_Folkers@d31.niaid.pc.niaid.nih.gov>
To: hauslerh@who.ch, htaylor@phnet.sph.jhu.edu, jsanvill@oash.ssw.dhhs.gov,
llanier@cpcra.niaid.nih.gov, rkaslow@epi.soph.uab.edu,
sgs@hivnet.fhcrc.org, sten@geomed.dom.uab.edu, yann@aol.com,
jkovacs@nih.gov, michael_polis@nih.gov
Subject: AIDS Daily Summary 10/24/95

AIDS Daily Summary
October 24, 1995

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"The Not-So-Naked City"
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"Thais Blamed for HIV Spread in Indonesia's Irian"
"In Immune System Model, Fittest Antibodies Survive"
"Contracts: the Central Virginia HIV Care Consortium"
"Life Partners Files Compliance Report; Clarifies Status of SEC Litigation"
"Emmy Awards Show Is Short of Polish"
"Red Cross Facing New Challenges in Blood Banking"
"NIAID to Fund Seven Cooperative STD Research Centers"

"The Not-So-Naked City"
Washington Post (10/24/95) P. B1; Span, Paula
A proposed zoning change in New York City would permit adult video stores, bookstores, theaters, and clubs to be situated only in industrial or specific commercial zones, not in residential areas. In addition, these X-rated businesses also would not be able to locate within 500 feet of a school, a day-care center, a "house of worship," or another X-rated concern. If the

legislation is to withstand challenges to its constitutionality, however, the city must demonstrate that such businesses have "adverse secondary effects" on neighborhoods and that citizens still have "reasonable access" to the restricted materials and establishments. Already, several primarily gay theaters are in court. Eight theaters have been closed since late last year due to violations of the state sanitary code, which prohibits sex in a commercial facility. "We think some HIV transmission occurs in these facilities because of lapses in safe-sex practices," explained action Health Commissioner Benjamin Mojica. The closings have sparked debate among gay rights and AIDS activists. A number of gay reporters have advocated Health Department action, while other community members take offense at the notion of vice cops closing gay social centers.

"Deaths: Michael Volante, Subject of AIDS Film"

Washington Post (10/24/95) P. C7

Michael Volante, the boy who attracted national attention when he and his mother were portrayed in a 1992 documentary about AIDS, died on Oct. 19 at the age of eight. His mother, Tammy Boccomino, became HIV-infected from her first husband, an injection drug user, but did not learn of her infection until after Michael was born. Their lives were featured in the documentary "Close to Home: The Tammy Boccomino Story," which won Emmy and Peabody awards, as well as the Alfred I. duPont-Columbia University Silver Baton Award for excellence in journalism.

"Thais Blamed for HIV Spread in Indonesia's Irian"

Reuters (10/24/95)

Thai fishermen working in the Fakfak region of Indonesia's Irian Jaya province have been charged with spreading HIV in that area, according to the Antara news agency. Antara also quoted Fakfak regent Suparlan Pasambuna as saying his part of Irian did not benefit from the operation of Thai fishing boats leased by an Indonesian firm. "Fakfak's marine resources are sent abroad and what [Thais] leave is the disease. I therefore urge the government to issue a new regulation banning Thai fishermen from leaving their boats when they are berthed there," he said. Antara reported that there were 95 people with HIV and AIDS in Irian Jaya, second only to the capital city of Jakarta, which has 180 cases.

"In Immune System Model, Fittest Antibodies Survive"

New York Times (10/24/95) P. C1; Blakeslee, Sandra

Two mathematicians believe they have discovered how the lymph glands produce highly specific molecules, known as antibodies, that attach themselves to foreign agents with incredible accuracy. According to the University of Maryland's Dr. Garrett Kelsoe, the new model "tells us how the immune system can make antibodies that are 100 times more effective in just two weeks." Novel series of equations indicate that the best method of creating effective antibodies is to have periods of rapid mutation followed by periods of rest. Dr. Alan Perelson, a theoretical immunologist at the Los Alamos National Laboratory in New Mexico who last year was part of a team that used mathematical models to show how HIV overwhelms people, explained that math can offer strong insight into immune system functioning. Perelson and Dr. Thomas B. Kepler, a biomathematician at North Carolina State University, recently published their findings in The Proceedings of the National

Academy of Sciences.

"Contracts: the Central Virginia HIV Care Consortium"
Richmond Times-Dispatch (10/23/95) P. D10

The Central Virginia HIV Care Consortium has extended a grant given to Richmond attorney Terry W. Raney. Raney will continue to use the grant to offer wills and estate planning services to people with HIV or AIDS.

"Life Partners Files Compliance Report; Clarifies Status of SEC Litigation"
Business Wire (10/23/95)

Brian D. Pardo, president of Life Partners Inc., has announced in a sworn report filed in federal court that the company "has developed revised methods of operation that it considers sufficient to eliminate any claim that the securities laws apply." Life Partners functions as the buyers' agent in viatical settlements, which allow people with terminal illnesses such as AIDS to sell their life insurance policies prior to death. The Securities and Exchange Commission (SEC) has not yet commented on the steps outlined in Pardo's report, but its court filings acknowledge that viatical transactions are not inherently securities, that the participation of an agent does not necessarily invoke the securities laws, and that the preliminary injunction issued in late August allows Life Partners to comply "by restructuring the transactions in such a way that they do not constitute securities." The SEC must file a response to the report by Nov. 2., after which time the court will deliberate the case.

"Emmy Awards Show Is Short of Polish"
Chicago Tribune (10/23/95) P. 2-8; Nidetz, Steve

At the 37th annual Chicago Emmy Awards on Saturday, journalist Rae Lewis-Thornton, who has AIDS, was recognized for having the best hard news feature series. "WBBM decided to talk about living with AIDS instead of dying with AIDS," Lewis-Thornton noted.

"Red Cross Facing New Challenges in Blood Banking"
American Medical News (10/16/95) Vol. 38, No. 39, P. 17

The American Red Cross has begun experiencing new problems as national laws adopted to make the blood supply safer have placed the federal government, and in some cases local governments, in charge of the blood supply. Red Cross President Elizabeth Dole said that the changes made during her tenure were necessary to respond to AIDS and that the advances that have kept the blood supply safe have also led to problems and demands. The restructuring is expected to cost \$162 million, with 52 blood centers being cut down to 9 and 800 of the 15,000 biomedical jobs eliminated. The Red Cross has also adopted a wage freeze, which has led to several strikes, and is running its first budget deficit, \$60 million for fiscal year 1995, since auditing first began 15 years ago. In addition, the blood supply is suffering from a yearly drop of one percent to three percent in donations since the late 1980's. Nonetheless, the Red Cross continues to handle about half of the nation's blood supply and is expected to remain an important part of handling blood.

"NIAID to Fund Seven Cooperative STD Research Centers"
Nation's Health (10/95) Vol. 25, No. 9, P. 5

The National Institute of Allergy and Infectious Diseases (NIAID) has created seven Sexually Transmitted Diseases Cooperative Research Centers to further collaborative multidisciplinary studies on these issues. In the first year, researchers at sites including Seattle, Boston, and Baltimore will receive grants totaling about \$6.2 million. The new studies are part of a larger NIAID plan to prevent and control sexually transmitted diseases (STDs), including AIDS. It is estimated that 12 million new STD infections, including 40,000 cases of HIV, will be acquired this year.

[342] From: GREG_FOLKERS (NIH.GREGFOLK) at SOFTSWITCH 10/23/95 2:34PM (10622 bytes: 186 ln)

To: Jane Sanville at ~ONAPC, *hauslerh@who.ch at SOFTSWITCH,
*htaylor@phnet.sph.jhu.edu at SOFTSWITCH, *llanier@cpcra.niaid.nih.gov at
SOFTSWITCH, *rkaslow@epi.soph.uab.edu at SOFTSWITCH, *sgs@hivnet.fhcrc.org at
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Date: Mon, 23 Oct 95 14:40:00 EST

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From: Greg Folkers <Greg_Folkers@d31.niaid.pc.niaid.nih.gov>

To: hauslerh@who.ch, htaylor@phnet.sph.jhu.edu, jsanvill@oash.ssw.dhhs.gov,
llanier@cpcra.niaid.nih.gov, rkaslow@epi.soph.uab.edu,
sgs@hivnet.fhcrc.org, sten@geomed.dom.uab.edu, yann@aol.com,
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[346] From: GREG_FOLKERS (NIH.GREGFOLK) at SOFTSWITCH 10/25/95 4:56PM (10114 bytes: 180 ln)

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From: Greg Folkers <Greg_Folkers@d31.niaid.pc.niaid.nih.gov>

To: hauslerh@who.ch, htaylor@phnet.sph.jhu.edu, jsanvill@oash.ssw.dhhs.gov,

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jkovacs@nih.gov, michael_polis@nih.gov

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October 25, 1995

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"Nationline: AIDS Bias Ruling"

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"Sixty Percent of China HIV Carriers Under 30"

"Somatogen Optimistic in Race to Develop Blood Substitute"

"Counseling Women in Assertiveness"

"Program Development Board Slates Forum on AIDS-Related Activities"

"AIDS Researcher Says He Was Told to Ignore Safety Measures"

"Multidrug-Resistant TB in UK"

"Company Sued for Firing HIV-Infected Driver"

Journal of Commerce (10/25/95) P. 3B

A California-based trucking firm is being sued by the U.S. Equal Employment Opportunity Commission for allegedly incorrectly firing an HIV-infected driver. DEF Express has been charged with violating the Americans with Disabilities Act in its dismissal of driver James Marion.

"Nationline: AIDS Bias Ruling"

USA Today (10/25/95) P. 3A; Leavitt, Paul; Rivera, Patricia V.

Dentists acted correctly in wearing protective clothing and covering up equipment when treating HIV-infected patients five and 10 years ago, New York's highest court has ruled. In separate cases, the Court of Appeals overturned decisions of the state Division of Human Rights, which had found discrimination and awarded monetary compensation to the patients.

"The Deadly Politics of AIDS"

Wall Street Journal (10/25/95) P. A14; Smith, Helen Mathews

American public health officials have longed ignored the key principles involved in plague control-- including routine testing, disease tracking, and warnings to groups at risk, writes Helen Mathews Smith in the Wall Street Journal. Smith, who is writing a book on the HIV/AIDS epidemic, notes that in 1987, the medical establishment chose individual rights over public health when examining the future role of HIV testing. Soon after, the Centers for Disease Control and Prevention (CDC) recommended that high-risk groups be "encouraged" to be tested for HIV, though it warned that persons should not be tested unless they had received "appropriate counseling" and given consent. Still, voluntary testing then created its own problems, offering information about the epidemic's past but not its future. Over the years, some progress has been made. For example, the CDC now recommends that "all" pregnant women be tested for HIV, not just those at high risk. The agency, however, has yet to deal with the question of whether the United States can continue to rely upon voluntary testing to bring the AIDS epidemic under control, Smith writes. No one knows if routine or mandatory HIV testing would end the epidemic, but at the very least, Smith concludes, thousands of lives would be preserved.

"Sixty Percent of China HIV Carriers Under 30"

Reuters (10/25/95)

China's Health Daily reports that 60 percent of the HIV-infected individuals in China are less than 30 years old. The newspaper quoted one health official as saying that China has diagnosed 1,774 people with HIV, of whom 60 percent are between the ages of 16 and 29. Experts, however, claim that inadequate reporting and misdiagnosis could bring the actual total of HIV-infected Chinese to more than 10,000. Meanwhile, the State Education Commission has started offering sex education and AIDS information to approximately 19 million sixth-grade elementary school students, nearly 59 million high-school students, and almost 3 million college students.

"Somatogen Optimistic in Race to Develop Blood Substitute"

Knight-Ridder/Tribune Business News (10/25/95); Algeo, David

Somatogen Inc. is likely within four or five years of applying for final approval from the U.S. Food and Drug Administration for its genetically engineered human blood substitute, company CEO and president Andre de Bruin said at the firm's annual shareholder meeting on Tuesday. De Bruin added that Eli Lilly and Co., which has put millions of dollars into Somatogen's research, is renovating a European plant where it will produce the product, known as Optro, in commercial volumes. In recent tests, medical teams used Optro instead of donated blood for transfusions and avoided exposing patients to such blood-borne diseases as AIDS or hepatitis, de Bruin added. The next stage of testing is expected

to be completed in 1997, after which time the final stage should soon commence.

"Counseling Women in Assertiveness"

Reuters (10/24/95)

Researchers at the University of Alabama at Birmingham announced Tuesday that disadvantaged women who are at high risk for contracting HIV are significantly more likely to consistently use condoms if exposed to a in-depth sexual counseling program. The researchers said that their study showed that women between the ages of 18 and 29 reacted most positively to peer health educators who discussed sexual situations and offered assertiveness counseling. "The social-skills intervention addressed how to successfully negotiate safer sex...within the context of a heterosexual relationship where women are often in unequal positions of power relative to men," explained study author Ralph DiClemente in the Journal of the American Medical Association.

"Program Development Board Slates Forum on AIDS-Related Activities"

Nation's Health (10/95) Vol. 25, No. 9, P. 15

The Program Development Board of the American Public Health Association (APHA) will sponsor an open forum on the association's AIDS-related functions at the APHA annual meeting in San Diego. The forum will offer such information as the APHA's past and present initiatives and the appropriate focus and nature of AIDS activities in the future. Organizers hope to obtain information to direct the current program and to identify new requirements.

"AIDS Researcher Says He Was Told to Ignore Safety Measures"

American Medical News (10/16/95) Vol. 38, No. 39, P. 19

Joseph Yourno, an AIDS Researcher, has filed suit in Albany, N.Y., claiming that New York state health department officials tried to ruin his career after he complained about the lack of basic safety procedures at a state laboratory. "Despite the fact that my research was in AIDS, my supervisors criticized my adherence to strict safety standards and voiced their desire for me to sacrifice safety for the purpose of advancing my research at a faster pace," said Yourno. Yourno's suit includes internal department memos that mentioned concern over tubes of blood dropped in the stairwells and hazardous waste thrown away in regular trash cans. He also described how a large bird flew through an open window in 1991 and knocked equipment around before flying away, raising concerns that it might spread infection. Yourno, a 16-year health department veteran earned \$107,797 a year, holds a Ph.D. in molecular biology, studied with AIDS researcher Robert Gallo at the National Institutes of Health, and had patented a new blood spot technique. After lodging complaints on the lab conditions, he was allegedly demoted to a desk job reviewing credential applications for laboratory scientists. Sheila Galvin, Yourno's attorney, said that her client only filed the suit after it became clear the matter could not be resolved internally and that he hopes the publicity will force the department to clean up its procedures.

"Multidrug-Resistant TB in UK"

Nature Medicine (10/95) Vol. 1, No. 10, P. 985; Kingman, Sharon

The first incident of hospital-acquired multidrug-resistant tuberculosis occurred in the United Kingdom. Five HIV-positive patients at the Chelsea and Westminster Hospital in London contracted the illness from sharing a room with a patient who died in June. One of the patients has died of AIDS, but the other four are being treated for tuberculosis and are expected to do well. The strain of tuberculosis isolated from the patients was resistant to rifamoin, rifabutin, isoniazid, pyrazinamide, clofazamine, and ethionamide, but proved sensitive to six alternate antibiotics.

[348] From: GREG_FOLKERS (NIH.GREGFOLK) at SOFTSWITCH 10/27/95 9:15AM (41981 bytes: 1 fl)

To: Jane Sanville at ~ONAPC, *hauslerh@who.ch at SOFTSWITCH,
*htaylor@phnet.sph.jhu.edu at SOFTSWITCH, *llanier@cpcra.niaid.nih.gov at
SOFTSWITCH, *rkaslow@epi.soph.uab.edu at SOFTSWITCH, *sgs@hivnet.fhcrc.org at
SOFTSWITCH, STEN (INTERNET.STEN1) at SOFTSWITCH, *yann@aol.com at SOFTSWITCH,
*jkovacs@nih.gov at SOFTSWITCH, *michael_polis@nih.gov at SOFTSWITCH

Subject: Text Attach: (null)

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[350] From: GREG_FOLKERS (NIH.GREGFOLK) at SOFTSWITCH 10/27/95 12:05PM (9894 bytes: 179 ln)

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*htaylor@phnet.sph.jhu.edu at SOFTSWITCH, *llanier@cpcra.niaid.nih.gov at
SOFTSWITCH, *rkaslow@epi.soph.uab.edu at SOFTSWITCH, *sgs@hivnet.fhcrc.org at
SOFTSWITCH, STEN (INTERNET.STEN1) at SOFTSWITCH, *yann@aol.com at SOFTSWITCH,
*jkovacs@nih.gov at SOFTSWITCH, *michael_polis@nih.gov at SOFTSWITCH
Subject: 10/27/95 AIDS Daily Summary

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27 Oct 1995 12:05:47 EDT

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id AA01757; Fri, 27 Oct 1995 12:10:30 -0400

Date: Fri, 27 Oct 95 12:12:09 EST

Message-Id: <309104d9@d31.niaid.pc.niaid.nih.gov>

X-Mailer: Unix/3Com MX v4.8 93.11.30

From: Greg Folkers <Greg_Folkers@d31.niaid.pc.niaid.nih.gov>

To: hauslerh@who.ch, htaylor@phnet.sph.jhu.edu, jsanvill@oash.ssw.dhhs.gov,
llanier@cpcra.niaid.nih.gov, rkaslow@epi.soph.uab.edu,
sgs@hivnet.fhcrc.org, sten@geomed.dom.uab.edu, yann@aol.com,
jkovacs@nih.gov, michael_polis@nih.gov

Subject: 10/27/95 AIDS Daily Summary

AIDS Daily Summary
October 27, 1995

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"Nationline: AIDS Bite"

"American Home in Deal with Apollon for Vaccines"

"Is That a Haunted House You're Buying?"

"Australian HIV Woman on Curfew to Curb Casual Sex"

"One Million Threatened by AIDS in S. African Province"

"RiboGene Awarded Phase II SBIR Grant to Develop Novel Antifungal
Drugs"

"GMC Revises Guidelines"

"At Risk"

"Correction"

"Nationline: AIDS Bite"

USA Today (10/27/95) P. 3A; Leavitt, Paul; Goodwin, M. David;
Rivera, Patricia V.; et al.

Officials at the Centers for Disease Control and Prevention (CDC) have confirmed that a 91-year-old man contracted HIV when he was bitten by a prostitute, according to Fort Lauderdale, Fla.'s Sun-Sentinel. This is the first confirmed instance of blood-to-blood HIV transmission through a human bite. Scientists

report that blood, not just saliva, was to blame for the infection because the prostitute had bleeding gums when she bit the man on the hand, arm, and leg.

"American Home in Deal with Apollon for Vaccines"

Wall Street Journal (10/27/95) P. B3

American Home Products Corp. has announced that it will pay as much as \$100 million to Apollon Inc. to develop and test DNA vaccines for AIDS, herpes infections, and human papilloma virus. The deal will bring American Home into direct competition with Merck & Co. and Rhone Poulenc SA, which are also testing experimental versions of such vaccines. Any products resulting from the collaboration will be produced by Apollon--which recently began clinical trials of its gene-based AIDS vaccine--and sold by Wyeth-Ayerst Laboratories, a Philadelphia division of American Home.

"Is That a Haunted House You're Buying?"

Wall Street Journal (10/27/95) P. B16; Fatsis, Stefan

Earlier this year, New York joined 28 states and the District of Columbia in establishing laws that reduce the onus of disclosure from brokers selling "stigmatized properties." Stigmatized properties are considered ones that have no physical problems but are worth less or are hard to sell for emotional or psychological reasons, including murder, suicide, and other crimes. While not specifically mentioned in the law, haunted houses are generally thought of as stigmatized. Also, federal law prohibits unsolicited disclosures that a resident has or had AIDS. For states that do not offer this protection, the National Association of Realtors counsels brokers to determine whether certain information would affect a sale.

"Australian HIV Woman on Curfew to Curb Casual Sex"

Reuters (10/26/95)

The health department in the state of Western Australia has given a Perth woman a curfew and placed her under round-the-clock supervision because she continued having unprotected sex with men after being diagnosed as HIV-positive one month ago. "It is an unusual step to confine someone but under the state's Health Act this situation is no different to any contagious disease," explained the state's chief health officer Dr. Andrew Penman. The woman's case has been publicized, Penman said, to increase the public's awareness of the increasing problem of AIDS among heterosexuals.

"One Million Threatened by AIDS in S. African Province"

Reuters (10/26/95)

Researchers from the University of Natal said in a study Thursday that nearly 1 million people in KwaZulu-Natal, the most populous province of South Africa, may be infected with HIV by 1996. "The HIV/AIDS epidemic is at a more advanced stage in KwaZulu-Natal than in the rest of South Africa," the survey said. The study was conducted to determine the impact of AIDS on the 8.7-million person province. Project leader Alan Whiteside said that based on the group's projections, 920,000 residents will have HIV by next year. In addition, the researchers predicted a surge in deaths in the under five-year age group and in the 25- to 40-year age group, and that the majority of the infections would be in poorer socio-economic groups, particularly blacks in townships or impoverished rural villages.

"RiboGene Awarded Phase II SBIR Grant to Develop Novel Antifungal Drugs"

Business Wire (10/25/95)

RiboGene, Inc. has been given a Small Business Innovation Research (SBIR) phase II grant worth up to \$750,000 over two years, for the development of novel drugs for fungal infections. The grant will be applied to the discovery and development of antifungal drugs using the company's proprietary approach, which is based on aspects of translation, or protein synthesis, that are singular to fungi. "RiboGene has now received two phase II SBIR grants in rapid succession: this new award for our antifungal program, and an award in August for our HIV program," noted Charles J. Casamento, chairman, president, and CEO.

"GMC Revises Guidelines"

Lancet (10/21/95) Vol. 346, No. 8982, P. 1092; Clark, Stephanie

The General Medical Council (GMC) of the United Kingdom has revised its guidelines, primarily clarifying existing ones.

"Duties of a Doctor" states that doctors must continually update their knowledge and skills throughout their careers, acknowledge the limits of their competence, recognize patients' rights to take part in decisions related to their care, and offer treatment on the basis of clinical need. In terms of HIV and AIDS, the council notes that it is unethical for a registered medical professional to deny treatment because the doctor might be exposed. It is also unethical for HIV-infected physicians to endanger patients by not getting counseling and following the given advice. In addition, the GMC said, doctors have a responsibility to inform on colleagues who have not reported their HIV infection. Finally, if a patient denies permission for disclosure of HIV status and the physician considers a member of the health-care team to be at risk without such information, the doctor may impart the data so long as he or she can justify that action.

"At Risk"

Advocate (10/31/95) No. 693, P. 22; Moss, J. Jennings

Medicaid reform proposals put forth by the Republicans will have a profound and difficult effect on people with AIDS and HIV infection if they become law. About 36 million people are covered by medicaid this year, including half of all people with AIDS or HIV infection. Republicans are trying to reduce federal medicaid spending by \$182 billion over a seven-year period by giving block grants to the states based on population and allowing the states to decide who is eligible. Clinton, who favors a \$54-million savings over a seven-year period, has said he will veto the package because it is too extreme. Sen. John Chafee (R-R.I.) tacked on an amendment in the Senate requiring states to cover low-income pregnant women, children under 12, and people with disabilities. However, the definition of disabilities was not clarified, which could mean that some HIV-positive people would not qualify for benefits. Jeffrey Crowley, senior policy associate at the National Association of People With AIDS, said, "Can you imagine what would happen to our health care system if medicaid wasn't providing coverage to roughly half the people with AIDS? The epidemic could get much worse."

"Correction"

The Oct. 17th AIDS Daily News contained an error. An abstract of a Sept. 12 Village Voice article entitled "Not Our Job" incorrectly stated that John Killen, director of NIAID's division of AIDS, said that "NIH has neglected a potentially effective vaccine strategy which uses whole killed virus." That statement is an editorial comment on the part of the author, Mark Schoofs. Killen said that "one can make a compelling case that whole-killed virus ought to be developed, that we ought to pursue it very, very aggressively."

[353] From: GREG_FOLKERS (NIH.GREGFOLK) at SOFTSWITCH 10/30/95 10:01AM (12309 bytes: 216 ln)

To: Jane Sanville at ~ONAPC, *hauslerh@who.ch at SOFTSWITCH,
*htaylor@phnet.sph.jhu.edu at SOFTSWITCH, *llanier@cpcra.niaid.nih.gov at
SOFTSWITCH, *rkaslow@epi.soph.uab.edu at SOFTSWITCH, *sgs@hivnet.fhcrc.org at
SOFTSWITCH, STEN (INTERNET.STEN1) at SOFTSWITCH, *yann@aol.com at SOFTSWITCH,
*zacariaf@paho.org at SOFTSWITCH, *jkovacs@nih.gov at SOFTSWITCH,
*michael_polis@nih.gov at SOFTSWITCH

Subject: AIDS Daily Summary

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(Soft*Switch Central V4L380P7);

30 Oct 1995 10:01:19 EDT

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Date: Mon, 30 Oct 95 10:03:18 EST

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From: Greg Folkers <Greg_Folkers@d31.niaid.pc.niaid.nih.gov>

To: hauslerh@who.ch, htaylor@phnet.sph.jhu.edu, jsanvill@oash.ssw.dhhs.gov,
llanier@cpcra.niaid.nih.gov, rkaslow@epi.soph.uab.edu,
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Subject: AIDS Daily Summary

Date: 10-30-1995 9:38am

From: {root@aspensys.com}:unix:niaid

To: greg folkers:31:niaid

Subj: CDC AIDS Daily Summary 10/30/95

AIDS Daily Summary
October 30, 1995

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"Internet Unveils AIDS Site"

"Fired Nurse Sues Center over HIV Case"

"Indonesian Company Sends Away Thais with AIDS"

"As Threat Grows, China Launches Anti-AIDS Drive"

"Indonesia and Australia Sign AIDS Agreement"

"Asian Child Prostitution on Rise Despite New Laws"

"HIV-Positive Man Doesn't Tell; Partner Gets Infected, Pregnant"

"Streptococcus Pneumoniae Resistant to Penicillin and

Tetracycline Associated With HIV Seropositivity"

"A Randomized Study of the Clinical Effects of Initiating or
Changing Antiretroviral Therapy Based on Plasma HIV RNA

Quantitation Compared with Initiating or Changing Therapy Based on Current Clinical Practice Alone"

"Internet Unveils AIDS Site"

Washington Post--Washington Business (10/30/95) P. 15

A new World Wide Web page, called The Body, is dedicated entirely to AIDS. Located at <http://www.thebody.com>, this Internet site is intended to be a place where AIDS patients and others can obtain information, talk with others, and organize politically. In addition, by using the Web's link capabilities, The Body acts as a directory to the variety of AIDS resources already online. Such groups as the Centers for Disease Control and Prevention, People for the American Way, and Johns Hopkins University AIDS Service will provide the site's contents.

"Fired Nurse Sues Center over HIV Case"

Houston Chronicle (10/27/95) P. 35A

A Texas nurse filed a federal lawsuit against a surgical facility on Thursday, alleging that she was dismissed from the center after testing HIV-positive. Jane Doe says she learned of her HIV status in January when she took a blood test that is part of standard prenatal care. According to the suit, Doe's supervisor at Surgicare, Karen Hatley, told her to take off as much time as she needed to deal with the shock. Doe claims she did take off two weeks, and then called her supervisor to say she would be back in a few days. Hatley allegedly said that Doe would have to meet with the facility's administrator before she could be cleared to return. However, instead of setting a meeting with the administrator, who was then out of town, the supervisor called Doe the next day and fired her for excessive absenteeism. The suit claims that Hatley said that Doe had been absent more than three days in a six-month period, but Doe's lawyer says that other non-HIV-infected Surgicare employees had been absent more than three days without being let go.

"Indonesian Company Sends Away Thais with AIDS"

Reuters (10/29/95)

Thai seamen applying for jobs at an Indonesian fishing company must provide certificates stating that they do not have AIDS, the official Antara news agency reported. "We are very aware of the danger of AIDS," explained Johan Sanggelorang, director of PT Istana Samudera. Officials in the Fakfak region of Irian Jaya province, the location of the company's headquarters, blame the Thai seamen for spreading HIV in the area.

"As Threat Grows, China Launches Anti-AIDS Drive"

Reuters (10/28/95)

China's Health Ministry announced on Saturday a new long-term anti-AIDS campaign, and admitted that the spread of the disease was likely greater than officials have said. The official Guangming Daily reported that health authorities estimate that the country has up to 100,000 HIV-infected persons, a figure often quoted by specialists in private yet never published. Still, the ministry's official count of HIV cases is only 2,428, of whom 77 have AIDS. Experts say that those numbers are almost meaningless and could be dangerously deceptive, reflecting poor reporting and misdiagnosis instead of an accurate account of the epidemic in China. The health ministry announced it was adopting seven new AIDS-related policies, including the creation of a

national committee to increase AIDS prevention and control. China's largest anti-AIDS effort will be a weeklong campaign to mark World AIDS Day on Dec. 1, and will use pamphlets, posters, and videotapes to educate Chinese on how to protect themselves.

"Indonesia and Australia Sign AIDS Agreement"

Reuters (10/30/95)

Indonesia and Australia have signed a memorandum of understanding for an AIDS prevention and care campaign worth A\$20.2 million, or US\$15.3 million, according to the Australian embassy. Ambassador Allan Taylor said that in addition to the national AIDS commission of Jakarta, the effort would support projects in Bali, East Nusa Tenggara, and South Sulawesi provinces. The memorandum, which also pertains to other sexually transmitted diseases, was signed by Taylor and Coordinating Minister for People's Welfare Azwar Anas.

"Asian Child Prostitution on Rise Despite New Laws"

Reuters (10/29/95); McIntosh, Alistair

Experts claim that child abuse in Asia is increasing despite a number of new laws and a growing international awareness of pedophilia. The most frequently cited reason for child prostitution is poverty, though other factors include misguided beliefs about AIDS, a breakdown of traditional social values, and corrupt law enforcers. "Child prostitution is increasing in Asia," said Dolores Alforte, Philippine coordinator for End Child Prostitution in Asian Tourism, an international pressure group. "We can now simply say that there are more than a million children in prostitution in Asia alone," she added. A UNICEF official in Bangkok noted that one factor in the industry's continued growth is the belief that "fresh young women" do not have AIDS. AIDS is also the reason why increasingly younger children are being abused, said Maureen Seneviratne, chairman of Sri Lanka's Protecting Environment and Children Everywhere.

"HIV-Positive Man Doesn't Tell; Partner Gets Infected, Pregnant"

American Medical News (10/16/95) Vol. 38, No. 39, P. 26

The conviction and sentencing of a man for intentionally exposing a woman to HIV was upheld by the Louisiana appellate court. He was rejected as a plasma donor when his blood tested positive for the disease, but he did not inform his girlfriend although they continued to have sexual intercourse. She became pregnant in February 1990, and the couple stopped using condoms. When the woman tested positive in March 1992 for HIV and her current boyfriend tested negative, she realized the father of her child was to blame and filed a criminal complaint. The man appealed after his conviction by a trial court, asserting a number of errors in the trial court's judgment. The man claimed that his test results should have been suppressed as evidence, that the statute under which he was convicted was vague, and that the state failed to prove the woman did not consent to intercourse. The court answered all these claims and held that the man had acted with complete disregard for the health of the woman. The court also denied his claim that his 10-year sentence was excessive; the penalty for knowingly exposing a person to AIDS is between five and 20 years.

"Streptococcus Pneumoniae Resistant to Penicillin and Tetracycline Associated With HIV Seropositivity"

Lancet (10/14/95) Vol. 346, No. 8981, P. 1034; Paul, John;

Kimari, Joseph; Gilks, Charles F.

A prospective study of community-acquired pneumonia was undertaken between April to September 1992 in Nairobi to investigate the relation between antibiotic-resistant pneumococci and HIV infection. Pneumococci were isolated from specimens obtained from 87 patients upon admittance to a hospital in Nairobi who exhibited clinical and radiological features typical of pneumococcal pneumonia. Minimum inhibitory concentrations (MIC) to penicillin, tetracycline, erythromycin, and chloramphenicol were determined to define susceptibility. Antibody status to HIV was determined with Wellcozyme VK 56 HIV 1 ELISA; 52 percent of patients had antibody to HIV-1, while 48 percent were HIV-seronegative. Resistance rates for penicillin, tetracycline, erythromycin, and chloramphenicol were 17 percent, 29 percent, zero percent, and six percent, respectively. The rates were higher in HIV-positive patients than in HIV-negative patients with a ratio of 27 percent to seven percent for penicillin and 40 percent to 17 percent for tetracycline. The association of antibiotic-resistant invasive pneumococcal disease with HIV infection is an important public health concern in a low-income country where HIV infection is widespread and many therapies are too expensive.

"A Randomized Study of the Clinical Effects of Initiating or Changing Antiretroviral Therapy Based on Plasma HIV RNA Quantitation Compared with Initiating or Changing Therapy Based on Current Clinical Practice Alone"

AIDS Clinical Trials Database (08/17/95)

In a randomized study known as CPCRA 036, researchers at the National Institute of Allergy and Infectious Diseases will compare the efficacy of two antiretroviral therapy decision-making processes. Decision making based only on current clinical practice (CCP) will be contrasted against decision making based on plasma HIV RNA quantitation plus CCP. In addition, the scientists will assess toxicity, biological markers, and patient management found in the two strategies. All patients in the RNA group and some of those in the CCP unit will have a plasma HIV RNA quantitation drawn every four months, and CD4 counts will be obtained at that frequency if the previous count was less than 20. The remaining CCP patients will have their CD4 levels determined following their clinicians' CCPs. It has been theorized that measuring HIV RNA in plasma could help determine the efficacy of clinical drugs. But it is still not certain whether aggressive antiretroviral treatment to reduce HIV RNA and maintain low volumes for as long as possible will result in clinical benefit as compared to management based on monitoring CD4 levels and symptoms related to HIV.

[359] From: GREG_FOLKERS (NIH.GREGFOLK) at SOFTSWITCH 10/31/95 9:48AM (11377 bytes: 205 ln)

To: Jane Sanville at ~ONAPC, *hauslerh@who.ch at SOFTSWITCH,
*htaylor@phnet.sph.jhu.edu at SOFTSWITCH, *llanier@cpcra.niaid.nih.gov at
SOFTSWITCH, *rkaslow@epi.soph.uab.edu at SOFTSWITCH, *sgs@hivnet.fhcrc.org at
SOFTSWITCH, STEN (INTERNET.STEN1) at SOFTSWITCH, *yann@aol.com at SOFTSWITCH,
*zacariaf@paho.org at SOFTSWITCH, *jkovacs@nih.gov at SOFTSWITCH,
*michael_polis@nih.gov at SOFTSWITCH
Subject: 10/31/95 AIDS Daily Summary

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From: Greg Folkers <Greg_Folkers@d31.niaid.pc.niaid.nih.gov>

To: hauslerh@who.ch, htaylor@phnet.sph.jhu.edu, jsanvill@oash.ssw.dhhs.gov,
llanier@cpcra.niaid.nih.gov, rkaslow@epi.soph.uab.edu,
sgs@hivnet.fhcrc.org, sten@geomed.dom.uab.edu, yann@aol.com,
zacariaf@paho.org, jkovacs@nih.gov, michael_polis@nih.gov

Subject: 10/31/95 AIDS Daily Summary

AIDS Daily Summary
October 31, 1995

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"Veterans, AIDS Patients May Lose Benefits"

"AIDS Groups Fear Loss of Health Care Benefits"

"Dole's Wife to Leave Job During Race"

"Roche Holding Ltd.: FDA Approves Cytovene for an AIDS
Application"

"Digest: Cel-Sci"

"Elton John Ties into a Good Cause"

"Glyko Biomedical Announces Grants for New Genetic and AIDS
Diagnostic Tests"

"ICAAC's Small Advances"

"AIDS Update: The Relaxation Response"

"Buy, Don't Rent"

"Veterans, AIDS Patients May Lose Benefits"

Washington Post (10/31/95) P. A11; Rich, Spencer

The AIDS Action Council and two Cabinet members, Department of Veterans Affairs (VA) Secretary Jesse Brown and Health and Human Services (HHS) Secretary Donna E. Shalala, said Monday that

hundreds of thousands of veterans and AIDS patients could lose present health benefits under Medicaid changes passed by Republicans in Congress. The problems of some of the veterans on Medicaid are "some of the most costly, including AIDS and psychiatric care," said Brown and Shalala. The two secretaries noted that "as many as 172,000 veterans could lose their Medicaid coverage by 2002," according to the House plan to block-grant the Medicaid system. Additionally, Mark Barnes, executive director of the AIDS Action Council, said the House Medicaid changes could "devastate health care for the AIDS community" by decreasing funds and permitting states to choose who will receive coverage. Meanwhile, a spokesman for the House Commerce Committee observed that the potential problems that veterans and people with AIDS face are based on Medicaid grants to the states in the committee bill, but that the House also added \$12 billion nationwide for the program.

"AIDS Groups Fear Loss of Health Care Benefits"

New York Times (10/31/95) P. A22; Dunlap, David W.

AIDS care organizations say they are concerned that the proposal to give more Medicaid control to states will force thousands of patients to do without such benefits as prescription drugs and home health care. These groups are worried that block grants will spur competition in state legislatures between AIDS patients, families, the elderly, and other disabled recipients. However, Craig Murphy, a spokesman for Rep. Joe L. Barton (R-Texas) who is a member of the House Commerce subcommittee, argued, "There's no reason to assume that there's anything wrong with the priorities a state would make." Republicans claim that Congress is not cutting back on care, citing the recent reauthorization of the Ryan White CARE Act as an example. Although grateful for that legislation, AIDS groups say it is not enough because "Ryan White dollars pale in comparison to the funding that Medicaid provides for so many people with AIDS," according to Dr. R. Scott Hitt, chairman of the Presidential Advisory Council on HIV/AIDS. Statistics from the Henry J. Kaiser Family Foundation show that in fiscal year 1994, public spending on health care for people with HIV and AIDS totaled \$3.75 billion--of which almost 70 percent was paid for by Medicaid, 15 percent by the Ryan White Act, and 13 percent by Medicare.

"Dole's Wife to Leave Job During Race"

New York Times (10/31/95) P. A17; Holmes, Steven A.

Elizabeth H. Dole, wife of Senate Majority Leader Robert J. Dole (R-Kan.), said she intends to keep her job as American Red Cross president even if her husband becomes President of the United States. Dole was granted a one-year unpaid leave of absence on Sunday to travel with her husband during the Presidential campaign. As she stepped down, Dole said she wanted to devote more time to the race and that she was worried that her continued presence as Red Cross leader would entangle the agency in politics. Earlier this year, Dole voiced concerns about information the Red Cross was preparing for an AIDS education program. A special panel, created in response to her complaints, also concluded that the material did not sufficiently warn people about the risk of AIDS and that the illustrations were too sexually explicit. Still, Dole's critics argued that she was trying to tone down the content to help her husband appeal to more conservative voters--a charge which she denies. Related

Story: 'Washington Post (10/31) P. A4

"Roche Holding Ltd.: FDA Approves Cytovene for an AIDS Application"

Wall Street Journal (10/31/95) P. B10

The U.S. Food and Drug Administration (FDA) has given Hoffmann-La Roche Inc., Nutley, N.J., approval to market its AIDS drug Cytovene (ganciclovir) as a preventative treatment for cytomegalovirus retinitis. Until this point, the drug was available only as a maintenance treatment for the infection. Hoffmann-La Roche is a division of the Swiss drug giant Roche Holding Ltd.

"Digest: Cel-Sci"

Washington Post (10/31/95) P. D2

Alpha 1 Biomedicals' interest in Viral Technologies of Washington, D.C., has been acquired by Alexandria, Va.-based Cel-Sci for nearly 160,000 shares of Cel-Sci common stock, giving Cel-Sci full ownership of the concern. Cel-Sci and Bethesda, Md.-based Alpha 1 formed the company nine years ago to investigate and develop a proprietary peptide that might be used in the treatment of AIDS.

"Elton John Ties into a Good Cause"

USA Today (10/31/95) P. 2D; Sparta, Christine

Singer Elton John has lent his name to the Elton John Foundation Necktie Collection. The Italian silk ties will be available in The Knot Shop, a chain of neckwear stores, beginning this week, though some department and specialty stores will also carry them in the spring. Tie designer Jon Blades of the California-based company Whimsey Ltd. says that between 16 percent and 25 percent of the wholesale price of each tie will be donated to John's AIDS organization.

"Glyko Biomedical Announces Grants for New Genetic and AIDS Diagnostic Tests"

Business Wire (10/30/95)

Glyko Biomedical Ltd., Novato, Calif., has been awarded two grants to be used for the development of diagnostic tests. The first grant is a Phase I SBIR award worth \$67,000 from the National Institutes of Health. The company received the second grant of \$60,000 in June from the Pediatric AIDS Foundation to investigate a novel test for AZT drug resistance in people with AIDS.

"ICAAC's Small Advances"

AIDS Treatment News (10/06/95) No. 232, P. 5; Smith, Denny

At the Inter-Science Conference on Antimicrobial Agents and Chemotherapy in September, scientists presented a number of studies that, while not dramatically important, could be useful for both doctors and patients on a day-to-day basis. For example, researchers from the University of Miami and the University of California in Los Angeles suggested conditions that could increase HIV penetration of the central nervous system. In the laboratory, they found that a model of the blood-brain barrier made out of human brain endothelial cells and a sublayer of fetal astrocytes could be broken by migrating monocytes, by tumor necrosis factor inflammation, and by exposure to the drug-abuse simulating cocaethylene. The researchers theorized that in humans, the blood-brain barrier can resist HIV when not

challenged by such disruptions. Meanwhile, researchers from the National Institutes of Health and elsewhere said that the mucolytic agent NAC (N-acetyl-L-cysteine) could block the germination of spores of several kinds of fungi that cause pulmonary infections in immunocompromised individuals. Finally, several reports presented at the conference supported the use of cytokines in AIDS treatments, while many new antifungals and antimycobacterials were also introduced.

"AIDS Update: The Relaxation Response"

Men's Health (11/95) Vol. 10, No. 9, P. 42

Researchers at the University of Florida say that stress can have a detrimental effect on the health of HIV-infected persons. The researchers assessed the impact of stress on the immune systems of symptom-free HIV-positive males, and found that those people described as having "severe stress" had lower numbers of some immune-system cells, compared to relaxed persons. The findings indicate that it may be beneficial to the health of HIV-infected individuals to reduce their level of stress.

"Buy, Don't Rent"

POZ (10/95-11/95) No. 10, P. 62

The Actors' Fund has become a major landlord, a position evidenced by the fact that 40 percent of the group's funds distributed last year went directly to pay rent for HIV-infected persons. The Fund views affordable, appropriate housing as the greatest unmet need of AIDS patients, and is therefore buying and constructing homes on both the East and West Coasts. In New York City, the Fund is purchasing The Aurora, an empty 178-unit apartment building on West 57th Street. The facility will include a Fund-staffed community center which will help residents obtain benefits, as well as provide counseling and recreation. Establishing this home relieves the Fund of paying its clients' costly New York City rent. Meanwhile, in West Hollywood, the Fund is setting up two centers--the Palm View for AIDS patients, and the King's Road for the elderly, the disabled, and the poor.

MEMORANDUM FOR THE PRESIDENT

FROM: Patricia S. Fleming, Director, National AIDS Policy Office

SUBJECT: Update on Status of HIV/AIDS

Summary

In preparation for your July 28 meeting with the new Presidential Advisory Council on HIV and AIDS, the following is a briefing on the status of the epidemic and Federal policies related to the epidemic.

I. State of the Epidemic

In mid-June, the nation entered the fifteenth year of the AIDS epidemic. Between 1981 and December 1994, the Centers for Disease Control and Prevention (CDC) report that a total of 441,000 cases of AIDS had been reported in the U.S. and an estimated 271,000 Americans had died as a result of complications related to HIV. In 1994 alone, nearly 81,000 cases of AIDS were reported to the CDC and an estimated 40,000 deaths occurred in that year. The CDC estimates that 40,000 Americans become infected with HIV each year and that between 800,000 and one million Americans are living with HIV.

The demographics of the epidemic have been shifting throughout the first fourteen years. While the early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers (New York, San Francisco, and Los Angeles), it has now been reported in every state of the union. In 1994, the CDC reported that the greatest number of AIDS cases were reported in the Southeast portion of the United States.

AIDS is having an enormous impact on our nation's ability to prepare itself for the 21st century. The CDC recently reported that AIDS is now the leading cause of death among all Americans between the ages of 25 and 44. An estimated 52 percent of American workers are in this age group. As a result, it is estimated that, in 1995, AIDS will cause a loss of 1.1 million years of productive life.

While gay and bisexual men continue to represent the largest number of AIDS cases, in 1994 they comprised less than half (44%) of all new cases, continuing a decline begun in the late 1980s. Among the populations being more heavily impacted are young men between 20 and 24 (53% of cases in 1994), women (18%), and heterosexual injecting drug users (24%). Communities of color are also being severely affected. African-Americans and Hispanics represent 40 percent of new cases in 1994. Most importantly, CDC estimates that more than 50 percent of all new cases are now related directly or indirectly to substance abuse, particularly the use of injectable drugs.

(i.e. trading sex for drugs)

Some of our
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treatment, pines for
2000-2001

In 1994
35% of
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injectable drugs
in urban
states?

course of the epidemic

30%
between
straight
If heterosexual
injectable drugs

In terms of new infections, young people are comprising a much greater proportion than in the past. The National Cancer Institute estimates that one-half of all new infections occurs among people under age 25; one-quarter of infections occurs in people under 20. While the number of cases among children remains small (1,017 cases in 1994), that represents an 8 percent increase over 1993. ^{never with} And the rising number of cases among women leads researchers to estimate that by the end of this decade, some 80,000 American children will be orphaned by AIDS. ✓

Global epidemic & pandemic
The American epidemic is part of a global pandemic. The World Health Organization (WHO) recently estimated that since 1981, 4.5 million cases of AIDS have occurred around the world. Between June 1994 and June 1995, nearly 184,000 cases were reported, an increase of 19 percent over the previous 12-month period. WHO ^{also} estimates that between 14 million and 15 million people are living with HIV. Among the areas with the largest growth rates are the nations of southern and central Africa and the nations of South Asia. ✓

II. The Federal Response

The first twelve years of the Federal response to AIDS were marked by an often indifferent and hostile Executive Branch. The Reagan and Bush administrations frequently rejected the requests by health agencies for additional funding for AIDS research, prevention, and care. The Congress consistently increased the Administration requests.

During the 1992 campaign, you promised a "loud, clear, and consistent war on AIDS." In the first 30 months of your Administration you have delivered on that promise. Among the steps taken are:

- A 40% increase in funding for AIDS research, prevention, and care. That compares with a 3% increase in overall discretionary spending.
- Full funding of the Ryan White CARE Act (including the FY1996 request, funding has increased by 108%).
- Easing of Social Security disability rules to speed approval of eligibility.
- Creation of the Office of National AIDS Policy at the White House; the Presidential Advisory Council on HIV and AIDS; and the National Task Force on AIDS Drug Development.
- A 46% increase in funding for Housing Opportunities for People with AIDS.
- The NIH Revitalization Act of 1993 strengthened the Office of AIDS Research at the National Institutes of Health.

III AIDS Research

There has been a substantial investment in AIDS-related research at the National Institutes of Health (NIH). In part, the size of this investment was necessary because of the fact that there was no existing AIDS research infrastructure at the NIH or at the major academic health centers that conduct much of the government-sponsored research. As a result, there were significant annual increases in NIH AIDS research funding during the 1980s. Since then, however, the increases have been more in line with overall increases in NIH funding.

Creation of the Office of AIDS Research at NIH has helped to focus research efforts. It has been termed, by some, as a functional equivalent of a "Manhattan Project" for AIDS research. OAR Director Dr. William Paul has published a well-received five-year plan for AIDS research which is already being implemented, providing a focused, targeted approach to HIV/AIDS research. The investment in AIDS research has produced some important advances in terms of understanding HIV, the treatment of opportunistic infections, and the development of drugs to delay the onset of full-blown AIDS. While several AIDS vaccines are in the preliminary stages of research, none is close to approval. However, after a period of uncertainty bordering on despair, there have been several recent advances that have improved the immediate outlook. They include:

- **Basic Research.** Based on a consensus among researchers and affected communities, Dr. Paul has created a greater emphasis on basic research into HIV. One important breakthrough in this area indicated that the body's immune system begins to confront HIV immediately after infection. This indicates that early treatment of HIV infection can have a greater impact on life expectancy.
- **Perinatal Transmission.** The results of AIDS Clinical Trials Group 076 showed that we can diminish the risk of perinatal transmission from 25% to 8% by giving AZT to a pregnant woman early in her pregnancy, during delivery, and to her newborn for six weeks. *Not only is this the first proof that we can block HIV transmission, it's the first time a drug has been shown to block transmission of any retroviral disease.*
- **Long-Term Non-Progressors.** A small subset of HIV+ people (5-7%) live with their immune systems intact. NIH is studying the characteristics of non-progressors to see what factors might apply to this defense. It is possible that we might be able to induce the same defense mechanism in others.

not really true - there are no clinical manifestations of their infection.

The 5-year plan was Fauci's not Paul's and was created ^{the} without scientific community or AIDS comm. input. But current plans do do this.

Due in great part to federally-sponsored research, persons with AIDS are now living for as long as they did a decade ago.

- **Promising Therapies.** There are several emerging therapies that show promise in repairing the damage done by HIV to the human immune system. Several versions of protease inhibitors are in the final stages of human testing and awaiting FDA approval. Protease inhibitors block replication of HIV and allow the human body to rebuild its damaged immune system. Early tests of Interleukin-2 therapy indicate that IL-2 can replenish the human immune system.

OAR has identified four priority areas: basic science; therapeutic research with an emphasis on drug discovery; second generation vaccine development and clinical evaluation; and prevention research, including enhanced studies of risk-taking behavior and the development of female controlled barriers, such as a vaginal microbicide.

IV. AIDS Prevention

In the absence of a
~~Absent~~ a vaccine or cure, education and prevention are our best hope for controlling the transmission of HIV. Through the CDC, the Federal government spends nearly \$600 million a year in partnership with states, local governments, and community-based organizations to develop and disseminate education materials and programs. These efforts have been quite successful in terms of increasing public awareness of AIDS, the methods of HIV transmission, and the means to prevent such transmission. There have been some real "success stories" with prevention, especially among gay men, where changes in behavior were initiated by community organizations and have helped to reduce the prevalence of HIV in this population. *incidence*

ongoing However, *in other populations* there has been mixed success at permanently changing behavior associated with HIV transmission (i.e. unprotected intercourse, sharing of contaminated needles and "works"). A major *challenge* concern is to find ways to sustain behavioral changes over a lifetime (e.g. consistent use of condoms during intercourse). Effective prevention programs must be continuous, so that they can reach new generations while reinforcing messages with older groups. *these messages* They must be targeted so that segments of society will recognize the applicability of the message. And they must be linked to other services -- substance abuse treatment, in particular.

Among the positive developments are:

- Establishment of a community planning process that involves local groups in the design and implementation of prevention programs. This is a "bottom up" approach as opposed to a "top down" approach.
- The Prevention Marketing Initiative, which features public service announcements encouraging sexual abstinence and the correct and consistent use of latex condoms.
- The elimination of restrictive rules on what can and can't be discussed in prevention materials.

✓ V. AIDS Treatment and Care

Given our knowledge about the behavior of HIV in the human body, it is critical that people who are infected be entered into a continuum of care as quickly as possible. Early in the epidemic, there was little that physicians could do for patients diagnosed with HIV or AIDS. As researchers discovered treatments to delay the onset of full-blown AIDS and to treat the opportunistic infections associated with HIV, the ability of the health care system to extend the lives of people living with HIV/AIDS improved dramatically. There were two major impediments to getting this care to the people who needed it. First, many physicians and other health care professionals knew little about these new treatment advances. Second, a significant percentage of people with AIDS did not have private health insurance.

A major source of care for people with HIV/AIDS is the Medicaid program. The Health Care Financing Administration (HCFA) estimates that more than 50 percent of people with AIDS receive Medicaid benefits. Among children with AIDS, that figure is 92 percent. Another 20 percent of people living with AIDS have private health insurance. The remaining 20 percent are uninsured.

In 1990, Congress enacted the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which authorized funds to provide outpatient care and support services to people living with HIV and AIDS. Under its four titles, the CARE Act provides funds to (1) cities that are heavily affected by AIDS; (2) all states; (3) community-based clinics; and (4) other nonprofit organizations. In 1994, the CARE Act provided care to more than 200,000 uninsured and underinsured people living with HIV or AIDS, paid the prescription drugs bills of 75,000 individuals, covered the cost of counseling and testing for nearly 100,000 people, provided early care for an estimated 85,000 HIV-infected individuals, and paid the medical costs of 15,000 women and children enrolled in AIDS-related clinical drug trials.

Also in 1990, Congress enacted the Housing Opportunities for People with AIDS (HOPWA) program to assist people living with HIV and AIDS retain or obtain affordable housing. In addition to providing people and their families with housing, HOPWA helps to improve the health status of people with AIDS by reducing the need to balance the cost of housing versus the cost of care and prescription drugs. Earlier this year, the House voted to rescind the entire \$186 million HOPWA appropriation for FY1995. Following efforts by the Administration, that figure was reduced to \$30 million in the legislation you vetoed. The current version of the rescissions bill cuts \$15 million in HOPWA funds.

✓ VI. The Advisory Council

On June 11, you signed an Executive Order directing the creation of the Presidential Advisory Council on HIV and AIDS. Twenty-three members of the 30-member council were named on June 12. (A list of members is attached).

VII. Advisory Council Recommendations

Advisory Council members will present you with recommendations in the following subject areas: Leadership, Prevention, Research, Care, Medicaid, and Drug Development. A draft copy of those recommendations is attached.

- **Leadership.** The AIDS community and members of the Council are looking for a greater level of visible Presidential leadership. The focus of this criticism is less on the policies you have advocated than the use of your voice.
- **Research.** While Council members are generally supportive of the funding increases for AIDS research and the strengthening of the Office of AIDS Research, some feel you have not fulfilled your promise of a "Manhattan Project" for AIDS research. Members are also quite concerned by the recent decision by the House Appropriations Committee not to provide a single appropriation to the OAR for FY1996.
- **Prevention.** Council members are generally pleased with the direction of prevention policy, in particular, the community planning process. Some would like to see a more aggressive approach, including more targeted efforts to reach young gay men, support for clean needle exchange programs, and a greater integration of AIDS prevention and substance abuse prevention programs.
- **Care.** Council members are very pleased with the investments in the Ryan White CARE Act but are concerned about the future of HOPWA and the potential for weakening amendments to the CARE Act reauthorization.
- **Medicaid.** Council members are quite alarmed by the proposals in Congress to sharply reduce Medicaid funding and convert that program to a state-run block grant since more than 50 percent of people living with AIDS rely on Medicaid for their health benefits. Managed care programs traditionally have not served the chronically ill well due to a lack of specialists and limits on benefits.
- **Drug Development/Approval.** While drug approval time is at an all-time best, Council members are concerned by the continuing slow pace of AIDS drug development. Of particular concern is the emerging class of drugs known as protease inhibitors. Manufacturers of these drugs will make them available only to a small number of people prior to FDA approval because they do not have the manufacturing capacity to make them available more broadly.

VIII. Attachments

- Membership of the Presidential Advisory Council on HIV and AIDS.
- Draft Advisory Council recommendations.
- Questions and Answers

*Drug dev - new class...
It is also a problem for antibiotics for all drugs.*

Questions and Answers

Why haven't you been more vocal and more visible in the fight against AIDS?

I have attempted to use my office to advocate for a greater government response to AIDS while reminding the American people of the importance of this matter and the need for greater compassion for people living with this disease. I would say we've been quite successful in obtaining more funding for AIDS research, prevention, and care and improving the quality of those programs. I do intend to speak out more on this issue and use the power of the "bully pulpit."

What about your promise for a Manhattan Project of AIDS research?

When I made that promise in 1992, I felt that our AIDS research efforts lacked the kind of focus that a Manhattan Project brings. I believe we have accomplished that through the combination of a much-strengthened Office of AIDS Research at NIH, the development of a comprehensive plan by Dr. Paul, and a 26 percent increase in AIDS research funding in two years. I would say this is the equivalent of a "Manhattan Project."

You promised to lift the ban on immigration of HIV-infected individuals yet you signed a bill continuing that policy. Why?

My Administration did attempt to lift the immigration ban. However, the Congress voted overwhelmingly to maintain the prohibition begun under the Reagan Administration. The Justice Department has tried to make sure that waivers are provided for important meetings and events like the Gay Games in New York.

The National AIDS Commission recommended the use of Federal funds for clean needle exchange programs yet your Administration refuses to fund them. Why?

As you know, the Congress has created some stringent rules on the use of Federal dollars for that purpose. So far, we have been unable to prove that such programs will not increase the use of drugs while simultaneously reducing the amount of risky behavior associated with HIV transmission. We will continue to study this issue.

Your policies regarding gays and lesbians have been severely criticized. Are your gestures toward AIDS policy a smoke screen for those failures?

Well, first of all, I would have to say that this has been the most inclusive Administration in our nation's history. We've made it clear that we cannot afford to waste anyone's skills and talents. Now we haven't gotten everything we want but I think our successes far outweigh our failures. Regarding AIDS policy, the war on AIDS is everyone's war. And, as I reminded Senator Helms earlier this month, AIDS is not just a gay issue. If we are to win it, we must all engage in it.

Is this Council just window-dressing? What about the recommendations of the last AIDS Commission?

The Council includes experts in all areas of this epidemic who can bring us "real-world" expertise on HIV and AIDS. I believe it is very important for government to listen to the people it serves. As to the previous AIDS Commission, I took those recommendations very seriously and we have worked hard to carry out their proposals. More than half of the 30 recommendations were implemented in the first few months of this Administration. Most of the rest were incorporated into the Health Security Act. I continue to work with the Congress on a package of health care reforms that would address many of these issues.

Why isn't the AIDS Czar a member of the Cabinet?

This is the first time that any President has created an office within the White House to deal with a single disease. It reflects my desire to have an expert on my staff who can keep me up to date on the epidemic and help drive the Administration's response. Patsy has done a tremendous job and is a very valuable member of my staff. She has my ear and she has access to all members of the Cabinet. We all share the commitment to do everything possible to defeat this disease.

Senator Helms and others say we're spending too much on AIDS compared with what we spend on cancer and heart disease. How do you respond?

I don't think that kind of divisiveness serves anyone's interests. People with AIDS deserve our compassion and they deserve our help. The investment in AIDS research is also an investment in science, including cancer research. We have to continue to make this investment if we are ever to find a cure to AIDS.

What is your position on the proposal to require testing of pregnant women and newborns?

It's remarkable that we now know how to block transmission of the AIDS virus from mothers to infants. The key is to get more women into prenatal care and to get all doctors to counsel pregnant women about the benefits of being tested and taking AZT if they are positive. The Public Health Service guidelines are an excellent way to accomplish this. They must be implemented aggressively so that they become the standard of care. I know Congressional leaders -- including Congressman Henry Waxman -- are working very hard to resolve issues around testing. I look forward to seeing the results of their efforts.

The Housing Opportunities for People with AIDS (HOPWA) program seems to be in danger. What will you do to save it?

We recognize that people with AIDS often have a difficult time continuing to pay their rent and many times end up homeless. HOPWA was created to keep people with AIDS in their homes and with their families. This has been a very successful program and we should build on that success. I will continue to fight for funding for this critical program.

The Pentagon continues to make plans to eliminate its AIDS research portfolio. Will you prevent this from happening?

It's important that we make sure that we explore all avenues of research and that we continue the clinical trials that are being conducted at the Department of Defense. We are looking into ways to achieve both of those goals and I believe we will be successful.

Drug manufacturers plan to make protease inhibitors available to only a small number of people with AIDS prior to FDA approval. Can you do something to make these drugs more available?

I would be very reluctant to interfere in that process regarding a specific drug or product. I will ask Dr. Kessler and Dr. Paul to look at ways to avoid this supply problem in the future. The key is that we must continue our investment in research so that more drugs are developed and made available as quickly as possible. The drug approval process is the fastest its ever been and we hope to make it even faster.

typos, grammar & content

MEMORANDUM FOR THE PRESIDENT

FROM: Patricia S. Fleming, Director, National AIDS Policy Office

SUBJECT: Update on Status of HIV/AIDS

Summary

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course of the epidemic

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True in 1994 35% of new cases were in southern states. Do you mean the rate of increase was greatest in southern states?

AIDS is having an enormous impact on our nation's ability to prepare itself for the 21st century. The CDC recently reported that AIDS is now the leading cause of death among all Americans between the ages of 25 and 44. An estimated 52 percent of American workers are in this age group. As a result, it is estimated that, in 1995, AIDS will cause a loss of 1.1 million years of productive life.

all

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gay/bisexual straight If heterosexual would say somewhat certain switch to age group demographic sexual orientation demographic

(i.e. trading sex for drugs)

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Define epidemic v. pandemic
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this.*

*Due in great part to federally
sponsored research, persons with AIDS
are now
living for
as long as
they did
a decade
ago.*

*not really
true - there
are no clinical manifestations of their infection.*

are no clinical manifestations of their infection.

- **Promising Therapies.** There are several emerging therapies that show promise in repairing the damage done by HIV to the human immune system. Several versions of protease inhibitors are in the final stages of human testing and awaiting FDA approval. Protease inhibitors block replication of HIV and allow the human body to rebuild its damaged immune system. Early tests of Interleukin-2 therapy indicate that IL-2 can replenish the human immune system.

OAR has identified four priority areas: basic science; therapeutic research with an emphasis on drug discovery; second generation vaccine development and clinical evaluation; and prevention research, including enhanced studies of risk-taking behavior and the development of female controlled barriers, such as a vaginal microbicide.

IV. AIDS Prevention

In the absence of a
~~Absent~~ a vaccine or cure, education and prevention are our best hope for controlling the transmission of HIV. Through the CDC, the Federal government spends nearly \$600 million a year in partnership with states, local government, and community-based organizations to develop and disseminate education materials and programs. These efforts have been quite successful in terms of increasing public awareness of AIDS, the methods of HIV transmission, and the means to prevent such transmission. There have been some real "success stories" with prevention, especially among gay men, where changes in behavior were initiated by community organizations and have helped to reduce the prevalence of HIV in this population. *incidence*

In other populations
However, there has been mixed success at permanently changing behavior associated with HIV transmission (i.e. unprotected intercourse, sharing of contaminated needles and "works"). A major *challenge* is to find ways to sustain behavioral changes over a lifetime (e.g. consistent use of condoms during intercourse). Effective prevention programs must be *ongoing* continuous, so that they can reach new generations while reinforcing messages with older groups. *These messages* They must be targeted so that segments of society will recognize the applicability of the message. And they must be linked to other services — substance abuse treatment, in particular.

Among the positive developments are:

- Establishment of a community planning process that involves local groups in the design and implementation of prevention programs. This is a "bottom up" approach as opposed to a "top down" approach.
- The Prevention Marketing Initiative, which features public service announcements encouraging sexual abstinence and the correct and consistent use of latex condoms.
- The elimination of restrictive rules on what can and can't be discussed in prevention materials.

V. AIDS Treatment and Care

Given our knowledge about the behavior of HIV in the human body, it is critical that people who are infected be entered into a continuum of care as quickly as possible. Early in the epidemic, there was little that physicians could do for patients diagnosed with HIV or AIDS. As researchers discovered treatments to delay the onset of full-blown AIDS and to treat the opportunistic infections associated with HIV, the ability of the health care system to extend the lives of people living with HIV/AIDS improved dramatically. There were two major impediments to getting this care to the people who needed it. First, many physicians and other health care professionals knew little about these new treatment advances. Second, a significant percentage of people with AIDS did not have private health insurance.

A major source of care for people with HIV/AIDS is the Medicaid program. The Health Care Financing Administration (HCFA) estimates that more than 50 percent of people with AIDS receive Medicaid benefits. Among children with AIDS, that figure is 92 percent. Another 20 percent of people living with AIDS have private health insurance. The remaining 20 percent are uninsured.

In 1990, Congress enacted the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which authorized funds to provide outpatient care and support services to people living with HIV and AIDS. Under its four titles, the CARE Act provides funds to (1) cities that are heavily affected by AIDS; (2) all states; (3) community-based clinics; and (4) other nonprofit organizations. In 1994, the CARE Act provided care to more than 200,000 uninsured and underinsured people living with HIV or AIDS, paid the prescription drugs bills of 75,000 individuals, covered the cost of counseling and testing for nearly 100,000 people, provided early care for an estimated 85,000 HIV-infected individuals, and paid the medical costs of 15,000 women and children enrolled in AIDS-related clinical drug trials.

Also in 1990, Congress enacted the Housing Opportunities for People with AIDS (HOPWA) program to assist people living with HIV and AIDS retain or obtain affordable housing. In addition to providing people and their families with housing, HOPWA helps to improve the health status of people with AIDS by reducing the need to balance the cost of housing versus the cost of care and prescription drugs. Earlier this year, the House voted to rescind the entire \$186 million HOPWA appropriation for FY1995. Following efforts by the Administration, that figure was reduced to \$30 million in the legislation you vetoed. The current version of the rescissions bill cuts \$15 million in HOPWA funds.

VI. The Advisory Council

On June 11, you signed an Executive Order directing the creation of the Presidential Advisory Council on HIV and AIDS. Twenty-three members of the 30-member council were named on June 12. (A list of members is attached).

VII. Advisory Council Recommendations

Advisory Council members will present you with recommendations in the following subject areas: Leadership, Prevention, Research, Care, Medicaid, and Drug Development. A draft copy of those recommendations is attached.

- **Leadership.** The AIDS community and members of the Council are looking for a greater level of visible Presidential leadership. The focus of this criticism is less on the policies you have advocated than the use of your voice.
- **Research.** While Council members are generally supportive of the funding increases for AIDS research and the strengthening of the Office of AIDS Research, some feel you have not fulfilled your promise of a "Manhattan Project" for AIDS research. Members are also quite concerned by the recent decision by the House Appropriations Committee not to provide a single appropriation to the OAR for FY1996.
- **Prevention.** Council members are generally pleased with the direction of prevention policy, in particular, the community planning process. Some would like to see a more aggressive approach, including more targeted efforts to reach young gay men, support for clean needle exchange programs, and a greater integration of AIDS prevention and substance abuse prevention programs.
- **Care.** Council members are very pleased with the investments in the Ryan White CARE Act but are concerned about the future of HOPWA and the potential for weakening amendments to the CARE Act reauthorization.
- **Medicaid.** Council members are quite alarmed by the proposals in Congress to sharply reduce Medicaid funding and convert that program to a state-run block grant since more than 50 percent of people living with AIDS rely on Medicaid for their health benefits. Managed care programs traditionally have not served the chronically ill well due to a lack of specialists and limits on benefits.
- **Drug Development/Approval.** While drug approval time is at an all-time best, Council members are concerned by the continuing slow pace of AIDS drug development. Of particular concern is the emerging class of drugs known as protease inhibitors. Manufacturers of these drugs will make them available only to a small number of people prior to FDA approval because they do not have the manufacturing capacity to make them available more broadly.

VIII. Attachments

- Membership of the Presidential Advisory Council on HIV and AIDS.
- Draft Advisory Council recommendations.
- Questions and Answers

*Drug dev - new class...
It is also
a problem for
antibiotics
all drugs.*

Questions and Answers

Why haven't you been more vocal and more visible in the fight against AIDS?

I have attempted to use my office to advocate for a greater government response to AIDS while reminding the American people of the importance of this matter and the need for greater compassion for people living with this disease. I would say we've been quite successful in obtaining more funding for AIDS research, prevention, and care and improving the quality of those programs. I do intend to speak out more on this issue and use the power of the "bully pulpit."

What about your promise for a Manhattan Project of AIDS research?

When I made that promise in 1992, I felt that our AIDS research efforts lacked the kind of focus that a Manhattan Project brings. I believe we have accomplished that through the combination of a much-strengthened Office of AIDS Research at NIH, the development of a comprehensive plan by Dr. Paul, and a 26 percent increase in AIDS research funding in two years. I would say this is the equivalent of a "Manhattan Project."

You promised to lift the ban on immigration of HIV-infected individuals yet you signed a bill continuing that policy. Why?

My Administration did attempt to lift the immigration ban. However, the Congress voted overwhelmingly to maintain the prohibition begun under the Reagan Administration. The Justice Department has tried to make sure that waivers are provided for important meetings and events like the Gay Games in New York.

The National AIDS Commission recommended the use of Federal funds for clean needle exchange programs yet your Administration refuses to fund them. Why?

As you know, the Congress has created some stringent rules on the use of Federal dollars for that purpose. So far, we have been unable to prove that such programs will not increase the use of drugs while simultaneously reducing the amount of risky behavior associated with HIV transmission. We will continue to study this issue.

Your policies regarding gays and lesbians have been severely criticized. Are your gestures toward AIDS policy a smoke screen for those failures?

Well, first of all, I would have to say that this has been the most inclusive Administration in our nation's history. We've made it clear that we cannot afford to waste anyone's skills and talents. Now we haven't gotten everything we want but I think our successes far outweigh our failures. Regarding AIDS policy, the war on AIDS is everyone's war. And, as I reminded Senator Helms earlier this month, AIDS is not just a gay issue. If we are to win it, we must all engage in it.

Is this Council just window-dressing? What about the recommendations of the last AIDS Commission?

The Council includes experts in all areas of this epidemic who can bring us "real-world" expertise on HIV and AIDS. I believe it is very important for government to listen to the people it serves. As to the previous AIDS Commission, I took those recommendations very seriously and we have worked hard to carry out their proposals. More than half of the 30 recommendations were implemented in the first few months of this Administration. Most of the rest were incorporated into the Health Security Act. I continue to work with the Congress on a package of health care reforms that would address many of these issues.

Why isn't the AIDS Czar a member of the Cabinet?

This is the first time that any President has created an office within the White House to deal with a single disease. It reflects my desire to have an expert on my staff who can keep me up to date on the epidemic and help drive the Administration's response. Patsy has done a tremendous job and is a very valuable member of my staff. She has my ear and she has access to all members of the Cabinet. We all share the commitment to do everything possible to defeat this disease.

Senator Helms and others say we're spending too much on AIDS compared with what we spend on cancer and heart disease. How do you respond?

I don't think that kind of divisiveness serves anyone's interests. People with AIDS deserve our compassion and they deserve our help. The investment in AIDS research is also an investment in science, including cancer research. We have to continue to make this investment if we are ever to find a cure to AIDS.

What is your position on the proposal to require testing of pregnant women and newborns?

It's remarkable that we now know how to block transmission of the AIDS virus from mothers to infants. The key is to get more women into prenatal care and to get all doctors to counsel pregnant women about the benefits of being tested and taking AZT if they are positive. The Public Health Service guidelines are an excellent way to accomplish this. They must be implemented aggressively so that they become the standard of care. I know Congressional leaders -- including Congressman Henry Waxman -- are working very hard to resolve issues around testing. I look forward to seeing the results of their efforts.

The Housing Opportunities for People with AIDS (HOPWA) program seems to be in danger. What will you do to save it?

We recognize that people with AIDS often have a difficult time continuing to pay their rent and many times end up homeless. HOPWA was created to keep people with AIDS in their homes and with their families. This has been a very successful program and we should build on that success. I will continue to fight for funding for this critical program.

The Pentagon continues to make plans to eliminate its AIDS research portfolio. Will you prevent this from happening?

It's important that we make sure that we explore all avenues of research and that we continue the clinical trials that are being conducted at the Department of Defense. We are looking into ways to achieve both of those goals and I believe we will be successful.

Drug manufacturers plan to make protease inhibitors available to only a small number of people with AIDS prior to FDA approval. Can you do something to make these drugs more available?

I would be very reluctant to interfere in that process regarding a specific drug or product. I will ask Dr. Kessler and Dr. Paul to look at ways to avoid this supply problem in the future. The key is that we must continue our investment in research so that more drugs are developed and made available as quickly as possible. The drug approval process is the fastest its ever been and we hope to make it even faster.

[3] From: Ted Foor 10/19/95 12:03PM (26116 bytes: 1 fl)
Subject: October 20, 1995 ASCII text MMWR - 1 of 2

----- Forwarded -----

From: OWNERMMWRASCEMB (CDC.OWNERMM3) at SOFTSWITCH 10/19/95 11:30AM (25930 bytes
: 1 fl)

To: Ted Foor at ~ONAPC, *mmwr-asc-emb@list.cdc.gov at SOFTSWITCH

Subject: October 20, 1995 ASCII text MMWR - 1 of 2

----- Message Contents -----

[5] From: Ted Foor 10/19/95 1:37PM (26937 bytes: 1 fl)

Subject: October 20, 1995 ASCII text MMWR - 2 of 2

----- Message Contents -----

[377] From: GREG_FOLKERS (NIH.GREGFOLK) at SOFTSWITCH 11/7/95 10:22AM (8073 bytes: 142 ln)

To: Jane Sanville at ~ONAPC, *hauslerh@who.ch at SOFTSWITCH,
*htaylor@phnet.sph.jhu.edu at SOFTSWITCH, *llanier@cpcra.niaid.nih.gov at
SOFTSWITCH, *rkaslow@epi.soph.uab.edu at SOFTSWITCH, *sgs@hivnet.fhcrc.org at
SOFTSWITCH, STEN (INTERNET.STEN1) at SOFTSWITCH, *yann@aol.com at SOFTSWITCH,
*zacariaf@paho.org at SOFTSWITCH, *jkovacs@nih.gov at SOFTSWITCH,
*michael_polis@nih.gov at SOFTSWITCH
Subject: AIDS Daily Summary 11/07/95

----- Message Contents -----

Received: from ALW.NIH.GOV by PCC.SSW.DHHS.GOV
(Soft*Switch Central V4L380P7);
07 Nov 1995 10:22:44 EST

Received: from odie.niaid.nih.gov by alw.nih.gov (5.61/1.35(alw-2.4))
id AA02839; Tue, 7 Nov 95 10:23:45 -0500

Received: from pc.niaid.nih.gov by odie.niaid.nih.gov (5.67b/mg-1.53)
id AA24209; Tue, 7 Nov 1995 09:15:33 -0500

Date: Tue, 07 Nov 95 10:25:36 EST

Message-Id: <309f7a70@d31.niaid.pc.niaid.nih.gov>

X-Mailer: Unix/3Com MX v4.8 93.11.30

From: Greg Folkers <Greg_Folkers@d31.niaid.pc.niaid.nih.gov>

To: hauslerh@who.ch, htaylor@phnet.sph.jhu.edu, jsanvill@oash.ssw.dhhs.gov,
llanier@cpcra.niaid.nih.gov, rkaslow@epi.soph.uab.edu,
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Subject: AIDS Daily Summary 11/07/95

AIDS Daily Summary
November 7, 1995

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"Panel Recommends New AIDS Drug"

"In Brief: FDA Commissioner David Kessler"

"Trying To Design Brand New Drugs By Supercomputer"

"Radiant: PDT Inc. Is Shining a Light on New Drug Treatments"

"Social Security Bars Claim in AIDS Bias Suit"

"HIV-Related Alterations in Sleep Physiology"

"Cats May Help Fight AIDS"

"Panel Recommends New AIDS Drug"

Washington Post (11/07/95) P. A5; Neergaard, Lauran

An advisory panel to the U.S. Food and Drug Administration (FDA) has recommended that the experimental drug 3TC be approved for use in moderately advanced to advanced AIDS patients and as an initial therapy for the disease as well. Recent studies have shown that a combination of 3TC and AZT boosted the immune system of infected individuals and reduced the level of HIV in their blood. The advisory committee noted that 3TC should not be used alone and warned that it must carry a warning that it may cause

pancreatitis in children, though the drug does not appear to cause any more side effects in adults than does AZT alone. The FDA is not required to adopt the recommendations of advisory panels, but it generally does. Related Stories: Wall Street Journal (11/07) P. B7; New York Times (11/07) P. C5; USA Today (11/07) P. 1D

"In Brief: FDA Commissioner David Kessler"

Investor's Business Daily (11/07/95) P. A1

A class of new drugs up for review at the U.S. Food and Drug Administration (FDA) represents "the best news we've had in a while" concerning AIDS, according to David Kessler, FDA Commissioner.

"Trying To Design Brand New Drugs By Supercomputer"

New York Times (11/07/95) P. C1; Brody, Jane E.

A different approach to designing drugs called rational or structure-based drug design is being pursued by researchers at Cornell University and other research institutions and drug companies. Using a supercomputer that can create an image of a molecule in three dimensions, scientists can manipulate computer dials to construct a molecule that disables it. The goal is to devise inhibitors that can block the enzymes crucial to disease progression. This systematic way of creating new drugs has not produced a drug yet, but it looks promising for developing treatments to combat AIDS, African sleeping sickness, and cancer, among others.

"Radiant: PDT Inc. Is Shining a Light on New Drug Treatments"

Investor's Business Daily (11/06/95) P. A4; Lau, Gloria

New light-activated drugs are making a name for California-based PDT Inc. The drugs, which are selectively retained by diseased or cancerous cells, are activated by light, which produces a photochemical reaction in the targeted area. The new process combines drugs with medical devices to treat numerous diseases including AIDS-related Kaposi's sarcoma, skin cancer, heart disease, eye disorders, and urological conditions. PDT has so far signed deals with Pharmacia SpA, Cordis, and Boston Scientific, and several of its innovative drugs are in clinical and preclinical trials.

"Social Security Bars Claim in AIDS Bias Suit"

Human Resource Executive (10/95) Vol. 9, No. 11, P. 14; Baran, Frank

A federal judge in Philadelphia has ruled that people who seek Social Security benefits cannot also claim to be a "qualified individual with a disability" who can work. U.S. District Judge Clarence C. Newcomer was ruling in the case of Leonard McNemar, who sued his former employer, The Disney Stores Inc., for allegedly firing him because he had AIDS. McNemar argued he was dismissed just one week after a district manager asked him if he was HIV-infected. However, Disney claimed that McNemar was fired for taking two dollars from the cash register to give to a salesperson to buy cigarettes for him. The salesperson turned McNemar in on the company's loss-prevention hotline. Despite these arguments, Newcomer chose instead to focus on McNemar's application for Social Security benefits. He granted Disney's request for summary judgment and dismissed the case. McNemar's application states that he is "totally and permanently disabled," though a physician claims on the same form that he is able to

work. McNemar's lawyer explains this disparity by noting that the Social Security Administration considers AIDS "a presumptive disability"--one that is equal to a finding of automatic disability.

"HIV-Related Alterations in Sleep Physiology"

Focus (10/95) Vol. 10, No. 11, P. 7

Two small studies determined that the sleep patterns of asymptomatic HIV seropositive men differed from standard cycles. In the first study, researchers found that although sleep efficiency was greater than 90 percent, there was an increase in slow wave sleep in the second half of the night--a finding contrary to normative sleep cycles. Researchers in the second study observed specific changes in the pattern of slow wave sleep, rapid eye movement (REM), non-REM sleep cycles, and overall percentage of slow wave sleep time. Both the seropositive and seronegative groups studied reported only vague and mild sleep complaints, most of which related to falling asleep and remaining asleep. There was, however, no correlation discovered between such sleep disturbances and the alterations in sleep cycles. Overall, these two studies confirm that sleep disturbances take place both before and separately from HIV-related secondary infections and psychiatric reasons.

"Cats May Help Fight AIDS"

Futurist (11/95-12/95) Vol. 29, No. 6, P. 5

Feline immunodeficiency virus (FIV) destroys cats' immune systems in a manner similar to how HIV attacks the human immune system, theorize researchers at Texas A&M University. The scientists are trying to find ways to bolster felines' immune systems so they can better defend themselves against FIV. As a result of this research, they hope to ultimately aid humans' fight against HIV/AIDS.

Received: from LIST.CDC.GOV by PCC.SSW.DHHS.GOV

(Soft*Switch Central V4L380P7);

19 Oct 1995 11:30:51 EDT

Received: (from bin@localhost) by list.cdc.gov (8.6.12/8.6.12) id KAA00485 for mmwr-asc-emb-outgoing; Thu, 19 Oct 1995 10:51:34 -0400 Date: Thu, 19 Oct 1995 10:51:34 -0400 From: owner-mmwr-asc-emb@list.cdc.gov Message-Id: <199510191451.KAA00485@list.cdc.gov> To: mmwr-asc-emb@list.cdc.gov Subject: October 20, 1995 ASCII text MMWR - 1 of 2 Sender: owner-mmwr-asc-emb@list.cdc.gov Precedence: bulk

The October 20, 1995 ASCII text edition of the Morbidity and Mortality Weekly Report is enclosed. Please note that this information is embargoed until 12:01 a.m. Friday, October 20, 1995.

October 20, 1995/Vol. 44/No. 41

Articles included:

- * Fluoroquinolone Resistance in Neisseria gonorrhoeae --- Colorado and Washington, 1995
- * Unintentional Carbon Monoxide Poisonings in Residential Settings
- * HIV Risk Practices of Male Injecting-Drug Users Who Have Sex with Men
- * Update: Venezuelan Equine Encephalitis --- Colombia, 1995
- * Use of Mammography Services by Women Aged *65 Years Enrolled in Medicare
- * Notice to Readers

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Fluoroquinolone Resistance in *Neisseria gonorrhoeae* -- Colorado and Washington, 1995

The fluoroquinolones ciprofloxacin and ofloxacin are among the antimicrobial agents recommended by CDC for treating gonorrhea (1). In the United States, decreased susceptibility or resistance of strains of *Neisseria gonorrhoeae* to the fluoroquinolones has been reported only sporadically, and treatment failure associated with in vitro resistance has not been described (2). However, the recent occurrence of resistant cases in Denver and Seattle suggests that clinically important resistance to the fluoroquinolones may be emerging. This report describes the findings of the investigations of these cases.

Denver

On May 24, 1995, a 35-year-old man presented to the Denver Public Health Sexually Transmitted Diseases Clinic with a history of dysuria and urethral discharge of approximately 1 month's duration. On March 11, he had returned from a "dating tour" of the Philippines during which he had had sexual contact with seven or eight female sex workers (i.e., prostitutes); he denied sexual contact since returning to the United States. He was treated with

400 mg ofloxacin orally in a single dose and was given 100 mg doxycycline to take orally twice a day for 7 days. A B-lactamase-positive strain of *N. gonorrhoeae* was isolated from a urethral specimen. On June 7, when the patient returned to the clinic with continuing symptoms, gram-negative intracellular diplococci were detected in a smear of urethral discharge. He denied sexual contact since the previous visit but reported he had not completed the prescribed doxycycline regimen. He was again treated with 400 mg ofloxacin and given 500 mg erythromycin to take orally four times a day for 7 days. A B-lactamase-negative strain of *N. gonorrhoeae* was isolated from a urethral specimen.

Because of suspected quinolone-resistant *N. gonorrhoeae* infection, the patient was recalled to the clinic on June 16 and treated with 250 mg ceftriaxone intramuscularly, even though his symptoms had resolved. He reported taking erythromycin for 3-4 days. Both a gram-stained smear and culture were negative for *N. gonorrhoeae*.

The susceptibilities of *N. gonorrhoeae* isolates from the patient's first and second visits were determined by agar dilution and disk diffusion tests (3). The minimum inhibitory concentrations (MICs) of the B-lactamase-positive isolate from the first visit were 1.0 ug/mL and 2.0 ug/mL of ciprofloxacin and ofloxacin, respectively (Table 1); the corresponding disk diffusion susceptibilities (inhibition zone diameters) were 21 mm to ciprofloxacin (5-ug disk) and 20 mm to ofloxacin (5-ug disk). This isolate possessed a 3.2-megadalton B-lactamase plasmid. The MICs of the B-lactamase-negative isolate from the second visit were 4.0 ug/mL and 8.0 ug/mL of ciprofloxacin and ofloxacin, respectively; corresponding inhibition zone diameters were 11 mm to ciprofloxacin and 12 mm to ofloxacin. Both isolates were susceptible to ceftriaxone (MICs, 0.004 ug/mL and 0.015 ug/mL); the second isolate was resistant to tetracycline-hydrochloride (HCl) (2.0 ug/mL). The isolates were further characterized by auxotype/ serovar (A/S) class; both belonged to the same A/S class, Pro/IB-8 (Table 1) (4).
Seattle

From late May through early August 1995, fluoroquinolone-resistant strains of *N. gonorrhoeae* were isolated from eight residents of Seattle-King County, Washington. These strains represented eight (4%) of 225 gonorrhea cases from which isolates were available for testing during this period. Of the eight cases, five occurred among women. Five (63%) of the eight patients infected with this strain were commercial sex workers or sex partners of sex workers compared with 14 (11%) of 126 of a random sample of patients infected with other *N. gonorrhoeae* strains (*p* less than 0.01). None of the patients infected with a fluoroquinolone-resistant strain had been treated with a quinolone or had a history of international travel; all had been treated with a broad-spectrum cephalosporin (cefixime or ceftriaxone). Despite expanded laboratory surveillance in King and adjacent counties, no additional cases have been identified since August 10.

These strains had ciprofloxacin and ofloxacin MICs of 8.0 ug/mL; inhibition zone diameters to ciprofloxacin and ofloxacin were 12 mm-14 mm and 10 mm-12 mm, respectively. All isolates had a 3.05 megadalton B-lactamase plasmid and were resistant to

tetracycline-HCl (2.0 ug/mL) but were susceptible to ceftriaxone, cefixime, and spectinomycin (Table 1). All isolates belonged to the same A/S class, Proto/IB-1, and had indistinguishable antimicrobial susceptibility profiles (Table 1), suggesting the spread of a single strain of *N. gonorrhoeae*.

Reported by: J Ehret, MS, JM Douglas, MD, FN Judson, MD, Denver Dept of Health and Hospitals, Colorado. J Hale, MS, Dept of Medicine, Univ of Washington; B Krekeler, MSPA, HH Handsfield, MD, Seattle-King County Dept of Public Health, Washington. Epidemiology and Surveillance Br, Div for Sexually Transmitted Diseases Prevention, National Center for Prevention Svcs; Gonorrhea, Chlamydia, and Chancroid Br, Div of AIDS, STD, and TB Laboratory Research, National Center for Infectious Diseases, CDC.

Editorial Note: The confirmation of the resistant strains in Colorado and Washington has at least four important epidemiologic and clinical implications. First, the infection in the patient from Denver failed to respond to therapy with the CDC-recommended dose of ofloxacin, and the susceptibilities of the infecting strains were consistent with fluoroquinolone resistance (5). Despite reports of sporadic therapy failures in Australia, Hong Kong, and the United Kingdom (6-8), this case report is the first documentation in the United States of a gonococcal infection caused by a strain with in vitro resistance failing to respond to fluoroquinolone therapy. Second, the report from Seattle is the first documentation of sustained transmission of this resistant phenotype in the United States. Third, both the case in Denver and the outbreak in Seattle were associated with commercial sex workers. The isolation of resistant strains from persons who may have large numbers of anonymous sexual contacts suggests the possibility of rapid spread of these strains. Finally, the fluoroquinolone MICs of these strains (Table 1) are substantially higher than those of other fluoroquinolone-resistant strains (ciprofloxacin MIC, 2.0 ug/mL) previously isolated in the United States (2).

The MICs of the strains isolated in both Denver and Seattle suggest that infections caused by such strains often would fail to respond to treatment with the CDC-recommended doses of these fluoroquinolones. Although doxycycline is used to treat patients with gonorrhea for possible coexisting chlamydial infection, one of the strains isolated from the patient in Denver and all the isolates from Seattle were resistant to tetracycline (Table 1) (3). Thus, infections caused by such strains that fail to respond to treatment with a fluoroquinolone also may fail to respond to doxycycline.

The patient in Denver probably acquired his fluoroquinolone-resistant gonococcal infection in the Philippines—an exposure that is consistent with a recent report of high-level fluoroquinolone-resistant *N. gonorrhoeae* among commercial sex workers in the Philippines (9). No international link has been identified for the cluster of cases in Seattle.

The findings in this report of high-level fluoroquinolone resistance are consistent with recent results from the Gonococcal Isolate Surveillance Project (GISP), a national surveillance system (10). During 1994, two (0.04%) of 4996 isolates from 24 sexually

transmitted diseases clinics had ciprofloxacin MICs greater than or equal to 1.0 ug/mL, the provisional criterion for resistance to ciprofloxacin (5). However, 65 (1.3%) of 4996 isolates exhibited decreased susceptibilities to ciprofloxacin (MICs, 0.125-0.5 ug/mL), an increase from 17 (0.3%) of 5238 isolates tested in 1991 (p less than or equal to 0.001). Only one additional ciprofloxacin-resistant *N. gonorrhoeae* case has been detected among approximately 2500 isolates tested by GISP during 1995 (CDC, unpublished data, 1995).

Although fluoroquinolone resistance does not appear to be widespread in the United States, the cases described in this report emphasize the need for heightened awareness about the potential for the emergence of clinically important resistance. Isolates obtained from patients whose infections fail to respond to fluoroquinolone therapy or from patients who have acquired their infections in certain parts of Asia should be tested for susceptibility to fluoroquinolones using the disk diffusion method recommended by the National Committee for Clinical Laboratory Standards (3). Based on theoretical predictions and a limited number of documented failures of gonococcal infections to respond to fluoroquinolones, CDC has proposed criteria for defining a resistance category of susceptibilities to ciprofloxacin and ofloxacin (5). Strains with MICs of greater than or equal to 1.0 ug/mL ciprofloxacin or greater than or equal to 2.0 ug/mL ofloxacin are interpreted as resistant to these agents. The corresponding inhibition zone diameters obtained by disk diffusion susceptibility testing are less than or equal to 29 mm to ciprofloxacin and less than or equal to 24 mm to ofloxacin (5).

Because fluoroquinolone-resistant *N. gonorrhoeae* strains appear to be occurring infrequently in the United States, CDC continues to recommend treating gonorrhea either with a single dose of 500 mg ciprofloxacin, 400 mg ofloxacin, 400 mg cefixime orally, or 125 mg ceftriaxone intramuscularly. Each agent should be followed by treatment with a regimen effective against possible infection with *Chlamydia trachomatis*. Lower doses of either the fluoroquinolones or cephalosporins should not be used. For patients who may have acquired infection in certain parts of Asia, clinicians should consider treatment with cefixime, ceftriaxone, or spectinomycin when treatment with a cephalosporin is contraindicated. The appropriateness of these recommendations will be reassessed based on surveillance of the prevalence of fluoroquinolone-resistant gonococci.

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Unintentional Carbon Monoxide Poisonings in Residential Settings -- Connecticut, November 1993-March 1994

Carbon monoxide (CO) gas is an environmental hazard, and unintentional CO poisonings have occurred in multiple settings, including residences, motor vehicles, and workplaces. In 1993, exposure to CO produced by a malfunctioning natural gas furnace in a Suffield, Connecticut, home resulted in the deaths of three children and hospitalization of four other family members. Publicity resulting from this and other CO poisoning incidents prompted concern that gas furnaces have been a primary cause of residential CO poisonings in Connecticut. To determine the sources of residential CO poisonings in Connecticut, the Connecticut Department of Public Health (CDPH) surveyed persons with cases of CO poisoning during November 1993-March 1994. This report presents the survey findings.

CDPH reviewed the daily telephone logs of the Connecticut Poison Control Center (CPCC) to identify potential nonfatal CO poisonings during November 1993-March 1994. To determine whether potential cases met the case definition for a CO poisoning and whether the source of CO was residential, nurses from the CPCC collected additional details about poisonings through telephone interviews. A case was defined as two or more symptoms consistent with CO poisoning (i.e., headache, nausea, diarrhea, dizziness, dry mouth, drowsiness, or vomiting) or CO poisoning diagnosed by a physician and a carboxyhemoglobin (COHb) level greater than 10% (normal concentration: less than 2% for nonsmokers, 5%-9% for smokers). A 32-item questionnaire was administered by CDPH to one adult respondent in each household to obtain information about demographics and socioeconomic status for each person in the

household with CO poisoning, as well as information about symptoms, potential CO sources, details of the investigation and remediation of CO in the home, and the respondent's knowledge of CO poisoning before the incident.

A total of 197 records of potential nonfatal CO poisonings were identified; of these, 139 (71%) contained both the name and telephone number of persons with potential cases. Overall, 61 (44%) persons could be contacted, and 51 (84%) were considered to have had CO poisoning resulting from exposure to a residential source of CO. These 51 persons ranged in age from 1 to 71 years (median: 32 years); most (83%) were aged 20-49 years. Persons with CO poisoning resided in 36 households: 19 (53%) single-family dwellings, 11 (31%) multifamily dwellings, four (11%) apartments, and two (6%) dwellings classified as other.

The most common source of CO in these 36 homes was heating systems: oil heating systems (16 households), gas heating systems (11), and kerosene heaters (three). Gas appliances and fireplaces were identified as the CO source in six households.

Reported symptoms for the 51 patients included headache (88%), dizziness (83%), nausea (75%), drowsiness (75%), dry mouth (44%), diarrhea (17%), and vomiting (11%). For 28 (55%) patients, the first symptom noted was headache; for eight (16%), dizziness; for seven (13%), nausea; for five (10%), dry mouth; and for three (6%), drowsiness. Twenty-two (43%) patients consulted a physician. Of the 33 patients who suspected they were experiencing CO poisoning, 10 (30%) became concerned because of information obtained previously from television news media; eight (24%), because of prior knowledge of CO poisoning; eight (24%), because of information previously learned from others; four (12%), because of an odor from a malfunctioning appliance; two (6%), because of a CO detector; and one (4%), because of some other reason. For 32 cases, data were available about the interval between onset of symptoms and the time at which the patient first considered CO as the cause of symptoms: for 10 (31%), the interval was less than 1 hour; for three (9%), 1-12 hours; for five (16%), 24.1 hours-4 days; for one (3%), 4.1-7 days; and for 13 (41%), greater than 7 days.

The 36 respondents also were asked about possible methods to prevent CO exposure: 22 (61%) provided one method, eight (22%) provided two, and one (3%) provided three; five (14%) were unable to list any method. Prevention methods included appropriate maintenance of appliances (16), use of a CO detector (14), proper ventilation of the room (five), public education (three), and other actions (three).

Sources of CO were identified primarily by heating-system technicians (48%) or a resident (38%). Sources also were identified by fire department personnel (10%) or building officials (3%). Methods of identification were visual inspection of the furnace or heating system (63%), process of elimination (18%), CO meters (11%), and other (7%). Actions taken to correct the CO emissions included replacing the furnace; ventilating the room; and/or cleaning, repairing, or discontinuing use of the malfunctioning appliance.

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Editorial Note: Unintentional CO poisonings result in approximately 600 deaths annually in the United States (1). A surveillance system implemented by the Colorado Department of Health in 1985 has helped to characterize the epidemiology of fatal and nonfatal CO poisonings (2). Findings from this system indicate that, during 1986-1991, the primary sources of 1149 CO poisonings in Colorado were furnaces in residential settings (40%), automobile exhaust (24%), and fires (12%). Furnaces were the source of CO in 46% of nonfatal CO poisonings but only 10% of fatal poisonings, suggesting that the primary sources of CO associated with nonfatal poisonings differ from those for fatal cases. In addition, findings from the Colorado surveillance system indicate that mortality data may underestimate the importance of furnaces as a source of CO in residential settings.

Other studies also have documented that furnaces are important sources of CO in residential CO poisonings. For example, of the 38 residential CO-related episodes investigated in West Virginia during 1978-1984, furnaces or space heaters were implicated in most (89%) incidents (3); 94% of the faulty units were fueled by methane or butane. In Connecticut, although most (75%) CO poisonings were caused by faulty furnaces, oil-fueled furnaces were the source of CO more often than natural gas--possibly reflecting a higher percentage of oil- or kerosene-fueled furnaces in homes in New England (51% in homes in New England compared with 6% in the Midwest, 7% in the South, and 2% in the West) (4). In addition, based on the 1990 census, the distribution of furnace types identified as sources of CO in this survey is representative of the distribution throughout Connecticut (gas furnaces, 28%, and oil or kerosene furnaces, 54%) (4).

CDPH is using the findings in this report to educate the public about sources of CO and strategies to prevent CO poisoning. Prevention of CO poisoning requires that 1) homeowners and renters recognize that all combustion appliances must be professionally installed to ensure both complete combustion of the fuel and adequate ventilation of combustion products (4); 2) combustion appliances be maintained and inspected annually; 3) fuels not be burned in confined spaces (e.g., tightly closed rooms); 4) public education efforts highlight the early manifestations of CO intoxication; 5) homeowners and renters be informed about the availability of low-cost CO detectors and public health agencies document the effectiveness of these devices; and 6) health-care providers--particularly emergency department personnel--consider the possibility of poisoning from residential exposure to CO in patients reporting typical symptoms (e.g., headache, nausea, vomiting, and malaise). Additional information about CO detectors is available from the Consumer Product Safety Commission hotline (800) 638-2772 or (301) 504-0220.

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Received: (from bin@localhost) by list.cdc.gov (8.6.12/8.6.12) id KAA00491 for mmwr-asc-emb-outgoing; Thu, 19 Oct 1995 10:52:12 -0400 Date: Thu, 19 Oct 1995 10:52:12 -0400 From: owner-mmwr-asc-emb@list.cdc.gov Message-Id: <199510191452.KAA00491@list.cdc.gov> To: mmwr-asc-emb@list.cdc.gov Subject: October 20, 1995 ASCII text MMWR - 2 of 2 Sender: owner-mmwr-asc-emb@list.cdc.gov Precedence: bulk

HIV Risk Practices of Male Injecting-Drug Users Who Have Sex with Men -- Dallas, Denver, and Long Beach, 1991-1994

As of June 1995, a total of 31,024 cases of acquired immunodeficiency syndrome (AIDS) had been reported in the United States among male injecting-drug users (IDUs) who also reported sexual contact with other men (1). Although male IDUs who report male sex partners have accounted for 7% of all AIDS cases and for 21% of cases reported among IDUs, the characteristics and risk practices of male IDUs who have sex with men (MSM) have not been clearly determined (2-4). To better characterize this group of men with multiple risk factors for human immunodeficiency virus (HIV) infection, data collected during February 1991 through June 1994 from three sites--Dallas; Denver; and Long Beach, California--were analyzed as part of the CDC-sponsored AIDS Community Demonstration Projects (5,6). This report summarizes results of that analysis.

The Community Demonstration Projects included interviews of male IDUs conducted in neighborhoods with a high prevalence of drug use. Trained interviewers approached potential respondents on the street to administer a screening interview that assessed recent HIV risk practices (i.e., needle sharing during the preceding 60 days or vaginal or anal intercourse during the preceding 30 days). At-risk persons also completed a second interview about perceived risk for HIV infection, drug- injection practices, and sexual behavior. A cash incentive or grocery vouchers were provided for completing each interview. This report presents data for men who reported injecting drugs during the preceding 30 days.

Nearly all (1697 [93%] of 1820) of the sexually active male IDUs who were screened completed the second interview. Of these, 297 (18%) reported having had one or more male sex partners during the preceding 30 days. The percentage of MSM IDUs varied by city (Denver, 28%; Dallas, 22%; and Long Beach, 10%). Nearly two thirds (178 [60%] of 297) of MSM IDUs self-identified as bisexual, 97 (33%) as heterosexual, and 15 (5%) as homosexual; seven (2%) were undecided about their sexual identity. Most MSM IDUs in this sample were black (192 [65%] of 297), aged greater than or equal to 30 years (224 [75%]), and recruited at the Denver site (167 [56%]).

A total of 224 (75%) MSM IDUs had traded sex for money or drugs during the preceding 30 days. Almost all (283 [95%]) had had more than one sex partner during the preceding 30 days. The mean number of male partners during the preceding 30 days was 3.8 (range: 1-41; standard deviation [SD]: plus or minus 5.6). Most (263 [89%]) reported having one or more (mean: 4.5, range: 0-61, SD: plus or minus 6.4) female sex partners. A total of 148 (50%) reported having had a partner whom they identified as their main or

primary sex partner. Of those with a main partner, 110 (74%) of 148 indicated this partner was female.

Nearly all MSM IDUs (290 [98%]) reported having ever had vaginal intercourse. During the preceding 30 days, 267 (90%) had had vaginal intercourse with main and/or other partners. Of those with a female main partner, 13 (12%) of 105 reported using a condom the last time they had vaginal intercourse; of those who had had vaginal sex with someone they did not consider to be their main partner (i.e., non-main partner), 30 (13%) of 233 had used a condom at last intercourse.

Nearly all (282 [95%]) had ever engaged in anal intercourse; 201 (71%) had had anal intercourse with both men and women, 51 (18%) with men only, and 30 (11%) with women only. Most (250 [84%] of 297) had also had anal intercourse during the preceding 30 days. Data regarding condom use during anal intercourse during the preceding 30 days were collected for a subset of respondents. Eight (23%) of 35 of those with a male main partner and eight (20%) of 41 of those with a female main partner used a condom the last time they had anal intercourse with this partner. Among MSM IDUs with non-main partners, 53 (27%) of 200 used a condom the last time they had anal intercourse.

During the preceding 60 days, 250 (86%) of 292 MSM IDUs reported having shared syringes or other paraphernalia used to prepare or inject illicit drugs. Less than one third (73 [29%] of 248) indicated that the last time they shared injection equipment they used bleach to clean their needle or syringe.

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Editorial Note: Approximately 18% of male IDUs interviewed at the three sites in this study reported having had sex with another male during the previous 30 days--a rate higher than that reported for a national sample of men aged 20-39 years (7), but consistent with previous studies of male IDUs (2,4). Although these previous studies were based on convenience samples and the estimates probably were not representative of the total population of IDUs, the range for the prevalence of MSM activity among IDUs is similar to that documented in the three sites in this report.

In this study, the prevalences of drug-injection and sexual practices associated with the transmission of HIV infection were high among MSM IDUs, including recent sharing of injection equipment, trading of sex for money or drugs, engaging in anal sex, and having had multiple sex partners. Because such practices increase the risk for acquiring and/or transmitting HIV infection to needle-sharing and sex partners, intervention programs for MSM IDUs should address both drug-related and sexual risk factors.

The findings in this report also indicate that sexual self-identification as heterosexual or homosexual may not

correspond with sexual practices. Assessment of risk for HIV infection should be based on behavior, regardless of self-identification. Self-identification as heterosexual or bisexual, however, may be useful in planning and conducting intervention activities (8). For example, efforts to provide preventive measures to MSM IDUs who do not self-identify as homosexual may need to be directed through a variety of settings because such men may ignore or resist messages that appear to be targeted toward men who are homosexual.

The use of neighborhood-based samples in Dallas, Denver, and Long Beach may have resulted in some biases. For example, some important subgroups (e.g., amphetamine users and men who self-identify as homosexual) probably were undersampled, while other groups (e.g., men who traded sex for money or drugs) may have been oversampled. Although these potential sampling biases may have influenced the patterns of HIV risk in this study, the extent to which these biases affected the estimates of HIV risk among MSM IDUs could not be assessed.

The development of programs for preventing HIV transmission among MSM IDUs requires that public health agencies and local community-planning groups characterize the risk for this group and examine available data from AIDS case reports, HIV counseling and testing sites, and behavioral surveillance surveys. Determinants for risk that may vary by location include demographic characteristics, patterns of sexual practices and of substance use, and access to HIV-prevention services.

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Update: Venezuelan Equine Encephalitis -- Colombia, 1995

During September 1-October 12, 1995, a total of 12,403 patient visits for Venezuelan equine encephalitis (VEE) were reported from La Guajira state, Colombia. The actual number of incident cases,

estimated from epidemiologic surveys, may exceed 45,000. This report updates the ongoing investigation of this outbreak (1).

Household surveys in urban areas of Manaure, Maicao, Riohacha, and Uribia during September 26-October 3 indicated an overall attack rate of 18%, ranging from 13% in Riohacha (the largest of the towns) to 57% in Manaure. In 101 patients in Manaure, Maicao, and Riohacha who sought medical care within 3 days of onset of acute febrile illness, the point prevalence of VEE-specific immunoglobulin M antibody was 45%, providing a minimum estimate of the specificity of the clinical case definition. Of the 18 VEE virus strains isolated from humans, three were identified antigenically as IC-subtype viruses, which have been the principal cause of epizootics in northern South America. Partial nucleotide sequencing of the strains indicated they were closely related to strains isolated from Venezuela earlier in 1995.

The outbreak has spread southwest along the coastline at a rate of approximately 3 miles (5 km) each day (Figure 1). In the coastal towns of Manaure, Mayapo, El Pajaro, and Dibulia, entomologic surveys have detected large populations of the vector mosquito *Aedes taeniorhynchus*. The initiation of mosquito-control programs was followed by declines in emergency department visits for acute febrile illness in Manaure, Maicao, Riohacha, and Uribia. In addition, entomologic surveys indicated 99%-100% declines in *Ae. taeniorhynchus* larval densities after breeding sites were treated with *Bacillus sphaericus* (a larvicide).

In the inland region south of Maicao, the outbreak has extended to the municipality of Riohacha, near El Cerrejon coal mine in Hatonuevo. Surveys in Maicao and the south of La Guajira Department have identified extensive breeding habitats for *Psorophora confinnis* and abundant larvae.

Households in Maicao, Riohacha, and Uribia that had more than one case were studied to determine whether secondary person-to-person transmission had occurred. A secondary case was defined as onset of acute febrile illness 1-5 days after onset of illness in the first case(s) in the household. Primary cases occurring within 5 days of the interview were excluded. The apparent secondary attack rate was 5% (50 of 992).

Public health efforts have focused on limiting the spread of the outbreak from La Guajira peninsula to the Magdalena Valley to the south at passes formed by the Sierra Nevada de Santa Marta Mountains (Figure 1). Ongoing active surveillance of all hospitals in La Guajira through October 12 indicated no evidence of human cases in the southern part of the state. Unconfirmed equine cases were reported near Santa Marta, but no human cases acquired in Magdalena have been confirmed. Sporadic equine deaths in Cordoba, Cesar, and Magdalena states have been confirmed serologically as cases of eastern equine encephalitis. In the area beyond the advance of the outbreak (Figure 1), approximately 5000 equines in La Guajira have been vaccinated with TC-83 vaccine; in neighboring Magdalena and Cesar states, 20,000 and 70,000 equines, respectively, have been vaccinated.

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Editorial Note: Although the VEE outbreak has spread rapidly through La Guajira, control measures have contained the outbreak within this northern-most state of Colombia, with no evidence of human cases in adjoining Magdalena and Cesar states. Equine vaccination creates an immune barrier against the spread of the virus by removing the most important vertebrate amplifying host from the epizootic transmission cycle. Larvicidal treatment of breeding sites reduces the number of vector mosquitoes, but its continued effectiveness may be difficult to maintain during the wet season--which in La Guajira usually lasts through November.

VEE appeared in Venezuela in April 1995 and spread westward, with the first cases in Colombia recognized in August at the common border of the two countries. The virus most likely was transferred in a viremic equine or human and spread from there to the western coast of La Guajira. Comparisons of viral strains from Colombia and Venezuela indicate a close genetic relation (2).

Because VEE virus has been recovered from pharyngeal cultures in 40% of patients (3) and aerosols of VEE virus have infected laboratory personnel, direct human-to-human transmission of VEE virus may be possible. However, it is unknown whether infectious VEE aerosols or respiratory droplets can be produced by infected humans. Human-to-human transmission by mosquitoes may occur during some epidemics, as suggested in previous outbreaks (4); however, the household survey in La Guajira found no evidence of direct person-to-person transmission.

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Use of Mammography Services by Women Aged greater than or equal to 65 Years Enrolled in Medicare -- United States, 1991-1993

The incidence of invasive breast cancer among women aged greater than or equal to 65 years is twice that among those aged 35-44 years (1), and the death rate from breast cancer is

approximately three times higher among women aged greater than or equal to 65 years than among women aged 35-64 years (2). Although routine screening mammography among women aged greater than or equal to 50 years can reduce breast cancer mortality by greater than or equal to 30% by detecting tumors at early, more treatable stages (3), older women are less likely to receive screening mammograms (4). The Health Care Financing Administration (HCFA) routinely examines trends in the use of health services by age, race, and sex to monitor access to medical care for Medicare beneficiaries. Using Medicare claims data, HCFA estimated rates of mammography use among women aged greater than or equal to 65 years during 1991-1993. This report presents the findings of this analysis.

Women enrolled in Medicare are eligible for diagnostic and screening mammograms under the Medicare Part B program, which enrolls approximately 96% of U.S. residents aged greater than or equal to 65 years. Biennial screening mammography for women aged greater than or equal to 65 years has been a Medicare benefit since January 1, 1991; previously, only diagnostic mammograms were covered under Medicare Part B. Both screening and diagnostic mammography are reimbursed at 80% of allowed charges after an annual deductible of \$100 for all Part B services.

For this analysis, Medicare claims data for services provided during 1991-1993, were used to calculate annual rates of mammography use for enrolled women aged greater than or equal to 65 years; age- and race-specific rates also were calculated.

Race-specific rates are presented for blacks and whites only because identification of other racial groups is incomplete in the Medicare administrative data system. Because claims are not submitted for the Medicare population enrolled in managed-care plans (approximately 7% in 1993) (5), rates are based on women enrolled in fee-for-service Medicare. Three cohorts of women were established using the Medicare denominator files for 1991, 1992, and 1993. Each annual cohort consisted of approximately 16 million women (Table 1) who were continuously enrolled in fee-for-service Medicare parts A and B. Women excluded from this analysis were those aged less than 65 years as of January 1 of the year, those enrolled in a health maintenance organization at any time during the year, and those who died during the year. Rates of mammography use represent the percentage of women in each cohort who had one or more mammograms (screening or diagnostic) during that year. Because providers do not uniformly apply the codes used to bill Medicare for mammograms, Medicare claims cannot reliably distinguish screening and diagnostic mammograms; therefore, both types of mammography are included in this analysis.

During 1991-1993, of each annual cohort of approximately 16 million women aged greater than or equal to 65 years who were continuously enrolled in fee-for-service Medicare, 3.8-4.0 million (approximately 25%) had one or more mammography claims (Table 1). During this period, rates of mammography use varied inversely with age of the beneficiary (Figure 1); in all years, the rate for women aged 80-84 years was less than half that for women aged 65-69 years. For all age groups, black women were less likely than white women to have received mammograms, although this difference

declined during each of the 3 years: in 1991, the black-to-white ratio of mammography rates was 0.64:1, compared with 0.71:1 in 1993 (Table 2).

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Editorial Note: The findings in this report are consistent with previous studies that indicate a low rate of mammography use among women aged greater than or equal to 65 years (4). In this analysis, black women and women aged greater than or equal to 85 years were least likely to have received mammograms under Medicare. A national health objective for the year 2000 is to increase to 60% the percentage of women aged greater than or equal to 50 years who received a mammogram and clinical breast examination during the previous 2 years (objective 16.11) (6). Among Medicare beneficiaries, the biennial rate of mammography use for 1992-1993 was 37% for women aged greater than or equal to 65 years (7).

In addition to the patient and physician attributes known to influence screening mammography use (8), three additional factors may explain the low rate of use among this elderly Medicare population. First, for women aged greater than or equal to 75 years, low rates of use may be a consequence of variations in recommendations by professional associations to perform screening mammography for women in this age group (9). Second, for black women, low rates may reflect financial barriers (e.g., the Part B deductible or copayments) and other obstacles in the delivery of health services to women of lower socioeconomic status. Finally, overall low use of mammography by Medicare beneficiaries also may reflect limited awareness of this health benefit: in 1992, approximately two thirds of elderly women were unaware that mammography was a Medicare benefit (10).

In response to the low awareness and low use of the Medicare mammography benefit, HCFA has organized multimedia outreach efforts through its national and regional offices. Since May 1995, approximately 50 major organizations have participated in campaigns to publicize mammography as a Medicare benefit; participating organizations have included CDC and other federal agencies, health-care provider associations, senior citizen groups, voluntary organizations, major corporations, and trade associations. These outreach efforts also are being promoted during National Breast Cancer Awareness Month in October. In addition to informational efforts aimed at elderly women enrolled in Medicare and their families, county-level and race-specific annual and biennial mammography rates were made available to local and national health organizations to assist in developing interventions to increase mammography use (7).

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influenza-associated deaths, the trend for mean weekly number of P&I deaths for the noninfluenza period (weeks 26-39) was analyzed. From 1979 through 1992, age-adjusted P&I death rates during these weeks increased from 3.1 to 3.7 per 1 million population. Analysis of P&I deaths listed in any position on the death certificate (multiple-cause-of-death data) indicated a similar increase."

Erratum: Vol. 44, No. RR-12

In the MMWR Recommendations and Reports "Recommendations for Preventing the Spread of Vancomycin Resistance: Recommendations of the Hospital Infection Control Practices Advisory Committee (HICPAC)," the publication date printed at the top of even-numbered pages ii-12 should have been September 22, 1995.

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Received: (from bin@localhost) by list.cdc.gov (8.6.12/8.6.12) id KAA00491 for mmwr-asc-emb-outgoing; Thu, 19 Oct 1995 10:52:12 -0400 Date: Thu, 19 Oct 1995 10:52:12 -0400 From: owner-mmwr-asc-emb@list.cdc.gov Message-Id: <199510191452.KAA00491@list.cdc.gov> To: mmwr-asc-emb@list.cdc.gov Subject: October 20, 1995 ASCII text MMWR - 2 of 2 Sender: owner-mmwr-asc-emb@list.cdc.gov Precedence: bulk

HIV Risk Practices of Male Injecting-Drug Users Who Have Sex with Men -- Dallas, Denver, and Long Beach, 1991-1994

As of June 1995, a total of 31,024 cases of acquired immunodeficiency syndrome (AIDS) had been reported in the United States among male injecting-drug users (IDUs) who also reported sexual contact with other men (1). Although male IDUs who report male sex partners have accounted for 7% of all AIDS cases and for 21% of cases reported among IDUs, the characteristics and risk practices of male IDUs who have sex with men (MSM) have not been clearly determined (2-4). To better characterize this group of men with multiple risk factors for human immunodeficiency virus (HIV) infection, data collected during February 1991 through June 1994 from three sites--Dallas; Denver; and Long Beach, California--were analyzed as part of the CDC-sponsored AIDS Community Demonstration Projects (5,6). This report summarizes results of that analysis.

The Community Demonstration Projects included interviews of male IDUs conducted in neighborhoods with a high prevalence of drug use. Trained interviewers approached potential respondents on the street to administer a screening interview that assessed recent HIV risk practices (i.e., needle sharing during the preceding 60 days or vaginal or anal intercourse during the preceding 30 days). At-risk persons also completed a second interview about perceived risk for HIV infection, drug- injection practices, and sexual behavior. A cash incentive or grocery vouchers were provided for completing each interview. This report presents data for men who reported injecting drugs during the preceding 30 days.

Nearly all (1697 [93%] of 1820) of the sexually active male IDUs who were screened completed the second interview. Of these, 297 (18%) reported having had one or more male sex partners during the preceding 30 days. The percentage of MSM IDUs varied by city (Denver, 28%; Dallas, 22%; and Long Beach, 10%). Nearly two thirds (178 [60%] of 297) of MSM IDUs self-identified as bisexual, 97 (33%) as heterosexual, and 15 (5%) as homosexual; seven (2%) were undecided about their sexual identity. Most MSM IDUs in this sample were black (192 [65%] of 297), aged greater than or equal to 30 years (224 [75%]), and recruited at the Denver site (167 [56%]).

A total of 224 (75%) MSM IDUs had traded sex for money or drugs during the preceding 30 days. Almost all (283 [95%]) had had more than one sex partner during the preceding 30 days. The mean number of male partners during the preceding 30 days was 3.8 (range: 1-41; standard deviation [SD]: plus or minus 5.6). Most (263 [89%]) reported having one or more (mean: 4.5, range: 0-61, SD: plus or minus 6.4) female sex partners. A total of 148 (50%) reported having had a partner whom they identified as their main or primary sex partner. Of those with a main partner, 110 (74%) of 148 indicated this partner was female.

Nearly all MSM IDUs (290 [98%]) reported having ever had vaginal intercourse. During the preceding 30 days, 267 (90%) had had vaginal intercourse with main and/or other partners. Of those with a female main partner, 13 (12%) of 105 reported using a condom the last time they had vaginal intercourse; of those who had had vaginal sex with someone they did not consider to be their main partner (i.e., non-main partner), 30 (13%) of 233 had used a condom at last intercourse.

Nearly all (282 [95%]) had ever engaged in anal intercourse; 201 (71%) had had anal intercourse with both men and women, 51 (18%) with men only, and 30 (11%) with women only. Most (250 [84%] of 297) had also had anal intercourse during the preceding 30 days. Data regarding condom use during anal intercourse during the preceding 30 days were collected for a subset of respondents. Eight (23%) of 35 of those with a male main partner and eight (20%) of 41 of those with a female main partner used a condom the last time they had anal intercourse with this partner. Among MSM IDUs with non-main partners, 53 (27%) of 200 used a condom the last time they had anal intercourse.

During the preceding 60 days, 250 (86%) of 292 MSM IDUs reported having shared syringes or other paraphernalia used to prepare or inject illicit drugs. Less than one third (73 [29%] of 248) indicated that the last time they shared injection equipment they used bleach to clean their needle or syringe.

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Editorial Note: Approximately 18% of male IDUs interviewed at the three sites in this study reported having had sex with another male during the previous 30 days--a rate higher than that reported for

a national sample of men aged 20-39 years (7), but consistent with previous studies of male IDUs (2,4). Although these previous studies were based on convenience samples and the estimates probably were not representative of the total population of IDUs, the range for the prevalence of MSM activity among IDUs is similar to that documented in the three sites in this report.

In this study, the prevalences of drug-injection and sexual practices associated with the transmission of HIV infection were high among MSM IDUs, including recent sharing of injection equipment, trading of sex for money or drugs, engaging in anal sex, and having had multiple sex partners. Because such practices increase the risk for acquiring and/or transmitting HIV infection to needle-sharing and sex partners, intervention programs for MSM IDUs should address both drug-related and sexual risk factors.

The findings in this report also indicate that sexual self-identification as heterosexual or homosexual may not correspond with sexual practices. Assessment of risk for HIV infection should be based on behavior, regardless of self-identification. Self-identification as heterosexual or bisexual, however, may be useful in planning and conducting intervention activities (8). For example, efforts to provide preventive measures to MSM IDUs who do not self-identify as homosexual may need to be directed through a variety of settings because such men may ignore or resist messages that appear to be targeted toward men who are homosexual.

The use of neighborhood-based samples in Dallas, Denver, and Long Beach may have resulted in some biases. For example, some important subgroups (e.g., amphetamine users and men who self-identify as homosexual) probably were undersampled, while other groups (e.g., men who traded sex for money or drugs) may have been oversampled. Although these potential sampling biases may have influenced the patterns of HIV risk in this study, the extent to which these biases affected the estimates of HIV risk among MSM IDUs could not be assessed.

The development of programs for preventing HIV transmission among MSM IDUs requires that public health agencies and local community-planning groups characterize the risk for this group and examine available data from AIDS case reports, HIV counseling and testing sites, and behavioral surveillance surveys. Determinants for risk that may vary by location include demographic characteristics, patterns of sexual practices and of substance use, and access to HIV-prevention services.

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Update: Venezuelan Equine Encephalitis -- Colombia, 1995

During September 1-October 12, 1995, a total of 12,403 patient visits for Venezuelan equine encephalitis (VEE) were reported from La Guajira state, Colombia. The actual number of incident cases, estimated from epidemiologic surveys, may exceed 45,000. This report updates the ongoing investigation of this outbreak (1).

Household surveys in urban areas of Manaure, Maicao, Riohacha, and Uribia during September 26-October 3 indicated an overall attack rate of 18%, ranging from 13% in Riohacha (the largest of the towns) to 57% in Manaure. In 101 patients in Manaure, Maicao, and Riohacha who sought medical care within 3 days of onset of acute febrile illness, the point prevalence of VEE-specific immunoglobulin M antibody was 45%, providing a minimum estimate of the specificity of the clinical case definition. Of the 18 VEE virus strains isolated from humans, three were identified antigenically as IC-subtype viruses, which have been the principal cause of epizootics in northern South America. Partial nucleotide sequencing of the strains indicated they were closely related to strains isolated from Venezuela earlier in 1995.

The outbreak has spread southwest along the coastline at a rate of approximately 3 miles (5 km) each day (Figure 1). In the coastal towns of Manaure, Mayapo, El Pajaro, and Dibulia, entomologic surveys have detected large populations of the vector mosquito *Aedes taeniorhynchus*. The initiation of mosquito-control programs was followed by declines in emergency department visits for acute febrile illness in Manaure, Maicao, Riohacha, and Uribia.

In addition, entomologic surveys indicated 99%-100% declines in *Ae. taeniorhynchus* larval densities after breeding sites were treated with *Bacillus sphaericus* (a larvicide).

In the inland region south of Maicao, the outbreak has extended to the municipality of Riohacha, near El Cerrejon coal mine in Hatonuevo. Surveys in Maicao and the south of La Guajira Department have identified extensive breeding habitats for *Psorophora confinnis* and abundant larvae.

Households in Maicao, Riohacha, and Uribia that had more than one case were studied to determine whether secondary person-to-person transmission had occurred. A secondary case was defined as onset of acute febrile illness 1-5 days after onset of illness in the first case(s) in the household. Primary cases occurring within 5 days of the interview were excluded. The apparent secondary attack rate was 5% (50 of 992).

Public health efforts have focused on limiting the spread of the outbreak from La Guajira peninsula to the Magdalena Valley to the south at passes formed by the Sierra Nevada de Santa Marta Mountains (Figure 1). Ongoing active surveillance of all hospitals in La Guajira through October 12 indicated no evidence of human cases in the southern part of the state. Unconfirmed equine cases were reported near Santa Marta, but no human cases acquired in Magdalena have been confirmed. Sporadic equine deaths in Cordoba, Cesar, and Magdalena states have been confirmed serologically as cases of eastern equine encephalitis. In the area beyond the advance of the outbreak (Figure 1), approximately 5000 equines in La Guajira have been vaccinated with TC-83 vaccine; in neighboring Magdalena and Cesar states, 20,000 and 70,000 equines, respectively, have been vaccinated.

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Editorial Note: Although the VEE outbreak has spread rapidly through La Guajira, control measures have contained the outbreak within this northern-most state of Colombia, with no evidence of human cases in adjoining Magdalena and Cesar states. Equine vaccination creates an immune barrier against the spread of the

virus by removing the most important vertebrate amplifying host from the epizootic transmission cycle. Larvicidal treatment of breeding sites reduces the number of vector mosquitoes, but its continued effectiveness may be difficult to maintain during the wet season--which in La Guajira usually lasts through November.

VEE appeared in Venezuela in April 1995 and spread westward, with the first cases in Colombia recognized in August at the common border of the two countries. The virus most likely was transferred in a viremic equine or human and spread from there to the western coast of La Guajira. Comparisons of viral strains from Colombia and Venezuela indicate a close genetic relation (2).

Because VEE virus has been recovered from pharyngeal cultures in 40% of patients (3) and aerosols of VEE virus have infected laboratory personnel, direct human-to-human transmission of VEE virus may be possible. However, it is unknown whether infectious VEE aerosols or respiratory droplets can be produced by infected humans. Human-to-human transmission by mosquitoes may occur during some epidemics, as suggested in previous outbreaks (4); however, the household survey in La Guajira found no evidence of direct person-to-person transmission.

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Use of Mammography Services by Women Aged greater than or equal to 65 Years Enrolled in Medicare -- United States, 1991-1993

The incidence of invasive breast cancer among women aged greater than or equal to 65 years is twice that among those aged 35-44 years (1), and the death rate from breast cancer is approximately three times higher among women aged greater than or equal to 65 years than among women aged 35-64 years (2). Although routine screening mammography among women aged greater than or equal to 50 years can reduce breast cancer mortality by greater than or equal to 30% by detecting tumors at early, more treatable stages (3), older women are less likely to receive screening

mammograms (4). The Health Care Financing Administration (HCFA) routinely examines trends in the use of health services by age, race, and sex to monitor access to medical care for Medicare beneficiaries. Using Medicare claims data, HCFA estimated rates of mammography use among women aged greater than or equal to 65 years during 1991-1993. This report presents the findings of this analysis.

Women enrolled in Medicare are eligible for diagnostic and screening mammograms under the Medicare Part B program, which enrolls approximately 96% of U.S. residents aged greater than or equal to 65 years. Biennial screening mammography for women aged greater than or equal to 65 years has been a Medicare benefit since January 1, 1991; previously, only diagnostic mammograms were covered under Medicare Part B. Both screening and diagnostic mammography are reimbursed at 80% of allowed charges after an annual deductible of \$100 for all Part B services.

For this analysis, Medicare claims data for services provided during 1991-1993, were used to calculate annual rates of mammography use for enrolled women aged greater than or equal to 65 years; age- and race-specific rates also were calculated.

Race-specific rates are presented for blacks and whites only because identification of other racial groups is incomplete in the Medicare administrative data system. Because claims are not submitted for the Medicare population enrolled in managed-care plans (approximately 7% in 1993) (5), rates are based on women enrolled in fee-for-service Medicare. Three cohorts of women were established using the Medicare denominator files for 1991, 1992, and 1993. Each annual cohort consisted of approximately 16 million women (Table 1) who were continuously enrolled in fee-for-service Medicare parts A and B. Women excluded from this analysis were those aged less than 65 years as of January 1 of the year, those enrolled in a health maintenance organization at any time during the year, and those who died during the year. Rates of mammography use represent the percentage of women in each cohort who had one or more mammograms (screening or diagnostic) during that year. Because providers do not uniformly apply the codes used to bill Medicare for mammograms, Medicare claims cannot reliably distinguish screening and diagnostic mammograms; therefore, both types of mammography are included in this analysis.

During 1991-1993, of each annual cohort of approximately 16 million women aged greater than or equal to 65 years who were continuously enrolled in fee-for-service Medicare, 3.8-4.0 million (approximately 25%) had one or more mammography claims (Table 1). During this period, rates of mammography use varied inversely with age of the beneficiary (Figure 1); in all years, the rate for women aged 80-84 years was less than half that for women aged 65-69

years. For all age groups, black women were less likely than white women to have received mammograms, although this difference declined during each of the 3 years: in 1991, the black-to-white ratio of mammography rates was 0.64:1, compared with 0.71:1 in 1993 (Table 2).

Reported by: AE Trontell, MD, Div of Health Information and Outcomes, Office of Research and Demonstrations; EW Franey, Institutional Payment and Studies Br, Div of Provider Data, Office of Health Care Information Systems, Bur of Data Management and Strategy, Health Care Financing Administration. Epidemiology and Statistics Br, Div of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, CDC.

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Comparison of the House & Senate Republican Medicaid Block Grant: 1996-2002
(Dollars in Millions, Federal Spending, Fiscal Years)

States	Baseline (1)	House Republican Medicaid Block Grant		Senate Republican Reduction in Medicaid		Difference + : Smaller Loss Under Senate - : Larger Loss Under Senate
		Reduction (2)	Percent Reduction	Reduction	Percent Reduction	
United States	954,338	\$182,366	19%	\$186,733	20%	
Alabama	13,823	1,155	8%	2,607	19%	(1,452)
Alaska	2,001	554	28%	394	20%	160
Arizona	12,903	1,328	10%	2,517	20%	(1,188)
Arkansas	11,081	2,964	27%	2,860	26%	104
California	95,663	18,693	20%	13,801	14%	4,892
Colorado	8,163	1,953	24%	1,297	16%	656
Connecticut	12,990	2,145	17%	3,544	27%	(1,400)
Delaware	1,728	415	24%	115	7%	300
District of Columbia	4,511	963	21%	734	16%	229
Florida	40,720	10,531	26%	8,944	22%	1,587
Georgia	26,050	5,776	22%	5,904	23%	(128)
Hawaii	2,732	443	16%	267	10%	176
Idaho	2,933	575	20%	581	20%	(6)
Illinois	33,242	6,135	18%	2,902	9%	3,233
Indiana	23,100	7,287	32%	8,624	37%	(1,337)
Iowa	7,807	936	12%	1,082	14%	(146)
Kansas	5,962	133	2%	704	12%	(571)
Kentucky	18,353	4,979	27%	4,928	27%	51
Louisiana	33,991	5,269	16%	15,352	45%	(10,082)
Maine	5,999	853	14%	946	16%	(93)
Maryland	13,478	2,516	19%	1,536	11%	980
Massachusetts	25,516	4,239	17%	5,652	22%	(1,413)
Michigan	32,153	4,253	13%	4,692	15%	(439)
Minnesota	14,665	2,072	14%	1,019	7%	1,053
Mississippi	12,640	1,938	15%	1,251	10%	688
Missouri	14,871	(321)	-2%	2,043	14%	(2,364)
Montana	3,409	943	28%	948	28%	(6)
Nebraska	4,448	932	21%	692	16%	239
Nevada	2,899	680	23%	850	29%	(170)
New Hampshire	3,728	(437)	-12%	1,164	31%	(1,601)
New Jersey	28,038	7,032	25%	7,172	26%	(141)
New Mexico	6,066	902	15%	615	10%	287
New York	119,527	24,588	21%	21,450	18%	3,138
North Carolina	29,014	8,596	30%	8,319	29%	277
North Dakota	2,491	511	21%	540	22%	(29)
Ohio	40,586	7,944	20%	6,683	16%	1,261
Oklahoma	11,074	3,235	29%	3,423	31%	(188)
Oregon	8,884	1,596	18%	35	0%	1,562
Pennsylvania	38,448	3,153	8%	2,422	6%	730
Rhode Island	5,465	1,638	30%	1,141	21%	497
South Carolina	15,252	1,516	10%	2,954	19%	(1,438)
South Dakota	2,380	378	16%	240	10%	137
Tennessee	24,576	6,424	26%	4,165	17%	2,259
Texas	61,167	7,001	11%	12,187	20%	(5,185)
Utah	5,128	1,116	22%	1,052	21%	64
Vermont	1,982	401	20%	205	10%	196
Virginia	13,022	3,300	25%	3,079	24%	220
Washington	18,203	5,434	30%	5,579	31%	(146)
West Virginia	13,723	4,460	32%	4,615	34%	(156)
Wisconsin	16,484	2,935	18%	2,639	16%	296
Wyoming	1,269	305	24%	264	21%	40

Based on the Commerce Committee's formula as of September 18, 1995; Senate Finance Committee formula as of September 27, 1995.

(1) From The Urban Institute's Medicaid Expenditure Growth Model

(2) From the General Accounting Office's & Senate Finance Committee's estimates of the spending by state under the proposal.

Source: U.S. DHHS

27-Sep-95

CONGRESSIONAL TESTIMONY



RAND

ONDCP's First Four Years as
a Policy AgencyPeter Reuter
Jonathan Caulkins

CT-110

November 1993

Drug Policy Research Center

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ONDCP's First Four Years as a Policy Agency**Testimony before the House Committee on Government Operations****October 5, 1993****Peter Reuter^{*}****Jonathan Caulkins^{**}**

We are grateful for the opportunity to testify before the Committee on ONDCP's performance as a policy management agency. We should start by identifying a potential conflict of interest. RAND does some research under contract to ONDCP and we both have roles in that research. To avoid conflict of interest, our testimony will be limited to ONDCP's performance in its first four years, before the current Director was pointed.

Summary

The impulse to create ONDCP was primarily the friction among federal agencies involved in controlling illicit drugs. A secondary goal was to give federal drug control a clear and reasoned policy direction. In effect these were complementary tactical and strategic goals. We will only address ONDCP's performance in its strategic role.

The office succeeded in identifying tangible goals and outlining a broad national policy or strategy. Opinions may differ as to the wisdom of those goals and/or the overall policy, but what is less debatable, and more discouraging, is that the goals and policy are decoupled. Little suggests that ONDCP systematically evaluated a wide range of possible strategies and selected the one best able to achieve the stated goals. Hence, it remains impossible to make an informed judgement about the

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appropriateness of budget allocations among different functions (e.g., treatment vs. prevention, interdiction vs. domestic investigation).

The situation is no better when one moves from broad policy formulation down to program management. ONDCP has not identified meaningful performance measures for individual agencies or functional areas. As a result, it is impossible to judge how well various agencies have performed within given functional areas (e.g., Customs vs. Coast Guard as interdiction agencies). Nor was enough done to relate agency performance to the achievement of the Strategy's goals. In fairness it should be noted that the task of providing convincing and feasible measures of effectiveness is an exceedingly difficult one, and there was nothing available "off the shelf" for that purpose. However, ONDCP appears to have done little to fill this gap in its first four years.

Policy formulation and management require data and analysis. The office did sponsor some important analytic research. Examples include Abt's pioneering effort to estimate total expenditures on illicit drugs¹ and BOTEC's integration of heroin indicators to assess the likelihood of a new epidemic.² It also did try to improve federal data collection and analysis (an area in which RAND is providing the Office with some research). However ONDCP did not succeed in noticeably improving the quality of data available for assessing problems or evaluating programs. The one change that was accomplished through ONDCP pressure, namely the massive increase in the National Household Survey sample, was clearly a mistaken investment. Major indicator data sets (e.g., STRIDE and DAWN) remained underutilized and essentially unavailable for outside analysis. The office failed to push for better integration of data sets, so that current indicators are hard to interpret collectively.

If ONDCP is to improve its performance as a policy manager it will have to make better use of its existing authorities with respect to budget review and the preparation of the annual Strategy. In both settings, agencies must be pressured to develop better performance measures so as to allow ONDCP to develop and justify a strategy that can be related to its goals.

¹ *What America's Users Spend on Illegal Drugs, 1991.*

² *Heroin Situation Assessment Report, 1992.*

Our detailed testimony covers three topics: policy formulation, management, and data collection and analysis.

Policy Formulation

When ONDCP was created at the end of 1988, federal drug strategy was a matter of images and political power. Images determined the general strategy, namely to punish dealers and to seize powder, and political power determined which agencies got the money for these activities, with Customs perhaps the most successful in expanding its share of the budgetary pot and the FBI not far behind. There was no agreement about goals or ways of measuring contributions to goals by program or agency. Indeed, there were no goals beyond the rhetorical, such as the "Drug Free America."

When the Bush administration left office the picture was not much changed. Goals had been established; not the ones we would have chosen but measurable and defensible goals nonetheless. But agencies continued to hawk their budgetary and statutory claims without any effort to establish how they contributed to the achievement of those goals. The goals did not in fact define a strategy. It is that which constitutes the central failure of ONDCP as a policy agency in its first four years.

By failing to tie goals to strategy, the office undermined its ability to guide fundamental decisions about how the federal government allocates its \$12 billion on drug control (a figure which is rather questionable itself³). Prevention, treatment and enforcement can all contribute to achieving most if not all of the ONDCP's stated goals but they are not all equally cost-effective for every goal. As the lead policy agency, ONDCP has a responsibility to give some account of what these expenditures have accomplished and why it has chosen a particular allocation. The tools for doing so did not exist when the office was formed, but ONDCP might have been expected in its first four years, with a relatively generous budget and substantial authority, to have pushed for the development of such tools, both with its own resources and with those of other agencies. It appears that it did not do so.

The disjunction between goals and strategy development also makes it essentially impossible to evaluate the national drug policy. It may be easy now to

³ This statement draws on Murphy, P., *Keeping Score: The Failures of the Federal Drug Budget*, (RAND, forthcoming).

ascertain whether the stated goals have or have not been achieved but not why, let alone what to do about shortfalls. Many factors beyond the control of policy makers influence the measures with which ONDCP has defined its goals. Hence missing or meeting these goals is as much an indicator of good fortune as of good leadership.

Program Management

Even good policies are hollow without effective implementation and management. Although, as required by the authorizing legislation, the annual Strategy has provided a set of numeric goals, there is no evidence that it asked how they contribute to the attainment of those goals. For example, ONDCP does not ask how spending another \$100 million on source country control would reduce the fraction of persons using an illegal drug (Objective 1 of the first Strategy) or the imports of illicit drugs (Objective 7, later dropped because it could not be quantified). No doubt it would have received incoherent answers the first time it tried but by rewarding the most cooperative agencies, iteration and continuous improvement might well have led to development of more helpful performance measures.

Consider for example the investigative agencies, such as DEA and FBI. They produce drug seizures and arrests; ultimately hoping to make drugs more expensive and difficult to obtain. These two agencies have followed somewhat different strategies. The DEA has emphasized arrests of high level dealers, while the FBI has apparently given more emphasis to total arrests. Which is more appropriate and effective, given the federal enforcement role? In the recent discussion of the possible merger between the two organizations, more accurately described as a hostile takeover, it has been striking how little analysis was offered to support claims for the relative effectiveness of these two strategies. The lack of any measures to allow comparison must be marked down as one of ONDCP's failures.

The best indicator of the problem was the failure of ONDCP to systematically evaluate federal enforcement efforts, even though these consumed most of the federal drug control budget. This omission was more striking in light of the recurring call for careful evaluation of treatment programs, though these received only about one-sixth of the total funds. The first Strategy made the right start. After noting that treatment and prevention were being thoroughly evaluated, it went on to say: "The majority of Federal resources are spent on supply reduction activities. In law enforcement, interdiction and international efforts, we need to evaluate programs and measure actual results against

stated goals. But cross-tactical evaluations between these specific supply reduction activity and the primarily demand reduction efforts of prevention and treatment are also badly needed. Having these evaluation results will allow us to make more fine-tuned, carefully targeted policy choices among a mix of drug supply and demand reduction programs." (pg. 84)

No such systematic evaluation has yet emerged. We should note that colleagues at RAND, working under ONDCP auspices, have been modeling treatment-enforcement tradeoffs for cocaine but these, or similar efforts, need to be extended to cover prevention, other drugs, user sanctions, etc.

In the absence of such guidance, the default strategy has been to "attack on all fronts" by doing as much of everything as was politically possible. In the crisis atmosphere of 1989 such an approach could possibly be justified. But drug problems, though still substantial, no longer appear a threat to civilization as we know it. Choices have to be made. It is unlikely that 1989's mix of programs and laws is still appropriate, given the diminution of concerns about an epidemic of new drug use. In its first four years ONDCP evidenced little willingness to make any noticeable changes in policy direction. Consistency is an admirable managerial quality; failure to adapt to changes is quite a different matter.

Data Quality and Analysis

Sensible policy formulation and management require data and analysis. The quality of data available to Congress and policy makers has been a cause of concern for many years; the quality of analysis should have been. The major indicators, such as the Drug Abuse Warning Network and the National Household Survey, have been heavily criticized, the first for the accuracy of the data it collects, the second for the populations it misses. Yet good analysis can squeeze information out of even poor data and the information locked in these data is critically important because drug abuse is an epidemic phenomenon. Prevalence and trends in prevalence today should guide strategic decisions about tomorrow. For example, whether the federal government should shift resources from cocaine toward heroin is very much a function of how we project the future of abuse of these two drugs. Analysis is what turns data into policy-relevant information.

For the obvious reason that drug use is illegal and stigmatized, measures of abuse and its consequences are hard to obtain. The precision of unemployment

measures or school graduation rates is not going to be attained. Yet there is no doubt that better indicators could be developed, that the existing indicators could be better analyzed and that such indicators and analysis would facilitate federal decision making. Given its cross-cutting responsibilities, ONDCP should have viewed itself as the principal catalyst for achieving improvements in these areas. It certainly failed to achieve significant improvement.

Consider STRIDE (System to Retrieve Information from Drug Evidence), which provides data on all purchases and seizures analyzed by DEA laboratories. For the undercover purchases STRIDE includes the quantity, purity and price paid for the drug. Since price increases are conventionally regarded as a principal indicator of the short-term success of enforcement efforts, and STRIDE is the only national system that collects price data, investigating the quality of data collection and improving the analysis and presentation of the data should be a high priority. Yet DEA continues to publish the crudest possible statistics on prices, presenting price ranges so broad that it is impossible to tell whether prices have increased or fallen from quarter to quarter to year to year. For example, the national price range reported in 1988 for one gram of cocaine was \$50-\$120. In 1990 this had become \$35-\$175, which made it difficult to tell whether prices had risen or fallen. Discussions with officials suggest that the agency reports the highest and lowest recorded figures and makes no effort to use standard statistical practices, e.g., reporting the interquartile range (i.e., the 75th and 25th percentiles) would greatly increase the information provided.

ONDCP, to its credit, did encourage some analyses of STRIDE data. Caulkins has, partly with ONDCP funding, written a number of papers on the reporting and analysis of price data.⁴ Abt Associates, under ONDCP auspices, analyzed the relationship between prices and DAWN,⁵ finding a surprisingly strong relationship, thus suggesting that if enforcement could increase the price of a drug it would indeed reduce the number of ER episodes involving that drug. However, ONDCP did not change DEA's reporting practices, so that published price series continue to be as uninformative as they were before 1988.

⁴ Caulkins, J., and R. Padman, "Quantity Discounts and Quality Premiums for illicit Drugs," *J. American Statistical Association*, Vol. 88, No. 423, 1993, pp. 748-757.

⁵ Hyatt, R., and W. Rhodes, "Price and Purity of Cocaine: The Relationship to Emergency Room Visits and Deaths, and to Drug Use Among Arrestees," *J. of Statistical Medicine*, forthcoming.

The one change in data collection accomplished by ONDCP was the massive expansion of the sample in the National Household Survey on Drug Abuse (NHSDA), from less than 10,000 respondents in 1988 to over 30,000 in 1992 and the move to an annual rather than biannual survey. ONDCP claimed that the increase was necessary to develop more precise estimates of the number of frequent users of expensive drugs, primarily cocaine. The survey now has an annual cost of over \$10 million per annum and consumes a large share of the total indicator collection budget. The expansion was accomplished against the advice of the expert community⁶ and has in fact not materially improved the quality of our estimates of the number of frequent drug users, simply because the weakness of those estimates comes more from selective reporting and omitted populations than from sampling variance. The move to an annual survey has had no useful consequences, in large part because ONDCP's policy choices cannot be related to movements in the NHSDA.

Other indicators remain problematic. Consider DAWT, the system that reports data from a sample of Emergency Rooms (ER) and Medical Examiners. The system dates back to 1972 and has been changed relatively little over that time period. In the mid-1980s certain questions were added to the form, providing important data about the reasons the individual used the drugs (e.g., dependence rather than psychoactive effects) and entered the ER (seeking detoxification or to deal with acute effects). In 1989 the sample was refined so as to allow estimates of the number of ER episodes involving particular drugs, nationally and for certain metropolitan areas. But the basic data collection procedures, which have been widely and persuasively criticized, have not changed. For example, a number of studies have found that the DAWN system missed many, if not most, trauma cases involving drugs.⁷

DAWN's primary policy role, as evidenced by Objective 6 of the Strategy, has been as a measure of trends in the size of the heavy user population. It is ill-suited for that role; drug-related ER admissions are also driven by the availability of treatment and the age and general health of the drug dependent population as well as by changes in the size of that population. Perhaps more refined analyses of the data, looking for

⁶ See for example Haaga, J., and P. Reuter (eds.), *Improving Data for Federal Drug Policy Decisions*, Santa Monica CA, RAND, 1990.

⁷ See e.g., Brookoff, et al., "The Underreporting of Cocaine Related Trauma: Drug Abuse Warning Network Reports vs. Hospital Toxicology Tests," *American J. Public Health*, March 1993, Vol. 83, No. 3, pp. 369-371.

8

example at the motives for entering the ER or reasons for using drugs, would help illuminate its value in the indicator role, but NIDA, the sponsoring agency for the first four years,⁸ neither conducted such analyses itself nor made the data available to outside analysts for that purpose.

In summary, ONDCP was assigned a difficult policy management task. It responded by formulating a coherent but unevaluated and inflexible set of goals. The strategy selected to pursue those goals was not subjected to systematic cost-effective analysis, and the data and analysis capability necessary to perform such analyses, though improved, were not advanced sufficiently.

Thank you again for giving us the opportunity to present our views.

⁸ Responsibility for the survey shifted in October 1992 to the newly formed Substance Abuse and Mental Health Services Administration.

(JS)

EXECUTIVE OFFICE OF THE PRESIDENT

20-Nov-1995 09:24am

TO: (See Below)

FROM: Bradie Metheny

SUBJECT: Life Science November 20, 1995

Life Science
November 20, 1995

SENATOR HATFIELD WARNS RESEARCHERS NOT TO LAY DOWN THEIR ARMS

Senator Mark Hatfield, R-OR, admonished the scientific community last week to not lay down their arms yet. Although the National Institutes of Health (NIH) promises to fare relatively well in FY 96--when a budget is finally approved--the long term funding battle has just begun, he said.

Selected by the Genome Action Coalition for the first annual James Watson Lecture, Hatfield used the opportunity to warn an audience at the National Academy of Sciences that scientific progress, such as the Human Genome Project, could be imperiled if a long term solution to funding stability is not found. That need is even more urgent as Congress debates ways to eliminate the federal deficit in seven years by cutting discretionary spending, he said.

The Genome Action Coalition is a recently formed advocacy group made up of patient and professional groups, scientists, and pharmaceutical and biotechnology companies who work together in support of genome research.

"Are we only going to fight this funding battle year by year? Or can the NIH community and Congress develop a realistic strategy for a stable funding path for this year to the year 2002?" Hatfield asked.

To that question, Hatfield gave the answer as proposed by him and Senator Tom Harkin, D-IA: a trust fund to augment NIH's annual budget.

"Funds generated by this proposal would increase the funds for NIH 35% over the fiscal year 1995 [budget]," Hatfield said. "This would allow many more research applications to be funded, for scientific opportunities of merit to be pursued and hopefully translated into cost effective treatments and cures."

The trust fund would be administered by the Treasury Department and financed by an increase in the federal tobacco tax--to 25 per pack and on smokeless products--and by a voluntary federal income tax check-off. The House and Senate Joint Committee on Taxation estimated that the fund could generate an additional \$4.2 billion annually for NIH, he said.

Five percent would be taken off the top of that supplemental amount and

divided among the NIH Director's Office, the National Center for Research Resources and the National Library of Medicine.

That 5% chunk would be used to maintain the biomedical research infrastructure as well as to give the NIH director flexibility to "fund a little extra money in some of those areas that are at a point of breakthrough," Hatfield said.

The remainder would be distributed among the various NIH institutes and centers in proportion to the amount each received under the appropriations process, Hatfield said.

"Given the budget situation we face, future increases will become even more difficult to achieve, thus threatening the ability to maintain the growth, continuation costs and new grants for medical research," Hatfield said.

"Absent such a plan, the slings and arrows of the budget process and dramatic fluctuations of available funds each year for new grants will continue to foster fear and uncertainty among our nation's health research and advocacy communities."

Hatfield's suggestion to the scientific community was to keep up the good work they launched into last spring when he issued his first "call to arms" as the House and the Senate prepared to slash billions of dollars from NIH's current level of funding.

"There are many battles ahead," Hatfield said. "I am afraid to say that congressional supporters of the NIH and research community still must weld a tighter and a closer bond of action and strategy to develop a long term plan to maintain a stable source of funding for medical research."

Watson, who introduced Hatfield as someone who looks and acts like a "real Senator," echoed the need for that bond.

"I think we need to have this continued friendship between leaders of science and our leaders in Congress. I think we have to continue to trust each other," Watson said. "We could continue to talk about where things have gone wrong, but Congress has come through for the sciences."

Watson called the Hatfield-Harkin National Fund for Research a "wonderful idea" and "the only real answer."

Watson also pointed out that it was Congress who rebuffed naysaying scientists and forged ahead with funding for the Human Genome Project.

Today that project, which seeks to locate 100,000 human genes and read the entire genetic script by 2005, is ahead of schedule and under budget.

Watson credited the Human Genome Project's success thus far to a good staff and very selective funding.

Watson also asserted that the project's commitment--and one of his major concerns--to looking at related ethical, legal and social issues "has given it legitimacy." But he warned against letting the ethical questions overwhelm the research.

"Through the project we could do an awful lot of good," Watson said, "and we should see that as our chief ethical dilemma and not privacy and all these other things, which I think, will be easy to make into newspaper stories but will be a small thing compared to the fact of parents having

EXECUTIVE OFFICE OF THE PRESIDENT

20-Nov-1995 09:44am

TO: levi_j

FROM: aidsnews

SUBJECT: CDC AIDS Daily Summary 11/20/95

AIDS Daily Summary
November 20, 1995

The Centers for Disease Control and Prevention (CDC) National AIDS Clearinghouse makes available the following information as a public service only. Providing this information does not constitute endorsement by the CDC, the CDC Clearinghouse, or any other organization. Reproduction of this text is encouraged; however, copies may not be sold, and the CDC Clearinghouse should be cited as the source of this information. Copyright 1995, Information, Inc., Bethesda, MD

"Epidemiology: Warding Off the AIDS Virus"

"Budget Bill Dismisses Moderates' Input, Aimed to Soften Most Conservative Plans"

"Obituaries: John Rico, Republican Activist"

"Genentech's Brewer Resigns and Jennings Will Be Reassigned"

"Latin American Women Face Rising AIDS Risks"

"Mother Theresa to Set Up AIDS Hospice in New Delhi"

"Ability of Primary Care Physicians to Recognize Physical Findings Associated with HIV Infection"

"Research Shows AZT and Either ddI or ddC Better than AZT Alone"

"Sociodemographic Characteristics and Sexual Behavior of Bisexual Men in France: Implications for HIV Prevention"

"Would Xenotransplants Produce Epidemics Worse than AIDS?"

"Epidemiology: Warding Off the AIDS Virus"

Washington Post (11/20/95) P. A2

An experimental drug called PMPA completely protected monkeys in a situation similar to that in which health care workers are exposed to HIV. PMPA is extremely close to AZT, the oldest AIDS drug, yet it works faster and is 100 times less toxic. After eight months, all 25 simian immunodeficiency virus (SIV)-injected monkeys who were treated with intravenous PMPA were not infected with SIV and experienced no side effects. The 10 animals that did not receive the drug did become infected. Researcher Che-Chung Tsai of the University of Washington Regional Primate Center said the next step will be to determine whether PMPA works as well in humans.

"Budget Bill Dismisses Moderates' Input, Aimed to Soften Most Conservative Plans"

Wall Street Journal (11/20/95) P. A16; Georges, Christopher

The final compromise between House and Senate Republicans in the ongoing battle of the seven-year budget overhaul indicates that House conservatives were able to ignore Senate moderates' endeavors, especially those concerning welfare and Medicaid. With Medicaid, for example, the final compromise version of the bill eliminates Senate provisions to maintain federal nursing home standards and to guarantee aid for all disabled poor individuals who qualify.

"Obituaries: John Rico, Republican Activist"

Washington Post (11/20/95) P. B4

Republican party official and political strategist John Rico died of AIDS on Saturday at age 45. In 1979, Mr. Rico ran Ronald Reagan's presidential campaign headquarters in Los Angeles. He later moved to Oregon, where he became chief of staff for the then-Republican state Senate from 1985 to 1991. Mr. Rico went public with the fact that he had AIDS, after learning he was infected in late 1991, and served on Oregon Gov. Booth Gardner's Advisory Council on HIV/AIDS. According to Mr. Rico, it was his "responsibility to help put a personal face on this disease, as well as homosexuality in general."

"Genentech's Brewer Resigns and Jennings Will Be Reassigned"

Wall Street Journal (11/20/95) P. C12

Genentech Inc. has announced the resignation of Richard Brewer, a high-ranking executive in charge of the biotech firm's marketing operations. An 11-year veteran of the company, Brewer had sparked anger among federal regulators and others for his aggressive marketing methods, but a Genentech spokesperson said that he was leaving for personal reasons and denied that any housecleaning was being undertaken. In addition, vice president of sales Edmon Jennings has been reassigned to a position not involving sales. Jennings was recently acquitted of allegations that he bribed physicians to prescribe more of a Genentech human growth hormone.

"Latin American Women Face Rising AIDS Risks"

Reuters (11/17/95); Orgill, Margaret

Health experts announced on Friday that Latin American housewives have among the region's greatest risk of AIDS because of infection from husbands having affairs or using drugs. "The most important risk factor for a Latin American woman is being married," said Fernando Zacarias, coordinator of the Pan American Health Organization's regional program on AIDS. Zacarias added that many married women are unable to persuade their husbands to wear condoms. Health workers report that oftentimes those women who do try to make their spouses wear the prophylactics risk violence or suspicion that they are having an affair. "The Rise in AIDS among normal women breaks the myth [that] it only affects prostitutes and drug-users," commented Jadira Rodriguez, who runs a health program for women workers in Puerto Rico. "Prostitutes know how to protect themselves," she said.

"Mother Theresa to Set Up AIDS Hospice in New Delhi"

Reuters (11/17/95)

Mother Theresa will establish an AIDS hospice in New Delhi, the Press Trust of India said last week. The news service reported

only that the 85-year-old nun said that at her center, which will be devoted to women and children, AIDS patients would receive "much needed" love. Mother Theresa, who termed AIDS patients in the 1980s as "the lepers of our times," has set up centers in the United States, and helped others in Haiti.

"Ability of Primary Care Physicians to Recognize Physical Findings Associated with HIV Infection"

Journal of the American Medical Association (11/01/95) Vol. 274, No. 17, P. 1380; Paauw, Douglas S.; Wenrich, Marjorie D.; Curtis, J. Randall; et al.

Paauw et al. assessed the ability of 134 general internists and family practitioners to recognize HIV-related physical findings. Just over 25 percent of 89 physicians correctly diagnosed a patient with Kaposi's sarcoma, while nearly 23 percent of 97 doctors detected oral hairy leukoplakia and just 17 percent of 133 physicians identified diffuse lymphadenopathy. Overall, experience with HIV seemed to influence the ability to identify oral hairy leukoplakia, but such experience did not affect the physicians' ability to identify the other two disorders. Additionally, there were no differences observed between the two types of physicians; furthermore, the doctors' years of medical school graduation had no relation to their identification of physical findings associated with HIV. According to the authors, despite the limited nature of this study, the findings suggest that primary care physicians may often miss critical HIV-related physical findings during patient examinations.

"Research Shows AZT and Either ddI or ddC Better than AZT Alone"
Nature Medicine (11/95) Vol. 1, No. 11, P. 1113; Moran, Nuala

Following the recently released conclusions of the Delta trial, Britain's Medical Research Council now recommends that people with HIV and AIDS receive a combination of two anti-AIDS drugs. The Delta trial stopped three months ahead of schedule when it became clear that a mixture of AZT with either ddI or ddC resulted in an average 38 percent reduction in death rates, versus taking only AZT.

"Sociodemographic Characteristics and Sexual Behavior of Bisexual Men in France: Implications for HIV Prevention"

American Journal of Public Health (11/95) Vol. 85, No. 11, P. 1543; Messiah, Antoine; Mouret-Fourme, Emmanuelle

The French National Survey on Sexual Behavior, a large-scale random telephone survey, provided information about a small number of bisexual men in France. The survey revealed that these bisexual men had fewer sexual partners than homosexual men, more than heterosexual males, but a comparable number to multipartnered heterosexuals. In terms of their last sexual encounter, bisexuals were similar to heterosexuals in their frequency of unprotected anal or vaginal penetration; however, their rates of condom use in the past year were about the same as those of both homosexuals and heterosexuals. Still, bisexuals were about equidistant between the two groups in regard to having discontinued penetrative sex since the beginning of the AIDS epidemic, and they were about 50 percent less likely than gay men to have been tested for HIV. According to the authors, these findings indicate a need for HIV prevention campaigns specially adapted to the characteristics of bisexuals.

"Would Xenotransplants Produce Epidemics Worse than AIDS?"

Science News (11/04/95) Vol. 148, No. 19, P. 299; Travis, John

The greatest concern about xenotransplantation may be whether it should be done, not whether it is feasible. According to virologist Jonathan S. Allan of the Southwest Foundation for Biomedical Research, the risk of introducing dangerous new viruses into the human population is real. Allan is concerned that baboons carry viruses similar to HIV and Ebola that scientists cannot eliminate from donor animals. In addition, baboons are extremely similar to humans, a factor which makes them perfect organ donors, but means that viruses which infect baboons may also take on humans. Other researchers and federal officials concede that xenotransplants do pose a risk of transmitting infectious organisms. An advisory panel to the U.S. Food and Drug Administration, for example, recently assessed the dangers involved in an operation in which baboon cells are transplanted into an AIDS patient. With Allan abstaining, the panel approved the single experiment, but one member of the research team said the experiment will likely transmit one known virus to the patient. Allan notes that investigators plan to transplant baboon hearts temporarily into young persons awaiting human hearts, who will probably survive their transplants and may spread viruses that go unrecognized for years. "You're going to pull the baboon heart out, but you're not pulling the baboon viruses out," Allan cautions.

EXECUTIVE OFFICE OF THE PRESIDENT

15-Nov-1995 09:42am

TO: levi_j
FROM: aidsnews

SUBJECT: CDC AIDS Daily Summary 11/15/95

AIDS Daily Summary
November 15, 1995

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"Advocates Want D.C. Declared a Disaster Area"
"The Ripple Effect: Empty Halls, Lost Money, Discontent"
"Addenda: Glaxo Wellcome"
"Lifeline: Play's the Thing"
"Cuba Has 1,180 HIV Positive Cases"
"Obituaries: Bruce B. Decker; Activist Served on State AIDS Panel"
"RBC-CD4 HIV/AIDS Therapy; Preliminary Results Show No Significant Adverse Effects in HIV Patients"
"OncoRx Announces Third Quarter Results"
"Multiple Introductions of HIV-1 Subtype E into the Western Hemisphere"
"Guess Who's Coming to Dinner"

"Advocates Want D.C. Declared a Disaster Area"
Washington Post (11/15/95) P. D1; Loeb, Vernon
A coalition of Washington, D.C. advocacy groups, known as the Fair Budget Coalition, plans to ask the Federal Emergency Management Agency to recommend that the city be declared a "modified emergency," based on widespread poverty, spreading infectious disease, poor healthcare, unemployment, and increasing homelessness. The organization held a public hearing on Tuesday to gather evidence to support its request. Jonathan M. Smith, executive director of the D.C. Prisoners' Legal Services Project and an organizer of the hearing said that conditions in many areas of the city are close to those in regions hit by hurricanes. Smith also noted that the District's current prison population of 10,265 represents nearly 2 percent of the total city's population. Approximately 10 percent to 25 percent of the

inmates are HIV-positive, according to Howard McDonough, board president of the Washington AIDS Ministry. "The ultimate fear of any inmate with HIV," he said, "is to die in prison." McDonough said he is aware of three such prisoners who died in the past three months because corrections officials did not process their medical parole forms in a timely manner.

"The Ripple Effect: Empty Halls, Lost Money, Discontent"

Washington Post (11/15/95) P. A1; Montgomery, David

The U.S. government closed on Tuesday, thanks to the federal budget impasse. Hundreds of thousands of government workers will be affected by the shutdown, and companies that do business with the government will face delayed payments. Jim Graham, executive director of the Whitman-Walker Clinic, the Washington, D.C. area's largest AIDS service provider, said that shutting down the government "would have a devastating impact. What does this do to the psychology of giving when people are facing days unpaid?"

"Addenda: Glaxo Wellcome"

New York Times (11/15/95) P. D7

Glaxo Wellcome has selected New York-based FCB Healthcare, a division of True North Communications, to manage the consolidated advertising account for its HIV drugs Retrovir, Mepron, Daraprim, and Septra. The account was previously distributed amongst FCB Healthcare and Harrison, Star, Wiener & Beitler, New York.

"Lifeline: Play's the Thing"

USA Today (11/15/95) P. 1D; Vigoda, Arlene

Betty Buckley, star of the Broadway show "Sunset Boulevard," is participating in a Norma Desmond Day. The highest bidder will work with Buckley for one day, both learning the role and doing a walk-on in the performance. The proceeds will benefit Broadway Cares/Equity Fights AIDS. Bids, which can be phoned in at 212-221-9413, will be accepted until the end of the year. The highest bid thus far is \$6,000.

"Cuba Has 1,180 HIV Positive Cases"

Reuters (11/14/95)

There have been 1,180 cases of HIV recorded in Cuba, the official news agency Presna Latina announced Tuesday. It reported that Manuel Hernandez, head of the national anti-AIDS campaign, said that 271 of that total had died and 413 had developed AIDS. Hernandez added that there have been 76 new HIV infections in Cuba thus far in 1995. The country has kept its AIDS rate relatively low via mass testing for HIV and a system of sanatoriums which cares for yet isolates patients. For the past two years, however, infected persons who have demonstrated responsible behavior have been allowed to live on their own.

"Obituaries: Bruce B. Decker; Activist Served on State AIDS Panel"

Los Angeles Times (11/14/95) P. A18; Oliver, Myrna

AIDS activist and philanthropist Bruce B. Decker died of AIDS-related complications on Saturday at the age of 45. Mr. Decker served four years as former Calif. Gov. George Deukmejian's chairman of the state AIDS Advisory Committee. In addition, he was the founder and finance chairman of a campaign against Proposition 64, a measure defeated in 1986 which would have included quarantining people with HIV and AIDS. Two years later, Mr. Decker resigned from his position, demonstrating his

THE WHITE HOUSE
WASHINGTON

Remarks of
Patricia S. Fleming
National AIDS Policy Director
to
The Presidential Advisory Council on HIV and AIDS

July 27, 1995

GOOD MORNING:

It's a great pleasure to join you today. Let me thank each of you for agreeing to serve on this important council and for your commitment to fighting HIV and AIDS. The Presidential Advisory Council will play an essential role in advancing the national effort to respond aggressively and compassionately to the challenges set before us by HIV and AIDS.

I know that some of you have heard others question the usefulness of advisory councils. Some critics say that we've had two AIDS commissions and seen no change as a result. Well, I would beg to differ. President Reagan's AIDS Commission, created in the early years of the epidemic, brought the issue of AIDS discrimination out of the closet and helped assure that HIV and AIDS were included in the protections of the Americans with Disabilities Act. The National AIDS Commission created by Congress in 1990, had a tremendous impact on a wide variety of policies, including clinical trials at NIH, drug approval at FDA, prevention programs at CDC, and, perhaps most significantly, the creation of the Ryan White CARE Act. Its recommendations have also helped to shape our national debate over health care reform by highlighting the ill effects of insurance rules that exclude people with pre-existing medical conditions.

So, in many ways, you have some big shoes to fill. But with the knowledge, the experience, and the commitment in this room, I am confident that you, too, will succeed.

Like many of you, this epidemic has changed my life. Ten years ago, when Congressman Ted Weiss asked me to begin working on AIDS issues for him in the House of Representatives, I was determined to make sure that the Federal government did all that it could and all that it should to put an end to this horrible disease. I spent much of the next eight years waging war on a government that I felt did not care enough about AIDS and clearly did not care enough about the people affected by AIDS. As the proud mother of a gay son, as an African American woman, and as a person who had dedicated her professional life to fighting discrimination, the government's response to AIDS was like a punch in the stomach.

Two and a half years ago, the people of this nation spoke and things began to change. For some -- including, perhaps, some in this room -- they have not changed quickly enough or dramatically enough. For others, they have changed too much and too quickly. And we see those negative forces trying very hard today to turn back the clock and return us to those earlier days of uncaring and divisive politics. No matter whether or not we think we have gone fast enough or far enough, we must be united in our determination that we will not go back. There is just too much at stake.

The Clinton Administration has pursued a vigorous policy of fighting this epidemic on all fronts including research, prevention, and treatment. We have tried, too, to instill a new sense of urgency in those who lead this fight in the Public Health Service. That has required new resources, better organization, and a greater degree of leadership.

I am personally quite proud of the fact that in the three budgets that President Clinton presented to the Congress since he took office in 1993, funding for AIDS research, prevention, and care has risen 40 percent. That figure is even more remarkable when you consider the fact that it comes at a time when virtually all government spending has been either cut or frozen in place. Is it enough? Could we use more? Of course it's not enough and certainly we could spend more. But it has enabled us to jump start our efforts across the government in pursuit of our common goals. Those goals are as follows. First, aggressive research into HIV that will result in both a cure for those who are afflicted and a vaccine to keep all of us safe from this virus. Second, creative and forward-thinking prevention programs that build on the best ideas of our communities to protect people from HIV. And, third, compassionate, state-of-the-art treatment and care for our brothers and sisters who are living with HIV and AIDS.

You will hear, later this afternoon and tomorrow, from the men and women who are responsible for these efforts, but I would like to speak about some of our broad goals and what we're doing to advance them. And then I'd like to talk about the challenges ahead.

In the area of research, one of the most important things we did was to strengthen the Office of AIDS Research and make it a permanent part of NIH. This wasn't an easy fight and there are still those who would like to return to the days of decentralization and confusion. The President and I will fight those efforts and I believe we will win.

The creation of OAR, and the appointment of Bill Paul to head that office, have brought new clarity to our research effort. It enables us to focus our research portfolio and create a plan for the future that lets the research community know where we are going. It allows us to create a balance between basic research and applied research while continuing our focus on a cure. Combined with the 25 percent increase in research funding that we have already achieved, this focus is beginning to pay some important dividends.

I'm sure you've heard some of the voices being raised against our investment in AIDS research. Some would like to set up a divisive debate over research priorities. They talk about cancer versus heart disease versus AIDS. But there is no rationality in a debate that pits one group of people against another. Because that's what it amounts to -- people against people. The President has made his opposition to this quite clear and he and I will continue to speak out against that kind of discussion.

Another important thing to remember is that research isn't only about finding a vaccine or a cure. It's also about prevention. That's why I'm so encouraged by the findings of the ACTG 076 study. And it's why I am so anxious to see further progress in the search for a vaginal microbicide that would empower women to prevent HIV infection with or without the cooperation of their partners. NIH is also actively pursuing behavioral research that will help in our prevention efforts.

When it comes to our prevention programs at CDC, we found the problem was not too little centralization but too much centralization. During the first twelve years of the epidemic, AIDS prevention efforts were known more for what they didn't say than what they did say. Public health experts and community organizations were operating with one arm tied behind their backs. As a result, we were spending nearly a half a billion dollars with very little to show for it. After President Clinton took office, we worked closely with community groups and people like Representative Nancy Pelosi to turn prevention programs around. Instead of making decisions on the content of programs here in Washington or down in Atlanta, we turned that authority over to the communities themselves. And we backed them up with the kind of frank, forward-thinking prevention campaigns like the Prevention Marketing Initiative, which tells our young people that delaying sex and the correct and consistent use of latex condoms are effective ways to prevent HIV transmission.

We've seen some improvement in our prevention efforts, but there are still very serious concerns. When you look at the demographics of this epidemic and then look at where the new infections are occurring it paints a very clear picture of where our prevention efforts are falling short. Communities of color -- gay and straight -- are being devastated by HIV. The fact that 14,000 women were diagnosed with AIDS last year -- 18 percent of all cases -- is an ominous sign. The fact that injecting drug users now represent a majority of all new cases clearly means we must do more. And the second wave of infections now sweeping through young gay and bisexual men is a frightening trend that demands our attention.

Recently, I went to New York City to visit with the staff and clients of the Hetrick-Martin Institute and to sit in on a class at their Harvey Milk School. What I heard was on one hand heartening -- all of those young people working hard to overcome the ignorance and prejudice that their families and their societies have thrown at them. But on the other hand it was heartbreaking to hear young people talk about their feeling that it is inevitable that they will become infected with HIV. As a society, we are failing them and we will pay a heavy price for that failure.

While I was in New York, I also visited Stand Up Harlem, an excellent program designed to get young people to stop using drugs and to protect themselves from HIV infection. As with my visit to Hetrick-Martin, I was incredibly impressed with the commitment these young people feel to improving their lives. We need to do more to make their job easier and to ensure its success.

One of my frustrations has been the limitations imposed by Congress on the use of Federal funds for clean needle exchange programs. So far, we are unable to meet the stringent tests imposed by the Congress. However, I continue to encourage states, local governments, and private organizations to use non-Federal funds to support such programs.

As many of you know, I have a particular concern for the impact of HIV on our young people. Today, more than 10,000 teenagers are infected with HIV every year. That's one out of every four new infections. And about half of all new infections occur among people under the age of 25. This fall, I will deliver to the President a report he requested when he announced my appointment last November. In it we will explain the dangers that HIV is posing to our young people and lay out a series of actions that can be taken to reverse those trends.

In the area of care, we have increased funding for the Ryan White CARE Act by 82 percent in two years. And, if we can get the Congress to agree, the President's request for FY1995 would bring that increase to 108 percent. As you know, the President last week sent a letter to Congress restating his request for additional Ryan White funding and we will continue to push for those dollars throughout the legislative process.

Those additional funds have helped to improve and extend the lives of thousands of Americans living with HIV and AIDS. Just last year, it provided care to 200,000 uninsured and underinsured people. It paid for early intervention services for 85,000 people and provided counseling and testing to nearly 100,000 more. Ryan White dollars help pay the prescription drug bills of nearly 75,000 Americans and covered the medical costs of 15,000 poor women and children enrolled in AIDS clinical trials.

This is the kind of direct assistance to people in need that our government was created to provide. And it's the main reason why we have such strong bipartisan support for this vital program.

We have also been vigilant in our support of the Housing Opportunities for People with AIDS program. Funding for HOPWA has been increased by 46 percent, bringing support to thousands of individuals and families who were facing homelessness. Like the Ryan White CARE Act, HOPWA is a cost-effective and compassionate program that keeps people healthy for as long as possible while preserving their basic human dignity.

This year, the Republicans in Congress have tried to wipe out HOPWA, claiming that somehow it is no longer needed. The President has stood up to those opponents and demanded that this program be continued. Earlier this year, he sent a letter opposing the House plan to eliminate HOPWA funding. And last month he vetoed a bill that cut funding by \$30 million. Today, we are fighting a similar battle for funding of this program in FY1996.

Together, programs like Ryan White and HOPWA provide a needed safety net of high-quality care. We must and we will fight any effort to weaken that commitment.

The weeks and months ahead will be filled with many challenges. Challenges that will, in many ways, shape our national response to AIDS for the next year and, perhaps, the rest of this decade. How those challenges are resolved will decide whether we continue on the path of progress or return to the days of despair.

One of our greatest challenges troubles me a great deal. That is the future of Medicaid. As you know, Medicaid is an indispensable program for people living with HIV and AIDS. Today, by conservative estimates, half of people with HIV and AIDS get their medical coverage from Medicaid. That includes more than 90 percent of children with AIDS.

When it comes to people with AIDS, there are still problems with Medicaid. For example, many states continue to refuse to cover the cost of HIV counseling and testing. In fact, they will only pay for counseling and testing if a person already shows signs of HIV infection. That doesn't make any sense and it has to change.

But with all of its problems, Medicaid is a god send for people living with AIDS. It pays for visits to the doctor. It pays for hospital stays. It pays for home care. And it pays for prescription drugs. It keeps people healthier for a longer period of time and it allows people access to the new breakthroughs that our scientists are working so hard to uncover.

Yet today, as we meet, the Republican Congress is barreling ahead with an ill-conceived plan to dismantle Medicaid and turn its remnants over to the states in the form of a block grant. They would reduce the Federal share of Medicaid spending by \$182 billion over the next seven years. That figure bears repeating -- \$182 billion dollars! That number is so large we would have to build more than twenty B-2 bombers to spend as much.

These proposals pose the greatest danger to people with AIDS of anything currently being debated in Congress. They would force states -- particularly the largest states like New York and California -- into an untenable situation.

States would have to choose among three very unattractive options: First, they could reduce what they pay for medical care for people on Medicaid. But Medicaid already pays less than anyone else. If it cut its rates further, many doctors and maybe even some hospitals would simply refuse to take Medicaid patients. Secondly, some states may choose to eliminate coverage for certain services or to squeeze down on the amount of services covered. For example, some states could do away with home care coverage. Others could start eliminating high-cost drugs from their formularies. What affect would that have on a person with HIV who needs AZT and DDI and gancyclovir just to stay healthy or to be able to see? Finally, some states will take the easiest way out. They will begin to cut people from the program. Remember that in 1981 -- the last time Congress did anything even vaguely similar to these cuts -- states threw more than one million people off of Medicaid and we've been paying the price ever since.

These proposals cannot pass if we are to gain control over the epidemic. It is that simple. It is that critical. I implore you to add your voices to this issue. We need to see the same fury and the same energy applied to holding on to Medicaid as we have seen on the issue of a single appropriations for AIDS research.

Let me make one more point about Medicaid. We have seen, in recent years, a sharp swing toward managed care for the Medicaid population. When it comes to people with HIV or AIDS, managed care is a very mixed bag. On one hand, we have seen that coordinated care and the use of a case manager can be highly beneficial to a person with a chronic condition. On the other, we have seen the danger of poorly conceived programs that fail to provide the kind of specialists that people with HIV or AIDS require.

That is one reason why we have been working very closely with the Health Care Financing Administration to develop a set of questions that each state must answer before it proceeds with a program of managed care for Medicaid beneficiaries. In addition, we recently arranged a meeting between HCFA and the New York AIDS Coalition so that community groups can have direct input into the Medicaid waiver process. I have received assurances from HCFA that this will become a standard part of the waiver consideration process.

Another significant challenge for all of us is the evolving discussion of HIV antibody testing. Let me state, right up front, that I believe in testing as a tool for personal empowerment. It is my strong belief that if more people voluntarily sought counseling and learned their antibody status that we would see a lot less risky behavior in this country. The trick is to do that in a way that encourages people to come forward instead of driving them away.

It is time that we all reexamine the role of counseling and testing. Let's start with what it is not. It is not, as some would argue, a means of prevention. And it is not, as some assert, a means of treatment. What it is, in reality, is a bridge to both prevention and care.

For testing to work as a bridge to prevention, it must be coupled with competent and comprehensive counseling by well-trained professionals. Giving someone a negative test result and simply sending them on their way does nothing to reward the positive action of coming in for testing.

And for testing to work as a bridge to care, it must be connected to a continuum of care that provides real access to services. To hand someone a positive test result without connecting them to care is simply cruel.

What we need is a set of policies that give voluntary testing a fair chance to prove what we believe to be the case. If our public health model works, and I believe it will, we will be able to show those who are still in doubt that it is an effective model that saves lives. One of our challenges is to create a system that makes sure that counseling and testing are available, that health care professionals are properly trained to provide those services, and that real access to care is assured for those women who test positive for HIV. We have to make sure that this system works because we know the alternative will not.

Finally, I would be remiss if I didn't touch on the international scene. I just returned this week from a trip to Geneva, where I headed the U.S. delegation to the United Nations' Joint and Cosponsored Program on AIDS. We heard some very troubling new reports on the spread of HIV around the world. Today, an estimated 15 million people worldwide live with HIV, about a million of them live in the U.S. Eighty percent of people with HIV live in developing countries and by the year 2000 that will reach 90 percent. And, an estimated 6,000 people around the world are infected with HIV every day.

As horrible as these numbers are, they don't begin to describe the ultimate misery and despair linked to an individual's personal battle with HIV and AIDS in many of these countries. In some developing countries, as many as 50 percent of the population are believed to be HIV-positive. We see thousands and thousands of children orphaned by AIDS. Some of these children are being raised by their grandparents. Others have lost their parents and their grandparents and their raising each other.

If we are to attack this pandemic, we need an alliance of the hearts and minds and resources of the world. That's one reason why the President is fighting so hard to preserve our leadership role in providing funding, technical assistance, research, and prevention programs around the world. To do that, we must also protect the agencies, like USAID, that carry out those important activities.

As the head of the U.S. delegation, I am proud of the fact that we have taken a strong stand in support of the newly established UNAIDS program and that we have convinced the participants to bring non-governmental organizations to the table. This inclusion is indicative of the new era of building and strengthening coalitions from the U.N. to the village level.

All of our efforts -- whether they are domestic or international -- must be guided by a common theme and a common purpose. That is to unleash the power of science and the skill of our public health and medical professions against this insidious disease while opening our hearts and our minds to the needs and the rights of those who are living with HIV and AIDS. If we keep those purposes at the top of our collective agenda, I believe we will succeed.

This council will play a critical role in the success of these efforts. Your job is to give us good advice, keep a watchful eye on what we do, tell us what is happening in that place called the "real world," and keep our feet to the fire. Remember that it is passion that brought you to this issue and passion that makes your opinions and your work most valuable. Don't lose that passion. In fact, unleash it on us all. It can only make us stronger.

Thank you.