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# MNWR

MORBIDITY AND MORTALITY WEEKLY REPORT

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## Current Trends

### **Comparison of Observed and Self-Reported Seat Belt Use Rates — United States**

To measure compliance with seat belt use laws, most states have estimated belt use by direct observation of vehicle occupants. In addition, since 1984, several states have recorded seat belt use data as part of the Behavioral Risk Factor Surveillance System (BRFSS) telephone survey (1-3). Previous studies indicate that telephone surveys usually report higher belt use than do observation surveys conducted in similar areas at similar times (4,5). A systematic comparison of self-reported belt use rates in 15 states\* from the 1987 BRFSS with observed belt use rates in 1987 in the same states follows.

The BRFSS telephone surveys used similar designs in each state. A statistically valid random sample of all adults in each state was obtained by random digit dialing. Each survey asked the same questions and classified the responses into the same five categories. Thus, the BRFSS surveys in each state can be considered replications of the same survey.

For the observation surveys, some states used probability sampling techniques to select locations and times. These surveys produced statistically valid estimates of the actual belt use rates under the conditions surveyed.<sup>†</sup> Other states used locations and times selected by judgment. The accuracy of the estimates from these surveys is unknown.

In the BRFSS self-reported surveys, the number of affirmative answers was derived in two ways: as the total number of respondents who reported "always" using seat belts and as the sum of those who reported "always" and "nearly always" using them. The average self-reported "always" use exceeded observed use by about 8% and ranged from 11% below observed use to 24% above. The average "always or nearly always" self-reported use exceeded observed use by 27%, with a range of 12% above observed use to 39% above. To further examine the relationship between observed and reported seat belt use, simple linear regressions were used for each state (Figures 1 and 2). The relation is described moderately well by either regression; approximately 54% of the variation in prevalence of observed use was accounted for

\*California, Florida, Hawaii, Illinois, Indiana, Maryland, Minnesota, Missouri, New Mexico, New York, North Carolina, Ohio, Tennessee, Utah, and Washington.

<sup>†</sup>Most surveys took place during daylight hours and measured belt use by the driver and right front seat passenger.



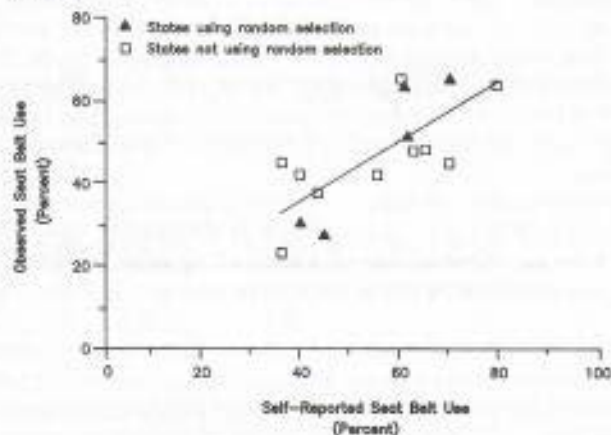
### Seat Belt Use — Continued

by the prevalence of self-reported use. In the regression line for which "always" was used as the definition, a 1 percentage point increase in self-reported use accounted for a 0.7 percentage point increase in observed use. When "always" and "nearly always" were used, a 1 percentage point increase in self-reported belt use accounted for a nearly 1 percentage point increase in observed use. However, these figures are valid only within the range of the self-reported seat belt use data.

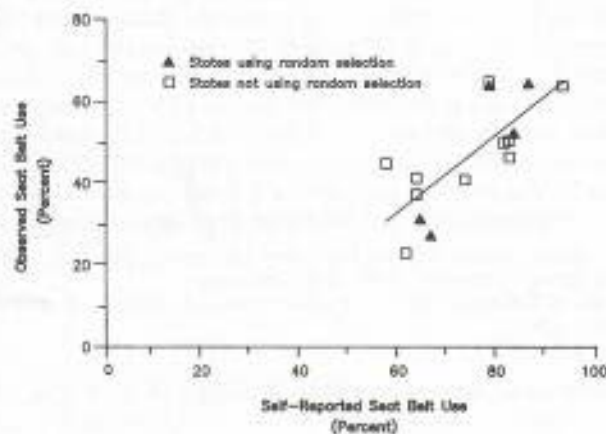
Reported by: Office of Driver and Pedestrian Research, National Highway Traffic Safety Administration, Div of Nutrition, Center for Health Promotion and Education, CDC.

**Editorial Note:** Worldwide experience has demonstrated that seat belt use laws can substantially reduce deaths and injuries on highways. More than 30 foreign countries, 31 states, and the District of Columbia now have laws requiring adult drivers and passengers to use seat belts.

**FIGURE 1. Comparison of observed and self-reported seat belt use ("always") — selected states, 1987**



**FIGURE 2. Comparison of observed and self-reported seat belt use ("always" plus "nearly always") — selected states, 1987**



*Seat Belt Use — Continued*

Direct observation surveys of seat belt use, if properly designed and conducted, can produce accurate estimates of use. However, observation surveys are expensive to conduct and usually observe only shoulder belt use. Furthermore, although they can estimate a driver's or occupant's age and sex, they cannot gather other information useful in understanding belt use, such as trip purpose or attitudes about belt use laws. Telephone surveys provide the opportunity to collect these additional data. They may also be less expensive to design and conduct than observation surveys. However, telephone surveys can record only the respondents' stated behavior, not their actual behavior.

Some of the divergence in the data analyzed here may be due to the fact that the self-reported data were collected each month throughout 1987 and thus estimate average belt use throughout the year. The observed data were collected at different times in each state. Furthermore, the self-reported data were drawn from a sample of the entire state while observed data from some states came from only a few sites. The moderate fit of the regression lines means that they are useful in describing general relations between observed and self-reported belt use, but they should not be used to predict observed use in a single state when only one self-reported survey is available.

More studies such as these are needed to establish reliably the relationship between the results from observation surveys and BRFSS telephone surveys. The results from observation surveys could then be used to help interpret the BRFSS responses and translate them into approximate actual belt use levels. The BRFSS data in turn could be used to investigate characteristics of belt users and nonusers that cannot be determined from observation surveys and to provide information on temporal trends without the expense of observation surveys. In these ways, the usefulness of both types of surveys would be enhanced.

*References*

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### **Quarterly Report to the Domestic Policy Council on the Prevalence and Rate of Spread of HIV and AIDS — United States**

This article summarizes the third report to the Domestic Policy Council (DPC) on the prevalence and rate of spread of human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) in the United States. The first report (1) extensively reviewed data on the prevalence and incidence of HIV infection. The second report was summarized in April 1988 (2). The third report was delivered to the DPC on July 22, 1988; its major points are summarized below, with information updated where appropriate.

## HIV and AIDS — Continued

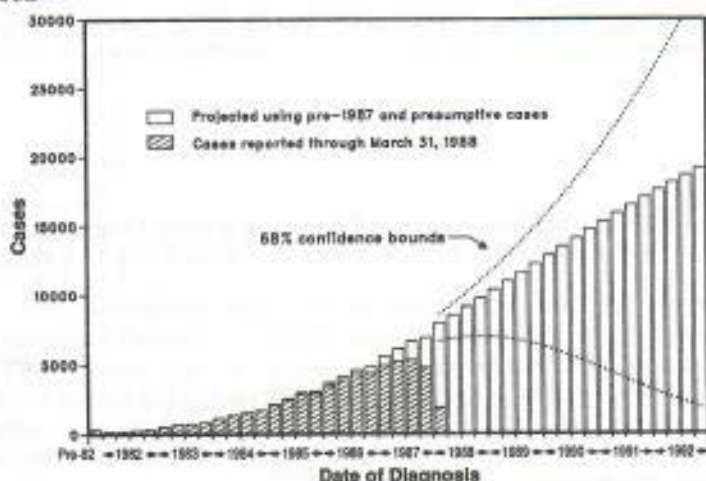
## A. Trends in Reported Cases of AIDS

- By August 29, 1988, a total of 72,024 AIDS cases had been reported in the United States, including over 12,500 cases since the last summary on April 15, 1988.
- In 1986, the Public Health Service (PHS) projected that approximately 270,000 cumulative AIDS cases would be diagnosed by the end of 1991, including 15,800 cases diagnosed in 1986 and 23,000 in 1987. The actual numbers of cases for these years, adjusted for reporting delays, are 17,100 and 25,200 cases, respectively. Using a method similar to that used in 1986 (3), the PHS now projects a cumulative total of 365,000 cases diagnosed by the end of 1992, with 263,000 cumulative deaths (Figure 1).
- In 1992 alone, 80,000 cases are expected to be diagnosed and 66,000 deaths to occur. A total of 172,000 AIDS patients will require medical care in 1992 at a cost expected to range from \$5 billion to \$13 billion.
- In September 1987, the AIDS case definition was revised to include a broader spectrum of HIV-associated diseases and to allow for presumptive diagnoses of certain conditions. Comparisons of cases reported from the 12-month period before September 1987 with those reported since then show this change has led to an increase in the proportion of reported AIDS cases among blacks from 24% to 36% of all reported cases and an increase in the proportion of reported cases among Hispanics from 13% to 16%. Cases in persons thought to have been infected through heterosexual contact also increased from 2.6% of all cases to 3.6%.

## B. Trends in Prevalence and Incidence of HIV Infection

- In April 1988, CDC convened a meeting of experts in mathematical modeling techniques to help estimate the number of Americans now infected with HIV.

FIGURE 1. Incidence of AIDS,\* by quarter and year of diagnosis — United States, pre-1982–1992



\*Projected from cases diagnosed as of June 30, 1987, and reported as of March 31, 1988.



*HIV and AIDS - Continued*

Based on two mathematical approaches, these experts agreed that the current CDC estimate of 1.0 million to 1.5 million is a reasonable working estimate of the number of persons now infected.

- Recent data, including prevalence rates in childbearing women in three states (2), patients at six sentinel hospitals, and prisoners in 15 states (see below), are consistent with this estimate.
- The current estimate for the number of infected Americans is the same as the estimate made in 1986. This does not mean that no new infections have occurred. The 1986 estimate was based on preliminary data and was probably too high.
- Data on the prevalence rate of HIV infection (based on antibody prevalence) are now available from six urban and suburban sentinel hospitals, predominantly in the midwest. In the first 18,809 tests conducted in persons admitted for reasons not associated with HIV infection, the overall seroprevalence was 0.3%. The observed rate is three to four times that found in military recruit applicants in the same cities. The higher rate in hospital patients is expected because persons with risk behaviors are to some extent excluded from military service.
- Seroprevalence in inmates from 15 state correctional systems and the Federal Bureau of Prisons ranges from 0 to 15% (median 0.4%). The risk factor most often reported in seropositive inmates is a history of intravenous-drug abuse.
- Seroprevalence in Job Corps entrants has been 0.4% for the first 65,960 persons tested. Infection rates are highest in males, blacks and Hispanics, and applicants from urban areas.
- Infection rates in sentinel populations that have been followed over time have not shown significant increases. These populations include first-time blood donors (33 months of observation), applicants for military service (30 months of observation), and admissions to sentinel hospitals (15 months of observation). These findings are consistent with some continued HIV transmission (which is also seen in seroconversions in repeatedly tested active-duty military personnel and in repeat blood donors) but argue against an explosive spread of HIV in the population.

**C. Status of HIV and AIDS-Associated Surveys**

- *Implementation of the Comprehensive Family of HIV Surveys*  
To conduct sentinel surveillance for HIV in 30 metropolitan areas, funding was awarded to health departments of 23 states, the District of Columbia, and Puerto Rico on January 29, 1988, with additional funds awarded May 1, 1988. More than 420 different surveys will be conducted in sexually transmitted diseases clinics, drug abuse treatment centers, tuberculosis clinics, women's health clinics, sentinel hospitals, and newborn infant screening programs (in which a sample of specimens routinely collected from newborns are anonymously tested to indicate the prevalence of HIV infection in childbearing women).  
A program to evaluate HIV seroprevalence in college students has begun. By the end of 1988, a total of 20 colleges will participate, and approximately 20,000 serum samples will have been tested.



## HIV and AIDS - Continued

- **National Household Seroprevalence Survey (NHSS)**

A contract for the NHSS was awarded to the Research Triangle Institute. The NHSS will be conducted in two phases. Phase I will be a pilot phase to determine the feasibility of conducting household interviews to obtain demographic information, HIV risk factors, and a blood test for HIV. If Phase I shows that the NHSS is feasible and if funds are available, Phase II, a probability sample of households from throughout the United States, would begin late in 1989 and would include approximately 50,000 respondents.

- **National Health Interview Survey: AIDS Attitudes and Knowledge Survey**

An AIDS questionnaire was developed for the National Health Interview Survey to provide estimates of public knowledge and attitudes about AIDS and changes in knowledge and attitudes over time. The first phase of the survey was conducted from August 1987 through January 1988 and showed continuous increases in knowledge of how HIV is transmitted. A second phase that began in early May 1988 contains additional questions to assist in the evaluation of the "Understanding AIDS" mailing (4).

(Continued on page 559)

TABLE I. Summary - cases of specified notifiable diseases, United States

| Disease                                         | 38th Week Ending |               |                  | Cumulative, 38th Week Ending |               |                  |
|-------------------------------------------------|------------------|---------------|------------------|------------------------------|---------------|------------------|
|                                                 | Sep. 10, 1988    | Sep. 12, 1987 | Median 1983-1987 | Sep. 10, 1988                | Sep. 12, 1987 | Median 1983-1987 |
| Acquired Immunodeficiency Syndrome (AIDS)       | 128              | U*            | 140              | 21,337                       | 13,254        | 5,267            |
| Aseptic meningitis                              | 227              | 467           | 418              | 3,782                        | 7,313         | 6,206            |
| Encephalitis: Primary (arthropod-borne & unspc) | 17               | 40            | 40               | 523                          | 860           | 768              |
| Post-infectious                                 | 4                | 4             | 2                | 88                           | 83            | 83               |
| Gonorrhea: Civilian                             | 10,853           | 13,820        | 15,540           | 463,960                      | 538,107       | 601,533          |
| Military                                        | 184              | 267           | 342              | 8,322                        | 11,649        | 14,591           |
| Hepatitis: Type A                               | 430              | 388           | 412              | 16,895                       | 16,360        | 15,040           |
| Type B                                          | 393              | 448           | 479              | 15,584                       | 17,758        | 17,597           |
| Non A, Non B                                    | 42               | 43            | 65               | 1,805                        | 2,154         | 2,510            |
| Unspecified                                     | 27               | 55            | 85               | 1,457                        | 2,152         | 3,264            |
| Legionellosis                                   | 20               | 6             | 18               | 635                          | 658           | 487              |
| Leprosy                                         | 1                | 4             | 3                | 115                          | 137           | 172              |
| Malaria                                         | 32               | 30            | 30               | 632                          | 637           | 606              |
| Measles: Total <sup>†</sup>                     | 21               | 13            | 29               | 2,178                        | 3,254         | 2,417            |
| Indigenous                                      | 19               | 12            | 19               | 1,952                        | 2,860         | 2,043            |
| Imported                                        | 2                | 1             | 8                | 226                          | 394           | 267              |
| Meningococcal infections                        | 24               | 35            | 30               | 2,097                        | 2,137         | 2,011            |
| Mumps                                           | 32               | 35            | 24               | 3,412                        | 10,260        | 2,421            |
| Pertussis                                       | 109              | 134           | 134              | 1,720                        | 1,716         | 1,716            |
| Rubella (German measles)                        | 7                | 7             | 10               | 158                          | 290           | 543              |
| Syphilis (Primary & Secondary): Civilian        | 640              | 818           | 438              | 27,898                       | 24,220        | 19,147           |
| Military                                        | -                | 1             | 2                | 113                          | 126           | 126              |
| Toxic Shock syndrome                            | 8                | 1             | 8                | 224                          | 228           | 271              |
| Tuberculosis                                    | 297              | 366           | 366              | 14,271                       | 14,572        | 14,613           |
| Tularemia                                       | 2                | 3             | 5                | 140                          | 145           | 145              |
| Typhoid Fever                                   | 10               | 2             | 11               | 231                          | 224           | 234              |
| Typhus fever, tick-borne (RMSF)                 | 29               | 17            | 27               | 480                          | 476           | 556              |
| Rabies, animal                                  | 67               | 91            | 122              | 2,878                        | 3,389         | 3,735            |

TABLE II. Notifiable diseases of low frequency, United States

|                                     | Cum. 1988 |                                                   | Cum. 1988 |
|-------------------------------------|-----------|---------------------------------------------------|-----------|
| Anthrax                             | -         | Leptospirosis                                     | 21        |
| Botulism: Foodborne                 | 17        | Plague (Co. 1)                                    | 12        |
| Infant                              | 25        | Polio-myelitis, Paralytic                         | -         |
| Other                               | 3         | Poliomyelitis (Co. 1; Wl. 1; Ia. 1; Or. 1; Ca. 1) | 61        |
| Brucellosis (Upstate N.Y. 1; Tx. 1) | 43        | Rabies, human                                     | -         |
| Cholera (Co. 1)                     | 2         | Tetanus (Tn. 1)                                   | 34        |
| Congenital rubella syndrome         | 3         | Trichinosis                                       | 36        |
| Congenital syphilis, ages < 1 year  | 304       |                                                   |           |
| Diphtheria                          | -         |                                                   |           |

\*Because AIDS cases are not received weekly from all reporting areas, comparison of weekly figures may be misleading.

<sup>†</sup>Two of the 21 reported cases for this week were imported from a foreign country or can be directly traceable to a known internationally imported case within two generations.

TABLE III. Cases of specified notifiable diseases, United States, weeks ending September 10, 1988 and September 12, 1987 (36th Week)

| Reporting Area | AIDS<br>Cum.<br>1988 | Aseptic<br>Mening-<br>itis<br>Cum.<br>1988 | Encephalitis            |                                      | Gonorrhea<br>(Chlilian) |         | Hepatitis (Viral), by type |                   |                        |                                  | Legionel-<br>losis<br>Cum.<br>1988 | Leprosy<br>Cum.<br>1988 |
|----------------|----------------------|--------------------------------------------|-------------------------|--------------------------------------|-------------------------|---------|----------------------------|-------------------|------------------------|----------------------------------|------------------------------------|-------------------------|
|                |                      |                                            | Primary<br>Cum.<br>1988 | Post-in-<br>fectious<br>Cum.<br>1988 | Cum.                    |         | A<br>Cum.<br>1988          | B<br>Cum.<br>1988 | NA, NB<br>Cum.<br>1988 | Unspeci-<br>fied<br>Cum.<br>1988 |                                    |                         |
|                |                      |                                            |                         |                                      | 1988                    | 1987    |                            |                   |                        |                                  |                                    |                         |
| UNITED STATES  | 21,337               | 3,782                                      | 523                     | 88                                   | 483,990                 | 538,187 | 16,855                     | 15,584            | 1,805                  | 1,487                            | 638                                | 115                     |
| NEW ENGLAND    | 957                  | 235                                        | 18                      | 4                                    | 14,564                  | 16,281  | 619                        | 867               | 100                    | 71                               | 27                                 | 16                      |
| Maine          | 26                   | 10                                         | 1                       | -                                    | 288                     | 489     | 17                         | 44                | 4                      | 1                                | 5                                  | -                       |
| N.H.           | 24                   | 31                                         | 1                       | 3                                    | 187                     | 282     | 37                         | 54                | 7                      | 4                                | 3                                  | -                       |
| Vt.            | 9                    | 13                                         | 6                       | -                                    | 91                      | 142     | 9                          | 29                | 5                      | 3                                | 1                                  | -                       |
| Mass.          | 533                  | 94                                         | 8                       | 1                                    | 4,980                   | 5,932   | 289                        | 521               | 67                     | 48                               | 15                                 | 14                      |
| R.I.           | 58                   | 56                                         | -                       | -                                    | 1,208                   | 1,462   | 70                         | 66                | 10                     | -                                | 3                                  | 1                       |
| Conn.          | 307                  | 31                                         | 3                       | -                                    | 7,810                   | 7,954   | 197                        | 153               | 7                      | 15                               | -                                  | -                       |
| MID. ATLANTIC  | 7,209                | 367                                        | 46                      | 4                                    | 89,498                  | 88,884  | 1,141                      | 2,185             | 128                    | 166                              | 169                                | 8                       |
| Upstate N.Y.   | 931                  | 225                                        | 27                      | 1                                    | 9,516                   | 12,014  | 516                        | 529               | 48                     | 15                               | 89                                 | -                       |
| N.Y. City      | 3,904                | 81                                         | 8                       | 3                                    | 28,013                  | 44,429  | 231                        | 906               | 12                     | 120                              | 29                                 | 7                       |
| N.J.           | 1,770                | 61                                         | 11                      | -                                    | 10,340                  | 11,272  | 203                        | 520               | 44                     | 28                               | 40                                 | 1                       |
| Pa.            | 604                  | -                                          | -                       | -                                    | 21,698                  | 18,168  | 191                        | 233               | 24                     | 3                                | 31                                 | -                       |
| E.N. CENTRAL   | 1,565                | 676                                        | 129                     | 13                                   | 76,736                  | 81,193  | 1,120                      | 1,558             | 164                    | 82                               | 129                                | 4                       |
| Ohio           | 345                  | 201                                        | 41                      | 3                                    | 17,736                  | 17,887  | 243                        | 378               | 26                     | 15                               | 52                                 | -                       |
| Ind.           | 80                   | 58                                         | 16                      | -                                    | 6,157                   | 6,390   | 106                        | 231               | 17                     | 20                               | 13                                 | -                       |
| Ill.           | 730                  | 69                                         | 27                      | 9                                    | 22,108                  | 24,851  | 336                        | 368               | 58                     | 19                               | -                                  | 3                       |
| Mich.          | 322                  | 221                                        | 32                      | -                                    | 25,192                  | 24,979  | 267                        | 492               | 42                     | 25                               | 46                                 | -                       |
| Wis.           | 78                   | 27                                         | 12                      | -                                    | 5,543                   | 7,188   | 168                        | 197               | 21                     | 3                                | 18                                 | 1                       |
| W.N. CENTRAL   | 509                  | 160                                        | 37                      | 7                                    | 19,848                  | 21,715  | 983                        | 725               | 80                     | 24                               | 59                                 | 1                       |
| Minn.          | 113                  | 27                                         | 9                       | 3                                    | 2,852                   | 3,365   | 78                         | 84                | 15                     | 3                                | 2                                  | -                       |
| Iowa           | 28                   | 24                                         | 8                       | -                                    | 1,471                   | 2,041   | 37                         | 69                | 13                     | 1                                | 15                                 | -                       |
| Mo.            | 295                  | 80                                         | 1                       | -                                    | 11,423                  | 11,439  | 539                        | 421               | 35                     | 12                               | 13                                 | -                       |
| N. Dak.        | 4                    | -                                          | 4                       | -                                    | 112                     | 206     | 4                          | 7                 | 2                      | 4                                | 1                                  | -                       |
| S. Dak.        | 5                    | 14                                         | 1                       | 1                                    | 361                     | 396     | 8                          | 4                 | 2                      | -                                | 14                                 | -                       |
| Nebr.          | 30                   | 5                                          | 8                       | 2                                    | 1,069                   | 1,368   | 42                         | 36                | 1                      | -                                | 5                                  | -                       |
| Kans.          | 73                   | 30                                         | 6                       | 1                                    | 2,730                   | 2,900   | 255                        | 94                | 12                     | 4                                | 9                                  | 1                       |
| S. ATLANTIC    | 3,583                | 833                                        | 75                      | 30                                   | 133,224                 | 140,401 | 1,548                      | 3,323             | 272                    | 233                              | 107                                | 1                       |
| Del.           | 52                   | 25                                         | 3                       | -                                    | 2,051                   | 2,211   | 26                         | 101               | 6                      | 2                                | 10                                 | -                       |
| Md.            | 359                  | 107                                        | 7                       | 3                                    | 13,891                  | 15,768  | 264                        | 478               | 29                     | 21                               | 15                                 | 1                       |
| D.C.           | 334                  | 16                                         | 1                       | 1                                    | 9,896                   | 9,312   | 12                         | 32                | 3                      | 1                                | 1                                  | -                       |
| Va.            | 225                  | 95                                         | 23                      | 3                                    | 9,203                   | 10,309  | 288                        | 234               | 58                     | 169                              | 8                                  | -                       |
| W. Va.         | 14                   | 20                                         | 14                      | -                                    | 890                     | 1,036   | 10                         | 47                | 3                      | 3                                | -                                  | -                       |
| N.C.           | 201                  | 99                                         | 18                      | -                                    | 18,752                  | 20,390  | 227                        | 586               | 68                     | -                                | 28                                 | -                       |
| S.C.           | 116                  | 14                                         | -                       | 1                                    | 10,332                  | 11,869  | 31                         | 364               | 9                      | 5                                | 18                                 | -                       |
| Ge.            | 503                  | 94                                         | 1                       | -                                    | 25,723                  | 25,044  | 347                        | 456               | 11                     | 6                                | 15                                 | -                       |
| Fla.           | 1,779                | 388                                        | 10                      | 22                                   | 42,828                  | 44,702  | 406                        | 1,037             | 87                     | 48                               | 14                                 | -                       |
| E.S. CENTRAL   | 527                  | 235                                        | 45                      | 6                                    | 36,366                  | 40,578  | 514                        | 940               | 127                    | 7                                | 28                                 | 1                       |
| Ky.            | 65                   | 68                                         | 11                      | 1                                    | 3,742                   | 4,091   | 385                        | 569               | 44                     | 2                                | 9                                  | -                       |
| Tenn.          | 235                  | 21                                         | 13                      | -                                    | 12,433                  | 14,147  | 78                         | 478               | 34                     | -                                | 7                                  | -                       |
| Ala.           | 136                  | 123                                        | 21                      | 2                                    | 11,274                  | 12,876  | 34                         | 228               | 41                     | 5                                | 9                                  | 1                       |
| Miss.          | 81                   | 25                                         | -                       | 3                                    | 8,607                   | 9,364   | 17                         | 65                | 8                      | -                                | 3                                  | -                       |
| W.S. CENTRAL   | 1,818                | 480                                        | 59                      | 3                                    | 51,690                  | 60,345  | 1,876                      | 1,308             | 164                    | 366                              | 15                                 | 19                      |
| Ark.           | 67                   | 8                                          | 3                       | -                                    | 5,145                   | 6,824   | 230                        | 73                | 3                      | 12                               | 3                                  | -                       |
| La.            | 251                  | 78                                         | 17                      | 1                                    | 10,510                  | 10,830  | 85                         | 242               | 20                     | 11                               | 5                                  | 1                       |
| Okla.          | 99                   | 45                                         | 4                       | -                                    | 4,895                   | 6,732   | 379                        | 320               | 34                     | 22                               | 7                                  | -                       |
| Tex.           | 1,389                | 348                                        | 35                      | 2                                    | 31,150                  | 35,758  | 1,271                      | 864               | 97                     | 321                              | -                                  | 18                      |
| MOUNTAIN       | 542                  | 140                                        | 22                      | 2                                    | 10,294                  | 14,202  | 2,364                      | 1,177             | 189                    | 117                              | 33                                 | 1                       |
| Mont.          | 10                   | 2                                          | -                       | -                                    | 320                     | 394     | 27                         | 42                | 10                     | 3                                | 1                                  | -                       |
| Idaho          | 8                    | 1                                          | -                       | -                                    | 296                     | 510     | 110                        | 80                | 5                      | 3                                | -                                  | -                       |
| Wyo.           | 5                    | 2                                          | -                       | -                                    | 147                     | 353     | 5                          | 11                | 3                      | -                                | 3                                  | -                       |
| Colo.          | 230                  | 51                                         | 3                       | -                                    | 2,271                   | 3,128   | 158                        | 146               | 53                     | 55                               | 8                                  | 1                       |
| N. Mex.        | 36                   | 12                                         | 2                       | -                                    | 983                     | 1,552   | 425                        | 171               | 16                     | 2                                | 1                                  | -                       |
| Ariz.          | 208                  | 41                                         | 8                       | 1                                    | 3,711                   | 4,848   | 1,234                      | 460               | 56                     | 36                               | 13                                 | -                       |
| Utah           | 50                   | 20                                         | 4                       | 1                                    | 381                     | 442     | 232                        | 95                | 31                     | 14                               | 3                                  | -                       |
| Nev.           | 95                   | 11                                         | 5                       | -                                    | 2,295                   | 3,024   | 173                        | 172               | 15                     | 4                                | 4                                  | -                       |
| PACIFIC        | 4,539                | 756                                        | 92                      | 20                                   | 51,220                  | 77,808  | 6,610                      | 3,402             | 591                    | 391                              | 71                                 | 65                      |
| Wash.          | 273                  | -                                          | 6                       | 4                                    | 4,716                   | 6,053   | 1,492                      | 582               | 148                    | 42                               | 14                                 | 4                       |
| Oreg.          | 136                  | -                                          | -                       | -                                    | 2,204                   | 2,836   | 952                        | 418               | 61                     | 21                               | -                                  | 1                       |
| Calif.         | 4,043                | 668                                        | 82                      | 16                                   | 43,144                  | 67,014  | 3,834                      | 2,318             | 376                    | 317                              | 54                                 | 52                      |
| Alaska         | 15                   | 14                                         | 2                       | -                                    | 725                     | 1,160   | 313                        | 45                | 5                      | 6                                | -                                  | 1                       |
| Hawaii         | 73                   | 74                                         | 2                       | -                                    | 431                     | 585     | 8                          | 39                | 4                      | 5                                | 3                                  | 7                       |
| Guam           | 1                    | -                                          | -                       | -                                    | 87                      | 193     | 9                          | 11                | -                      | 2                                | 1                                  | 4                       |
| P.R.           | 844                  | 39                                         | 3                       | 1                                    | 947                     | 1,459   | 31                         | 187               | 34                     | 32                               | -                                  | 3                       |
| V.I.           | 32                   | -                                          | -                       | -                                    | 287                     | 188     | 1                          | 5                 | 2                      | -                                | -                                  | -                       |
| Amer. Samoa    | -                    | -                                          | -                       | -                                    | 65                      | 69      | 3                          | 2                 | -                      | 5                                | -                                  | 2                       |
| C.N.M.I.       | -                    | -                                          | -                       | -                                    | 34                      | -       | 1                          | 2                 | -                      | 4                                | -                                  | 1                       |

N: Not notifiable

U: Unavailable

C.N.M.I.: Commonwealth of the Northern Mariana Islands

TABLE III. (Cont'd.) Cases of specified notifiable diseases, United States, weeks ending September 10, 1988 and September 12, 1987 (36th Week)

| Reporting Area | Malaria<br>Cum.<br>1988 | Measles (Rubella) |              |           |              | Total<br>Cum.<br>1987 | Meningo-<br>coccal<br>infections<br>Cum.<br>1988 | Mumps |              | Pertussis |              |              | Rubella |              |              |
|----------------|-------------------------|-------------------|--------------|-----------|--------------|-----------------------|--------------------------------------------------|-------|--------------|-----------|--------------|--------------|---------|--------------|--------------|
|                |                         | Indigenous        |              | Imported* |              |                       |                                                  | 1988  | Cum.<br>1988 | 1988      | Cum.<br>1988 | Cum.<br>1987 | 1988    | Cum.<br>1988 | Cum.<br>1987 |
|                |                         | 1988              | Cum.<br>1988 | 1988      | Cum.<br>1988 |                       |                                                  |       |              |           |              |              |         |              |              |
| UNITED STATES  | 631                     | 19                | 1,952        | 2         | 229          | 2,254                 | 2,007                                            | 32    | 3,412        | 108       | 1,720        | 1,718        | 7       | 158          | 290          |
| NEW ENGLAND    | 47                      | 1                 | 81           | -         | 50           | 254                   | 181                                              | 2     | 107          | 5         | 125          | 108          | -       | 5            | 1            |
| Maine          | 2                       | -                 | 7            | -         | -            | 2                     | 7                                                | -     | -            | -         | 11           | 26           | -       | -            | -            |
| N.H.           | 1                       | -                 | 66           | -         | 44           | 152                   | 21                                               | 1     | 98           | 1         | 34           | 27           | -       | 3            | -            |
| Vt.            | 3                       | -                 | -            | -         | -            | 26                    | 13                                               | 1     | 4            | -         | 3            | 4            | -       | -            | -            |
| Mass.          | 26                      | -                 | 1            | -         | 2            | 49                    | 83                                               | -     | 7            | 3         | 50           | 36           | -       | 1            | -            |
| R.I.           | 6                       | -                 | -            | -         | -            | 2                     | 21                                               | -     | -            | -         | 10           | 1            | -       | 1            | -            |
| Conn.          | 9                       | 1                 | 7            | -         | 4            | 22                    | 36                                               | -     | -            | 1         | 17           | 14           | -       | -            | -            |
| MID. ATLANTIC  | 57                      | 7                 | 801          | 1         | 47           | 576                   | 214                                              | 2     | 298          | 4         | 106          | 203          | -       | 12           | 15           |
| Upstate N.Y.   | 24                      | -                 | 19           | -         | 18           | 40                    | 88                                               | 2     | 80           | 3         | 65           | 119          | -       | 2            | 9            |
| N.Y. City      | 49                      | 1                 | 41           | 11        | 5            | 459                   | 52                                               | -     | 94           | 1         | 4            | 4            | -       | 7            | 1            |
| N.J.           | 11                      | -                 | 217          | -         | 11           | 39                    | 83                                               | -     | 35           | -         | 4            | 10           | -       | 1            | 1            |
| Pa.            | 13                      | 6                 | 524          | -         | 13           | 38                    | 1                                                | -     | 77           | -         | 33           | 70           | -       | 2            | -            |
| E.N. CENTRAL   | 34                      | -                 | 132          | 1         | 47           | 312                   | 294                                              | 8     | 699          | 3         | 164          | 211          | 2       | 26           | 35           |
| Ohio           | 8                       | -                 | 2            | 11        | 23           | 5                     | 97                                               | -     | 97           | -         | 25           | 85           | -       | 1            | -            |
| Ind.           | 2                       | -                 | 57           | -         | -            | -                     | 24                                               | 1     | 68           | -         | 61           | 13           | -       | -            | -            |
| Ill.           | 2                       | -                 | 55           | -         | 15           | 137                   | 63                                               | 6     | 294          | 2         | 28           | 15           | 2       | 21           | 25           |
| Mich.          | 18                      | -                 | 18           | -         | 5            | 29                    | 62                                               | 1     | 175          | 1         | 30           | 41           | -       | 4            | 9            |
| Wis.           | 3                       | -                 | -            | -         | 4            | 141                   | 38                                               | -     | 94           | -         | 20           | 87           | -       | -            | 1            |
| W.N. CENTRAL   | 16                      | -                 | 11           | -         | 1            | 230                   | 78                                               | -     | 118          | 8         | 108          | 96           | 2       | 2            | 1            |
| Minn.          | 5                       | -                 | 10           | -         | 1            | 39                    | 17                                               | -     | -            | 7         | 48           | 13           | -       | -            | -            |
| Iowa           | 2                       | -                 | -            | -         | -            | -                     | -                                                | -     | 31           | 1         | 20           | 31           | -       | -            | 1            |
| Mo.            | 5                       | -                 | 1            | -         | -            | 189                   | 27                                               | -     | 30           | -         | 15           | 24           | -       | -            | -            |
| N. Dak.        | -                       | -                 | -            | -         | -            | 1                     | -                                                | -     | -            | -         | 11           | 11           | -       | -            | -            |
| S. Dak.        | -                       | -                 | -            | -         | -            | -                     | 3                                                | -     | 1            | -         | 5            | 3            | -       | -            | -            |
| Nebr.          | 1                       | -                 | -            | -         | -            | -                     | 11                                               | -     | 11           | -         | -            | 1            | -       | -            | -            |
| Kans.          | 3                       | -                 | -            | -         | -            | 1                     | 20                                               | -     | 45           | -         | 6            | 13           | 2       | 2            | -            |
| S. ATLANTIC    | 77                      | -                 | 289          | -         | 16           | 130                   | 357                                              | 7     | 540          | 17        | 197          | 245          | 1       | 17           | 14           |
| Del.           | 1                       | -                 | -            | -         | -            | 32                    | 2                                                | -     | -            | -         | 7            | 5            | -       | -            | 2            |
| Md.            | 10                      | -                 | 11           | -         | 3            | 5                     | 42                                               | 3     | 103          | -         | 32           | 11           | -       | 1            | 2            |
| D.C.           | 11                      | -                 | -            | -         | -            | 1                     | 7                                                | 1     | 214          | -         | 1            | -            | -       | -            | -            |
| Va.            | 11                      | -                 | 141          | -         | 2            | 1                     | 41                                               | -     | 119          | 2         | 21           | 47           | -       | 11           | 1            |
| W. Va.         | -                       | -                 | 6            | -         | -            | -                     | 6                                                | -     | 9            | 1         | 8            | 35           | -       | -            | -            |
| N.C.           | 11                      | -                 | -            | -         | 4            | 5                     | 60                                               | 1     | 41           | 8         | 55           | 103          | -       | -            | 1            |
| S.C.           | 8                       | -                 | -            | -         | -            | 2                     | 33                                               | -     | 5            | -         | 1            | -            | -       | -            | -            |
| Ga.            | 4                       | -                 | -            | -         | -            | 1                     | 54                                               | 2     | 27           | 1         | 31           | 23           | 1       | 2            | 1            |
| Fla.           | 21                      | -                 | 131          | -         | 7            | 83                    | 122                                              | -     | 22           | 5         | 41           | 21           | -       | 3            | 7            |
| E.S. CENTRAL   | 10                      | -                 | 55           | -         | -            | 5                     | 199                                              | 4     | 389          | 5         | 65           | 32           | -       | 2            | 3            |
| Ky.            | -                       | -                 | 35           | -         | -            | -                     | 40                                               | -     | 174          | -         | 6            | 1            | -       | -            | 2            |
| Tenn.          | -                       | -                 | -            | -         | -            | -                     | 116                                              | 3     | 200          | -         | 20           | 9            | -       | 2            | 1            |
| Ala.           | 6                       | -                 | 1            | -         | -            | 3                     | 30                                               | 1     | 12           | 5         | 37           | 17           | -       | -            | -            |
| Miss.          | 4                       | -                 | 19           | -         | -            | 2                     | 13                                               | N     | N            | -         | 2            | 5            | -       | -            | -            |
| W.S. CENTRAL   | 58                      | -                 | 11           | -         | 3            | 409                   | 135                                              | 1     | 699          | 1         | 94           | 216          | -       | 7            | 11           |
| Ark.           | 3                       | -                 | -            | -         | 1            | -                     | 17                                               | -     | 91           | -         | 11           | 10           | -       | 3            | 2            |
| La.            | 9                       | -                 | -            | -         | -            | -                     | 39                                               | -     | 262          | -         | 16           | 40           | -       | -            | -            |
| Okla.          | 9                       | -                 | 8            | -         | -            | 3                     | 14                                               | -     | 173          | 1         | 40           | 115          | -       | 1            | 5            |
| Tex.           | 37                      | -                 | 3            | -         | 2            | 408                   | 65                                               | 1     | 143          | -         | 27           | 51           | -       | 3            | 4            |
| MOUNTAIN       | 31                      | -                 | 118          | -         | 21           | 491                   | 59                                               | 3     | 162          | 54        | 533          | 145          | -       | 8            | 24           |
| Mont.          | 5                       | -                 | 6            | -         | 19           | 128                   | 2                                                | -     | 2            | 1         | 2            | 6            | -       | -            | 6            |
| Idaho          | 1                       | -                 | -            | -         | 1            | -                     | 7                                                | -     | 3            | 21        | 203          | 44           | -       | -            | 1            |
| Wyo.           | -                       | -                 | -            | -         | -            | 2                     | -                                                | -     | 2            | -         | 1            | 5            | -       | -            | -            |
| Colo.          | 11                      | -                 | 112          | -         | 1            | 9                     | 14                                               | -     | 28           | -         | 14           | 50           | -       | 2            | -            |
| N. Mex.        | 1                       | -                 | -            | -         | -            | 317                   | 11                                               | N     | N            | 6         | 45           | 9            | -       | -            | -            |
| Ariz.          | 8                       | -                 | -            | -         | -            | 31                    | 15                                               | 2     | 108          | 28        | 187          | 29           | -       | -            | 4            |
| Utah           | 4                       | -                 | -            | -         | -            | 1                     | 9                                                | -     | 6            | -         | 30           | 2            | -       | 3            | 10           |
| Nev.           | 1                       | -                 | -            | -         | -            | 3                     | 1                                                | 1     | 13           | -         | 1            | -            | -       | 1            | -            |
| PACIFIC        | 261                     | 11                | 454          | -         | 41           | 847                   | 592                                              | 5     | 442          | 12        | 330          | 460          | 2       | 81           | 190          |
| Wash.          | 15                      | -                 | 2            | -         | -            | 41                    | 52                                               | -     | 40           | 7         | 79           | 98           | -       | -            | 2            |
| Oreg.          | 11                      | -                 | 3            | -         | -            | 78                    | 31                                               | N     | N            | 1         | 28           | 58           | -       | -            | 2            |
| Calif.         | 223                     | 11                | 448          | -         | 33           | 726                   | 478                                              | 5     | 369          | 4         | 174          | 161          | 2       | 57           | 121          |
| Alaska         | 3                       | -                 | -            | -         | -            | -                     | 6                                                | -     | 9            | -         | 6            | 6            | -       | -            | 3            |
| Hawaii         | 9                       | -                 | 3            | -         | 8            | 4                     | 15                                               | -     | 13           | -         | 45           | 171          | -       | 24           | 63           |
| Guam           | -                       | -                 | -            | -         | 1            | 2                     | -                                                | -     | 2            | -         | -            | -            | -       | 1            | 1            |
| P.R.           | 2                       | -                 | 180          | -         | -            | 737                   | 8                                                | -     | 8            | -         | 13           | 16           | -       | 2            | 2            |
| V.I.           | -                       | -                 | -            | -         | -            | -                     | -                                                | -     | 25           | -         | -            | -            | -       | -            | -            |
| Amer. Samoa    | -                       | -                 | -            | -         | -            | -                     | 2                                                | -     | 3            | -         | -            | -            | -       | -            | -            |
| C.N.M.I.       | 1                       | -                 | -            | -         | -            | -                     | 1                                                | -     | 2            | -         | -            | -            | -       | -            | -            |

\*For measles only, imported cases includes both out-of-state and international importations.

N: Not notifiable U: Unavailable <sup>1</sup>International <sup>2</sup>Out-of-state



TABLE III. (Cont'd.) Cases of specified notifiable diseases, United States, weeks ending September 10, 1988 and September 12, 1987 (36th Week)

| Reporting Area | Syphilis (Chl/lan)<br>(Primary & Secondary) |              | Toxic-<br>shock<br>Syndrome | Tuberculosis |              | Tala-<br>remia | Typhoid<br>Fever | Typhus Fever<br>(Tick-borne)<br>(RMSF) | Rabies,<br>Animal |
|----------------|---------------------------------------------|--------------|-----------------------------|--------------|--------------|----------------|------------------|----------------------------------------|-------------------|
|                | Cum.<br>1988                                | Cum.<br>1987 |                             | Cum.<br>1988 | Cum.<br>1987 |                |                  |                                        |                   |
| UNITED STATES  | 27,858                                      | 24,220       | 224                         | 14,271       | 14,572       | 140            | 231              | 490                                    | 2,878             |
| NEW ENGLAND    | 769                                         | 417          | 19                          | 354          | 443          | 4              | 20               | 10                                     | 12                |
| Maine          | 12                                          | 1            | 4                           | 18           | 21           | -              | -                | -                                      | 1                 |
| N.H.           | 6                                           | 3            | 3                           | 8            | 16           | -              | -                | -                                      | 4                 |
| Vt.            | 3                                           | 2            | 2                           | 3            | 9            | -              | 1                | -                                      | -                 |
| Mass.          | 298                                         | 195          | 8                           | 200          | 249          | 3              | 14               | 5                                      | -                 |
| R.I.           | 24                                          | 8            | -                           | 32           | 35           | -              | -                | 2                                      | -                 |
| Conn.          | 426                                         | 208          | 2                           | 93           | 113          | 1              | 5                | 3                                      | 7                 |
| MID. ATLANTIC  | 7,653                                       | 4,515        | 34                          | 3,762        | 3,463        | -              | 43               | 18                                     | 332               |
| Delaware N.Y.  | 373                                         | 167          | 18                          | 388          | 351          | -              | 7                | 9                                      | 17                |
| N.Y. City      | 5,137                                       | 3,262        | 5                           | 1,470        | 1,157        | -              | 25               | 6                                      | -                 |
| N.J.           | 625                                         | 476          | 3                           | 459          | 465          | -              | 11               | -                                      | 12                |
| Pa.            | 918                                         | 590          | 8                           | 465          | 480          | -              | -                | 3                                      | 303               |
| E.N. CENTRAL   | 765                                         | 646          | 33                          | 1,586        | 1,657        | 1              | 34               | 42                                     | 107               |
| Ohio           | 74                                          | 77           | 23                          | 297          | 316          | -              | 6                | 35                                     | 5                 |
| Ind.           | 39                                          | 45           | -                           | 161          | 153          | -              | 2                | 2                                      | 17                |
| Ill.           | 255                                         | 240          | 1                           | 678          | 733          | -              | 11               | 2                                      | 23                |
| Mich.          | 275                                         | 129          | 9                           | 377          | 380          | 1              | 4                | 2                                      | 30                |
| Wis.           | 22                                          | 47           | -                           | 73           | 75           | -              | 1                | 1                                      | 32                |
| W.N. CENTRAL   | 162                                         | 137          | 27                          | 372          | 434          | 66             | 3                | 72                                     | 261               |
| Minn.          | 16                                          | 14           | 5                           | 61           | 89           | 3              | 2                | 2                                      | 108               |
| Iowa           | 17                                          | 20           | 5                           | 40           | 30           | -              | -                | -                                      | 13                |
| Mo.            | 100                                         | 66           | 7                           | 185          | 238          | 39             | 1                | 44                                     | 16                |
| N. Dak.        | 1                                           | -            | 2                           | 10           | 6            | 1              | -                | -                                      | 72                |
| S. Dak.        | -                                           | 10           | 1                           | 25           | 22           | 16             | -                | 7                                      | 101               |
| Nebr.          | 22                                          | 7            | 2                           | 10           | 10           | 2              | -                | 1                                      | 11                |
| Kans.          | 6                                           | 20           | 5                           | 40           | 33           | 5              | -                | 18                                     | 30                |
| S. ATLANTIC    | 8,687                                       | 8,262        | 16                          | 3,664        | 3,126        | 4              | 25               | 155                                    | 951               |
| Del.           | 74                                          | 54           | 1                           | 22           | 32           | 1              | -                | 1                                      | 40                |
| Ms.            | 524                                         | 420          | 3                           | 299          | 253          | -              | 1                | 20                                     | 226               |
| D.C.           | 473                                         | 247          | -                           | 132          | 106          | -              | 1                | -                                      | 5                 |
| Va.            | 274                                         | 205          | -                           | 276          | 311          | 2              | 10               | 14                                     | 257               |
| W. Va.         | 34                                          | 6            | -                           | 54           | 77           | -              | -                | 2                                      | 75                |
| N.C.           | 549                                         | 464          | 7                           | 313          | 333          | -              | 1                | 85                                     | 6                 |
| S.C.           | 479                                         | 521          | 2                           | 339          | 331          | -              | -                | 16                                     | 73                |
| Ga.            | 1,839                                       | 1,188        | -                           | 511          | 542          | 1              | 2                | 12                                     | 191               |
| Fla.           | 5,641                                       | 5,168        | 3                           | 1,139        | 1,112        | -              | 10               | 4                                      | 78                |
| E.S. CENTRAL   | 1,361                                       | 1,318        | 18                          | 1,175        | 1,249        | 8              | 3                | 64                                     | 199               |
| Ky.            | 46                                          | 13           | 7                           | 270          | 292          | 4              | 1                | 18                                     | 78                |
| Tenn.          | 583                                         | 530          | 9                           | 325          | 355          | 3              | -                | 34                                     | 55                |
| Ala.           | 408                                         | 342          | 3                           | 395          | 355          | -              | 1                | 8                                      | 64                |
| Miss.          | 323                                         | 433          | -                           | 214          | 227          | 1              | 1                | 6                                      | 2                 |
| W.S. CENTRAL   | 2,919                                       | 2,822        | 20                          | 1,791        | 1,707        | 42             | 7                | 114                                    | 388               |
| Ark.           | 170                                         | 167          | 1                           | 194          | 200          | 28             | -                | 20                                     | 62                |
| La.            | 964                                         | 516          | -                           | 200          | 188          | -              | 3                | 1                                      | 7                 |
| Okla.          | 107                                         | 105          | 7                           | 168          | 155          | 12             | -                | 80                                     | 27                |
| Tex.           | 2,078                                       | 2,114        | 12                          | 1,229        | 1,154        | 2              | 4                | 13                                     | 292               |
| MOUNTAIN       | 541                                         | 479          | 24                          | 379          | 435          | 10             | 8                | 11                                     | 266               |
| Mont.          | 3                                           | 8            | -                           | 12           | 10           | -              | 1                | 5                                      | 159               |
| Idaho          | 2                                           | 5            | 3                           | 14           | 25           | -              | -                | 1                                      | 9                 |
| Wyo.           | 1                                           | 3            | -                           | 2            | 2            | 2              | -                | 3                                      | 32                |
| Colo.          | 79                                          | 80           | 3                           | 43           | 125          | 5              | 3                | 1                                      | 24                |
| N. Mex.        | 39                                          | 40           | -                           | 74           | 73           | 2              | 1                | -                                      | 7                 |
| Ariz.          | 115                                         | 230          | 9                           | 170          | 162          | -              | 3                | -                                      | 30                |
| Utah           | 12                                          | 21           | 9                           | 18           | 18           | 1              | -                | -                                      | 5                 |
| Nev.           | 289                                         | 92           | -                           | 96           | 20           | -              | -                | -                                      | -                 |
| PACIFIC        | 4,611                                       | 5,534        | 33                          | 2,788        | 3,056        | 6              | 98               | 4                                      | 272               |
| Wash.          | 116                                         | 102          | 4                           | 147          | 179          | -              | 6                | 1                                      | -                 |
| Oreg.          | 198                                         | 203          | 1                           | 102          | 80           | -              | 6                | 1                                      | -                 |
| Calif.         | 4,263                                       | 5,217        | 28                          | 2,382        | 2,625        | 3              | 83               | 2                                      | 264               |
| Alaska         | 10                                          | 3            | -                           | 29           | 42           | 2              | -                | -                                      | 8                 |
| Hawaii         | 24                                          | 9            | -                           | 108          | 132          | -              | 3                | -                                      | -                 |
| Guam           | 3                                           | 2            | -                           | 16           | 26           | -              | -                | -                                      | -                 |
| P.R.           | 430                                         | 648          | -                           | 165          | 208          | -              | 4                | -                                      | 47                |
| V.I.           | 1                                           | 4            | -                           | 4            | 2            | -              | -                | -                                      | -                 |
| Amer. Samoa    | -                                           | -            | -                           | 3            | 7            | -              | 1                | -                                      | -                 |
| C.N.M.I.       | 1                                           | -            | -                           | 17           | -            | -              | -                | -                                      | -                 |

U: Unavailable



TABLE IV. Deaths in 121 U.S. cities,\* week ending  
September 10, 1988 (36th Week)

| Reporting Area      | All Causes, By Age (Years) |       |       |       |      |    | P&I** | Reporting Area        | All Causes, By Age (Years) |       |       |       |      |     | P&I** | Total |
|---------------------|----------------------------|-------|-------|-------|------|----|-------|-----------------------|----------------------------|-------|-------|-------|------|-----|-------|-------|
|                     | All Ages                   | >65   | 45-64 | 25-44 | 1-24 | <1 |       |                       | All Ages                   | >65   | 45-64 | 25-44 | 1-24 | <1  |       |       |
| NEW ENGLAND         | 579                        | 373   | 135   | 39    | 19   | 13 | 59    | S. ATLANTIC           | 1,037                      | 605   | 213   | 121   | 54   | 44  | 37    |       |
| Boston, Mass.       | 176                        | 108   | 42    | 16    | 4    | 6  | 22    | Atlanta, Ga.          | 142                        | 74    | 33    | 18    | 8    | 9   | 1     |       |
| Bridgeport, Conn.   | 34                         | 21    | 8     | 3     | 2    | -  | -     | Baltimore, Md.        | 174                        | 108   | 33    | 23    | 6    | 4   | 12    |       |
| Cambridge, Mass.    | 18                         | 11    | 6     | 1     | -    | -  | -     | Charlotte, N.C.       | 62                         | 41    | 16    | 3     | 2    | -   | 8     |       |
| Fall River, Mass.   | 25                         | 16    | 7     | 2     | -    | -  | -     | Jacksonville, Fla.    | 74                         | 53    | 10    | 4     | 1    | 6   | -     |       |
| Hartford, Conn.     | 38                         | 27    | 9     | 1     | 1    | -  | -     | Miami, Fla.           | 94                         | 66    | 22    | 19    | 4    | 3   | -     |       |
| Lowell, Mass.       | 31                         | 17    | 11    | 1     | 2    | -  | -     | Norfolk, Va.          | 52                         | 32    | 9     | 5     | 4    | 2   | 2     |       |
| Lynn, Mass.         | 17                         | 14    | 2     | 1     | -    | -  | -     | Richmond, Va.         | 71                         | 36    | 17    | 8     | 7    | 3   | 4     |       |
| New Bedford, Mass.  | 25                         | 17    | 4     | 3     | 1    | -  | -     | Savannah, Ga.         | 53                         | 31    | 10    | 2     | 5    | 6   | 4     |       |
| New Haven, Conn.    | 36                         | 18    | 10    | 4     | 3    | 1  | 5     | St. Petersburg, Fla.  | 58                         | 32    | 1     | 1     | 4    | -   | 4     |       |
| Providence, R.I.    | 30                         | 21    | 5     | 1     | 1    | 2  | 3     | Tampa, Fla.           | 60                         | 40    | 12    | 4     | 2    | 2   | 1     |       |
| Somerville, Mass.   | 3                          | 2     | 1     | -     | -    | -  | -     | Washington, D.C.      | 178                        | 79    | 49    | 30    | 11   | 10  | 1     |       |
| Springfield, Mass.  | 49                         | 31    | 13    | 1     | -    | 4  | 1     | Wilmington, Del.      | 19                         | 14    | 1     | 4     | -    | -   | -     |       |
| Waterbury, Conn.    | 49                         | 37    | 7     | 2     | 3    | -  | 3     | E.S. CENTRAL          | 880                        | 405   | 150   | 48    | 26   | 31  | 38    |       |
| Worcester, Mass.    | 45                         | 30    | 10    | 3     | 2    | -  | 3     | Birmingham, Ala.      | 82                         | 52    | 17    | 6     | 1    | 6   | -     |       |
| MID. ATLANTIC       | 2,276                      | 1,439 | 488   | 264   | 85   | 49 | 95    | Chattanooga, Tenn.    | 28                         | 21    | 3     | 2     | 1    | 1   | 2     |       |
| Albany, N.Y.        | 48                         | 33    | 9     | 2     | 2    | 2  | 1     | Knoxville, Tenn.      | 119                        | 76    | 27    | 4     | 10   | 2   | 11    |       |
| Allentown, Pa.      | 18                         | 17    | -     | -     | 1    | -  | -     | Louisville, Ky.       | 65                         | 34    | 17    | 1     | 2    | 1   | 3     |       |
| Buffalo, N.Y.       | 90                         | 54    | 21    | 8     | 3    | 3  | 7     | Memphis, Tenn.        | 158                        | 83    | 40    | 14    | 6    | 13  | 14    |       |
| Camden, N.J.        | 34                         | 21    | 6     | 5     | -    | 2  | -     | Mobile, Ala.          | 52                         | 36    | 7     | 5     | 3    | 1   | 2     |       |
| Elizabeth, N.J.     | 31                         | 22    | 4     | 5     | -    | -  | -     | Montgomery, Ala.      | 62                         | 40    | 13    | 6     | 1    | 3   | 4     |       |
| Erie, Pa.           | 35                         | 24    | 8     | 1     | 2    | -  | 2     | Nashville, Tenn.      | 106                        | 63    | 27    | 10    | 2    | 4   | 2     |       |
| Jersey City, N.J.   | 78                         | 42    | 17    | 13    | 1    | 3  | 5     | W.S. CENTRAL          | 1,600                      | 980   | 348   | 165   | 55   | 49  | 54    |       |
| N.Y. City, N.Y.     | 1,287                      | 780   | 252   | 172   | 38   | 25 | 39    | Austin, Tex.          | 56                         | 41    | 7     | 3     | 4    | 1   | 3     |       |
| Newark, N.J.        | 41                         | 15    | 11    | 13    | 1    | 1  | 1     | Baton Rouge, La.      | 43                         | 24    | 13    | 5     | -    | 1   | 1     |       |
| Paterson, N.J.      | 42                         | 24    | 7     | 7     | 3    | 1  | 2     | Corpus Christi, Tex.† | 49                         | 38    | 10    | 1     | -    | -   | 1     |       |
| Philadelphia, Pa.   | 196                        | 116   | 52    | 11    | 10   | 7  | 11    | Dallas, Tex.          | 180                        | 102   | 39    | 21    | 8    | 10  | 4     |       |
| Pittsburgh, Pa.†    | 27                         | 15    | 10    | 1     | 1    | -  | -     | El Paso, Tex.         | 55                         | 38    | 12    | 3     | 1    | 1   | 6     |       |
| Reading, Pa.        | 23                         | 19    | 3     | 1     | -    | -  | 2     | Fort Worth, Tex.      | 77                         | 55    | 7     | 5     | 4    | 6   | 4     |       |
| Rochester, N.Y.     | 109                        | 87    | 10    | 8     | 2    | 2  | 6     | Houston, Tex.‡        | 723                        | 426   | 168   | 89    | 24   | 16  | 19    |       |
| Schenectady, N.Y.   | 33                         | 23    | 5     | 4     | -    | 1  | 1     | Little Rock, Ark.     | 95                         | 18    | 10    | 6     | -    | 1   | -     |       |
| Scranton, Pa.†      | 40                         | 30    | 9     | 1     | -    | -  | 4     | New Orleans, La.      | 111                        | 68    | 27    | 13    | 6    | 4   | -     |       |
| Syracuse, N.Y.      | 82                         | 57    | 20    | 3     | -    | 2  | 6     | San Antonio, Tex.     | 135                        | 89    | 27    | 9     | 3    | 7   | 8     |       |
| Trenton, N.J.       | 28                         | 16    | 8     | 4     | -    | -  | 3     | Shreveport, La.       | 63                         | 43    | 14    | 2     | 2    | 2   | 5     |       |
| Utica, N.Y.         | 22                         | 20    | 6     | 2     | -    | -  | 3     | Tulsa, Okla.          | 73                         | 48    | 14    | 8     | 3    | -   | 3     |       |
| Yonkers, N.Y.       | 34                         | 24    | 6     | 3     | 1    | -  | 3     | MOUNTAIN              | 618                        | 407   | 115   | 65    | 20   | 19  | 25    |       |
| E.N. CENTRAL        | 2,045                      | 1,334 | 421   | 164   | 47   | 75 | 69    | Albuquerque, N. Mex.  | 53                         | 64    | 14    | 9     | 3    | 3   | 5     |       |
| Akron, Ohio         | 64                         | 41    | 16    | 1     | 1    | 5  | -     | Colo. Springs, Colo.  | 42                         | 28    | 7     | 7     | 1    | 1   | -     |       |
| Canton, Ohio        | 38                         | 26    | 11    | 1     | -    | -  | -     | Denver, Colo.         | 106                        | 72    | 21    | 9     | 3    | 1   | 5     |       |
| Chicago, Ill.‡      | 564                        | 362   | 125   | 45    | 10   | 22 | 18    | Las Vegas, Nev.       | 71                         | 44    | 18    | 9     | 1    | 1   | 3     |       |
| Cincinnati, Ohio    | 103                        | 70    | 18    | 6     | 3    | 3  | 5     | Ogden, Utah           | 18                         | 15    | 3     | -     | -    | -   | 1     |       |
| Cleveland, Ohio     | 135                        | 83    | 34    | 11    | 3    | 4  | 4     | Phoenix, Ariz.        | 113                        | 62    | 22    | 13    | 9    | 7   | 7     |       |
| Columbus, Ohio      | 118                        | 75    | 15    | 15    | 6    | 8  | 2     | Pueblo, Colo.         | 29                         | 17    | 3     | -     | -    | -   | 1     |       |
| Dayton, Ohio        | 82                         | 56    | 18    | 5     | 3    | -  | 2     | Salt Lake City, Utah  | 44                         | 29    | 9     | 3     | -    | 3   | -     |       |
| Detroit, Mich.      | 208                        | 118   | 38    | 37    | 8    | 9  | 5     | Tucson, Ariz.         | 108                        | 78    | 20    | 5     | 3    | 3   | 3     |       |
| Evansville, Ind.    | 28                         | 19    | 8     | 1     | -    | -  | -     | PACIFIC               | 1,708                      | 1,071 | 332   | 196   | 62   | 36  | 81    |       |
| Fort Wayne, Ind.    | 39                         | 22    | 8     | 5     | 1    | 3  | -     | Berkeley, Calif.      | 14                         | 9     | 2     | 3     | -    | -   | 1     |       |
| Gary, Ind.          | 16                         | 6     | 6     | 2     | 2    | 2  | 10    | Fresno, Calif.        | 94                         | 48    | 19    | 11    | 3    | 3   | 3     |       |
| Grand Rapids, Mich. | 82                         | 56    | 14    | 3     | 2    | 7  | 4     | Glendale, Calif.      | 40                         | 27    | 11    | -     | 1    | 1   | 1     |       |
| Indianapolis, Ind.  | 162                        | 104   | 32    | 9     | 1    | 6  | 4     | Honolulu, Hawaii      | 65                         | 35    | 17    | 10    | -    | 3   | 8     |       |
| Madison, Wis.‡      | 36                         | 26    | 6     | 2     | 1    | 1  | 2     | Long Beach, Calif.    | 69                         | 45    | 11    | 5     | 3    | 4   | 7     |       |
| Milwaukee, Wis.     | 95                         | 67    | 20    | 5     | 2    | 2  | 1     | Los Angeles, Calif.   | 477                        | 284   | 96    | 57    | 21   | 9   | 11    |       |
| Peoria, Ill.        | 50                         | 36    | 7     | 3     | 2    | 2  | 4     | Oakland, Calif.       | 44                         | 31    | 6     | 3     | 3    | 1   | 2     |       |
| Rockford, Ill.      | 30                         | 24    | 2     | 2     | -    | 2  | 1     | Pasadena, Calif.      | 25                         | 17    | 4     | 1     | 1    | 2   | 1     |       |
| South Bend, Ind.    | 28                         | 19    | 8     | 1     | -    | -  | -     | Portland, Oreg.       | 94                         | 54    | 21    | 15    | 4    | -   | 1     |       |
| Toledo, Ohio        | 113                        | 79    | 23    | 7     | 2    | 2  | 8     | Sacramento, Calif.    | 147                        | 92    | 28    | 18    | 6    | 4   | 17    |       |
| Youngstown, Ohio    | 63                         | 45    | 14    | 3     | -    | 1  | 1     | San Diego, Calif.     | 114                        | 83    | 17    | 12    | 2    | -   | 9     |       |
| W.N. CENTRAL        | 720                        | 489   | 144   | 38    | 25   | 23 | 27    | San Francisco, Calif. | 152                        | 96    | 28    | 32    | 5    | 1   | 5     |       |
| Des Moines, Iowa    | 60                         | 48    | 9     | 2     | -    | 1  | 3     | San Jose, Calif.      | 156                        | 101   | 35    | 12    | 6    | 2   | 17    |       |
| Duluth, Minn.       | 19                         | 14    | 4     | -     | -    | 1  | 1     | Seattle, Wash.        | 135                        | 88    | 24    | 13    | 6    | 4   | -     |       |
| Kansas City, Kans.  | 23                         | 15    | 7     | 1     | -    | -  | -     | Spokane, Wash.        | 48                         | 37    | 6     | 1     | -    | 1   | 5     |       |
| Kansas City, Mo.    | 111                        | 68    | 20    | 11    | 6    | 5  | 5     | Tacoma, Wash.         | 47                         | 33    | 9     | 3     | 1    | 1   | 3     |       |
| Lincoln, Nebr.      | 34                         | 23    | 6     | 2     | 1    | 2  | 2     | TOTAL                 | 11,241**                   | 7,103 | 2,316 | 1,090 | 373  | 343 | 482   |       |
| Minneapolis, Minn.  | 156                        | 111   | 30    | 6     | 7    | 2  | 6     |                       |                            |       |       |       |      |     |       |       |
| Omaha, Nebr.        | 80                         | 54    | 11    | 6     | 3    | 6  | 3     |                       |                            |       |       |       |      |     |       |       |
| St. Louis, Mo.      | 114                        | 67    | 28    | 9     | 6    | 5  | 1     |                       |                            |       |       |       |      |     |       |       |
| St. Paul, Minn.     | 52                         | 35    | 15    | -     | 2    | -  | 3     |                       |                            |       |       |       |      |     |       |       |
| Wichita, Kans.‡     | 71                         | 54    | 14    | 1     | 1    | 1  | 3     |                       |                            |       |       |       |      |     |       |       |

\*Mortality data in this table are voluntarily reported from 121 cities in the United States, most of which have populations of 100,000 or more. A death is reported by the place of its occurrence and by the week that the death certificate was filed. Fetal deaths are not included.

\*\*Pneumonia and influenza.

†Because of changes in reporting methods in these 3 Pennsylvania cities, these numbers are partial counts for the current week. Complete counts will be available in 4 to 6 weeks.

‡Total includes unknown ages.

§Data not available. Figures are estimates based on average of past available 4 weeks.

*HIV and AIDS - Continued*

Reported by: AIDS Program, Center for Infectious Diseases; National Center for Health Statistics, CDC.

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*Epidemiologic Notes and Reports***Imported Dog and Cat Rabies - New Hampshire, California**

In 1987, rabies was reported in a dog in New Hampshire and a cat in California. Both animals had been recently imported from Mexico.

**New Hampshire.** The first case of dog rabies in New Hampshire since 1967 was confirmed on January 17, 1988, in a 5-month-old puppy that had been imported into the United States 3½ weeks earlier. The dog was presented to a veterinarian on January 16 because of whimpering, tremors of one leg for 3 days, urinary and fecal incontinence for 12 hours, and excessive salivation for 2 hours. Based on the puppy's history and symptoms, the veterinarian suspected rabies, and the dog was euthanized.

The dog was brought into New Hampshire by a 13-year-old girl who adopted it while visiting her mother near Mexico City. The dog was immunized against parvovirus, but not rabies, by a veterinarian in Mexico who also issued a health certificate for the dog the day before departure. The girl flew with the dog from Mexico City to New York City on December 30. On arrival, a U.S. Customs official at the airport briefly inspected the puppy and questioned the girl about its health. She presented the health certificate, and the dog was permitted entry without proof of rabies immunization or the required isolation at the final destination. The girl and dog arrived in New Hampshire on December 31.

The girl brought the dog to school, various parties, and babysitting jobs. Seventeen people received rabies postexposure prophylaxis primarily because of facial exposure to the dog's saliva. The total cost of doctors' visits, rabies vaccine, and rabies immune globulin was \$12,100.

**California.** A similar case of imported animal rabies from Mexico occurred in a cat in Los Angeles (1). In September 1987, a stray cat of unknown rabies immunization status was adopted by a woman vacationing in Acapulco. The cat passed through U.S. Customs even though it was sick at the time. The woman presented the cat to three veterinarians; based on its history and symptoms (including incoordination, nervousness, twitching, salivation), two of the three suspected rabies and recommended euthanasia. Four days after arrival, the cat died and was found positive for rabies. Twenty persons subsequently received rabies postexposure prophylaxis.

All U.S. Customs officials have been notified of these incidents and have been reminded that proof of rabies immunization must accompany all dogs  $\geq 3$  months of age entering the United States from rabies-endemic countries and that all animals must be in good health upon entry.



*Rabies — Continued*

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**Editorial Note:** Dog and cat rabies is hyperendemic in Mexico and most countries of Africa, Asia, and Central and South America (2,3). Dog rabies is extremely rare in the New England states; the most recent cases were reported from Maine and Vermont in 1978 (4). Veterinarians should suspect rabies when a dog, cat, or other susceptible animal is imported from a rabies-hyperendemic area and develops an unexplained rapidly progressive neurologic disease.

Public Health Service quarantine regulations (42 CFR 71.51) require that all dogs  $\geq 3$  months of age imported from countries not free of rabies have a valid rabies vaccination certificate and be vaccinated at least 30 days before entering the United States (5). Unimmunized dogs may be permitted entry if they are vaccinated for rabies and confined for at least 30 days after vaccination. However, a recent case of rabies in an imported dog, which occurred despite appropriate rabies immunization before entry, illustrates that these regulations, even when followed correctly, may not always prevent imported rabies (6). It is highly recommended that cats from rabies-hyperendemic countries be immunized before entry. Dogs, cats, and other rabies-susceptible animals should not be imported as pets from rabies-hyperendemic countries. Travelers to such countries should not take their pets with them or acquire pets abroad unless absolutely necessary.

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### Assessing Exposures of Health-Care Personnel to Aerosols of Ribavirin — California

In April 1986, a hospital in the San Francisco Bay area asked the Occupational Health Surveillance and Evaluation Program (OHSEP) of the California Department of Health Services to evaluate occupational risks to health-care workers of exposure to aerosols of ribavirin, an antiviral agent effective against many RNA and DNA viruses. OHSEP subsequently asked the National Institute for Occupational Safety and Health (NIOSH) for technical assistance in assessing environmental exposures.

From December 1986 through March 1987, OHSEP investigators performed surveys in the pediatric intensive-care units (ICUs) of four San Francisco Bay area hospitals to evaluate exposure levels associated with the various methods of administering ribavirin aerosol. Twelve personal-breathing-zone air samples from 10 nurses and two respiratory therapists and 14 air samples from the bedside area were

*Ribavirin - Continued*

collected during the administration of ribavirin aerosols through oxygen tents, mist masks, or ventilators. The health-care workers studied spent an average of 50% of their workshifts (range: 20%–80%) at the bedsides of patients who received such therapy. Shifts lasted 7–12 hours, and several health-care workers wore surgical masks while delivering direct patient care.

Personal-breathing-zone air samples were collected on 37-mm glass fiber filters using personal sampling pumps held in open-faced cassettes attached to the lapels of the exposed health-care workers. Samples were collected over full shifts during which workers provided care for patients receiving aerosolized ribavirin, including periods when the workers were away from ribavirin-delivery areas. Air samples were collected in the bedside area with similar pumps and cassettes placed at the heads of the beds of treated patients. NIOSH analyzed environmental samples for aerosolized ribavirin using high-performance liquid chromatography (detection limit: 1.0–1.4  $\mu\text{g}$  per sample). Four of the general bedside-air samples were collected in duplicate for independent confirmatory analysis by a radioimmunoassay technique.

Of the 12 workers evaluated, the six nurses and two respiratory therapists providing direct care to patients who received ribavirin through an oxygen tent were exposed to the highest air levels over the workshift (mean ribavirin concentration in personal air samples: 161  $\mu\text{g}/\text{m}^3$ , range: 69–316  $\mu\text{g}/\text{m}^3$ ). The three nurses attending patients who received ribavirin through a ventilator were exposed to the lowest air concentrations (range: <1 to 6  $\mu\text{g}/\text{m}^3$ ), and one nurse providing care for a patient who received ribavirin through a mist mask was exposed to a mean concentration of 62  $\mu\text{g}/\text{m}^3$ . Bedside area samples, collected continuously in the ribavirin-delivery areas, showed generally higher ribavirin concentrations than the corresponding personal samples, averaging 317  $\mu\text{g}/\text{m}^3$  during administration through an oxygen tent. Samples analyzed by radioimmunoassay confirmed the results obtained by high-performance liquid chromatography. In four of the six measurements performed, ventilation in the ICUs exceeded the minimum room-air exchange rate recommended by the U.S. Department of Health and Human Services for hospital ICUs (6 air changes per hour) (1). No correlation between unit ventilation and the results of personal or area sampling was noted.

To evaluate the absorption of ribavirin by exposed hospital personnel, samples of serum, red blood cells (RBCs), and urine were collected from each participant at each of three sampling times: before, immediately after, and 3–7 days after the first workshift with ribavirin exposure. Biological samples were analyzed for ribavirin by a radioimmunoassay technique with a detection limit of 0.002  $\mu\text{g}/\text{mL}$  (2).

Eight nurses and two respiratory therapists submitted a total of 30 serum samples, 30 RBC samples, and 30 urine samples. Ribavirin was not detected in any urine or serum samples but was detected at a concentration of 0.44  $\mu\text{g}/\text{mL}$  in one RBC sample collected from a nurse 5 days after the first shift in which she gave direct care to a patient receiving ribavirin through an oxygen tent. Environmental samples collected during the work shift of this nurse showed the highest concentrations of ribavirin in air (personal: 316  $\mu\text{g}/\text{m}^3$ , bedside area: 1048  $\mu\text{g}/\text{m}^3$ ) observed in the study. This nurse did not report any unusual or increased activity related to patient care that might have resulted in increased exposure.

No symptoms were reported by any health-care workers in this study.

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*Ribavirin - Continued*

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**Editorial Note:** Ribavirin (1- $\beta$ -5-D-ribofuranosyl-1,2,4-triazole-3-carboxamide [Virazole\*]) is a synthetic nucleoside analog that appears to restrict the synthesis of viral proteins and interferes with formation of the cap on viral-messenger RNA (3). In 1986, the Food and Drug Administration approved it for aerosol treatment of infants and young children with severe respiratory syncytial virus infection (4-6). Ribavirin is usually administered through a specific aerosol generator, which produces respirable particles (mass median diameter approximately 1.3  $\mu$ m) at a rate of 12.5 L of ribavirin/air mixture per minute. The aerosol/air mixture is delivered through a mist mask or oxygen tent to the patient; the excess is exhausted directly into the room. Ribavirin may also be used as an investigational drug administered through a ventilator, with the excess aerosol in expired air being filtered to limit release into patient-care areas (7). The administration route is usually determined by clinical considerations. Duration of treatment is generally 3-5 days for 12-20 hours each day, although longer periods may also be employed.

Ribavirin causes reabsorption of the fetus in pregnant rabbits and malformations in the offspring of all rodent species tested (8,9). It also causes tubular atrophy in the testes of adult rats (8). Based on data from studies in animals, ribavirin is contraindicated for use in pregnant women (10,11).

Pharmacokinetic studies indicate that absorbed ribavirin is concentrated in the RBCs of humans (12). In the only previous study of occupational exposure, ribavirin was not detected in the RBCs, plasma, or urine of nurses administering ribavirin aerosol; air samples were not collected in that study (13). A simple mathematical model, incorporating breathing-zone air level, respiratory minute volume, and a factor of 70% (14) for the fraction of the inhaled dose absorbed, estimates an average absorbed dose per workshift (8-12 hours) of 13.5  $\mu$ g/kg body weight for nurses in the present study who attended patients receiving ribavirin through oxygen tents (15). This estimated absorbed dose exceeds 1/100 of the short-term, daily-dose levels that were teratogenic in hamsters and embryo-lethal in rabbits (8).

Until a specifically designed control system is developed to reduce aerosol emissions, health-care workers who are pregnant or may become pregnant should be advised of the potential risks of exposure during direct patient care when patients are receiving ribavirin through oxygen tent or mist mask and should be counseled about risk-reduction strategies, including alternative job responsibilities. Also, because visitors may spend considerable time in close proximity to a patient's bedside, female visitors who are pregnant or may become pregnant should be informed of the potential risks of exposure to aerosolized ribavirin. Because all area samples were obtained only in direct proximity to the bedside, these data cannot be extrapolated reliably to assess possible risks to persons working elsewhere in a room or ward where ribavirin is being administered through oxygen tent or mask.

Ribavirin exposure levels that do not cause adverse health effects cannot be specified because of the lack of dose-response data in humans. Nevertheless, because of the potential for exposure to a potent animal teratogen, employers should

\*Use of trade names is for identification only and does not imply endorsement by the US Department of Health and Human Services or the Public Health Service.

*Ribavirin — Continued*

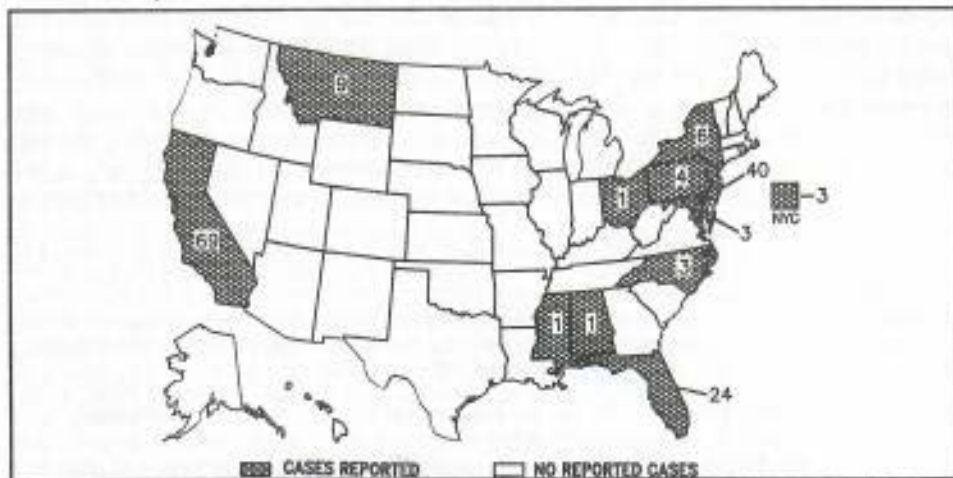
develop procedures designed to reduce employee exposure. Use of surgical masks to reduce inhaled ribavirin dose is unlikely to be effective (16) and therefore does not warrant recommendation as a protective measure. Although patient-care considerations typically determine the route of ribavirin administration, hospital staff should be aware that in this study, exposures to personnel were greatest when ribavirin was administered by oxygen tent, less by mist mask, and least by ventilator. Worker exposures in this and other health-care settings deserve increased attention as the extent and complexity of occupational hazards in this environment become apparent.

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16. Tuomi T. Face seal leakage of half masks and surgical masks. *Am Ind Hyg Assoc J* 1985;46:308-12.



FIGURE I. Reported measles cases — United States, Weeks 32–35, 1988



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

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SEP 20 1988

MEMO TO: Steven Grossman  
Deputy Assistant Secretary for Health  
Planning and Evaluation

FROM: Gerald H. Britten  
Deputy Assistant Secretary  
for Program Systems

SUBJECT: Response to the President's Requirement for  
Implementing the HIV Commission Report.

I have attached, per Dr. Macdonald's request, a summary of HHS actions in response to the President's directives on the HIV Commission Report. Please note that we have several (items B, D and G) for which more details will be forthcoming soon.

In addition, we are preparing a memorandum from Secretary Bowen summarizing the more important actions for the report the President asked for in September.

Attachment  
a/s

cc: Peter Fischinger  
Tim Ray  
Ralph Reed

## LIST OF REQUIREMENTS

### President's Requirements for HHS in August 5, 1988 Memorandum

- A. Review budgets for FY 1989-90
- B. Hold consensus conferences on public health protection
- C. Increase community-based education programs
- D. Improve protection of national blood supply
- E. Accelerate drug and vaccine development
- F. Assess private incentives for development and marketing of HIV products
- G. Evaluate the national health care financing system
- H. Conduct special studies:
  - 1. Out of hospital care and case management
  - 2. State risk pools
  - 3. Children with AIDS
  - 4. Low-income disabled with AIDS
- I. Update national plan for combatting HIV epidemic

### Other Requirements from President

- J. Establish an AIDS emergency fund
- K. Implement OPM guidelines



7.20.1980 17.00

A. REVIEW FY 1989 AND FY 1990 BUDGETS

Requirement: The President directed the Secretary of HHS to review FY 1989 spending plans to incorporate relevant recommendations of the HIV Commission. In addition, the Secretary said, in a letter to Dr. Macdonald, that HHS would review the Commission recommendations in developing our FY 1990 budget.

Background

The FY 1989 Appropriations Conference action provides \$1.29 billion (assumes FDA at Senate level) for AIDS activities in PHS. This represents a 1.2% decrease from the President's budget request.

The FY 1990 Budget Request for HHS was submitted to OMB on September 1 and includes almost \$3 billion for AIDS: \$1.94 billion for the Public Health Service activities, \$710 million for Medicaid and Medicare and \$305 million for Disability Insurance.

Response/Status

As a follow-up to the Commission report, all components of the Department have been asked to review their FY 1989 AIDS spending plans to incorporate the recommendations of the AIDS Commission. Additionally, components have been asked to identify all FY 1989 and FY 1990 resources devoted to each of the Commission recommendations to which the Department has no disagreement.

The AIDS component of the FY 1990 budget request to OMB has been developed taking into account the AIDS Commission recommendations.

Specifically for the PHS, the FY 1989 spending plans of each of the PHS agencies have been reviewed within the context of the recommendations proffered by the Presidential Commission on the Human Immunodeficiency Virus Epidemic. The fact that the Commission released an interim report several months earlier which addressed many substantive issues related directly to various agencies' budgets was very helpful for fiscal planning for FY 1989.

A second element is represented by the development of the Charlottesville Report and the HHS Implementation Plan for AIDS which collectively represent the major departmental planning exercise relative to the control of the HIV epidemic. Many of the goals and objectives of the report and plan are congruent with the recommendations of the Commission, and have therefore



already been considered in the formulation of the FY 1990 budget.

To date, with two exceptions, no HHS agency identified any Commission recommendations which have not been taken into account already during the budget formulation process. The exceptions are (1) the implementation of actions to protect the blood supply, and (2) HCFA has not budgeted specifically for the cost of the required evaluation of the health care system (see summary G). We currently are addressing how to deal with both of these items.

## B. CONSENSUS CONFERENCES ON HEALTH PROTECTIONS

Requirement: Convene a series of consensus conferences over a 12-month period involving state, local, and private groups to encourage them to adopt the specific public health measures discussed in the Commission's Report, such as increased counseling and testing, reporting of HIV infection, partner notification, and health care worker safety. One conference should address restrictive measures and criminal statutes directed to HIV-infected persons who knowingly persist in maintaining behaviors that transmit their infection. Another possible topic is the serious problem of neighborhood resistance to facilities for the care of HIV patients, drug abusers, and group homes for HIV-infected infants and children.

### Response/Status

HHS has already initiated a series of conferences which partially fulfill this directive. A U.S. Health Summit on HIV Infection is scheduled for November 28-29, 1988, in Washington, D.C. Participants will include State Health Commissioners, gubernatorially appointed AIDS Coordinators, representatives of State Medical Societies, and local health officers. The purpose of the meeting is to strengthen public health measures to reduce the spread of AIDS. The conference will provide a forum for public/private sector collaboration on efforts to reduce the spread of HIV infection and an opportunity to share information about HIV-policies, programs and further needs. Workshops will be included where participants will develop recommendations for the conduct and content of the future consensus conferences.

Numerous other conferences, either held recently or planned by the PHS during the next 12 months, meet the definition of consensus conferences.

- The CDC, together with NIMH and other PHS agencies, sponsored the National Conference on Prevention of HIV Infection and AIDS in Racial and Ethnic Minorities in August 1988; over 2,000 participants attended. Follow-up PHS regional conferences involving all PHS Agencies and the Office of Minority Health are expected in fiscal year 1989.
- CDC will jointly support, with the Department of Labor, a conference to be held in January 1989 on the OSHA workplace standards for blood-borne diseases.
- HRSA is planning a second national conference on the planning and management of health care services for HIV-infected patients, following the conference held in Charleston, S.C. on August 4-6, 1988. One major topic will be the health care facilities and housing needs of HIV patients.



- In October, HRSA will co-sponsor a conference on drugs and AIDS, organized by the New York State Hospital Association. The conference will address issues related to providing family oriented care for IV drug abusers.
- HRSA will sponsor a two-year followup to the April, 1987 Surgeon General's Workshop on Children with HIV Infection and Their Families in Los Angeles.
- HRSA is joining with NIDA and NIMH to sponsor a series of conferences on developing appropriate services for adolescents and youth at risk of HIV infection.
- The HRSA supported Regional Education and Training Centers will be conducting consensus conferences during FY 1989, addressing such topics as the safety of health care workers.
- OASH and ADAMHA are developing a Gubernatorial Consensus Conference on Federal-State strategies to overcome neighborhood resistance to drug abuse treatment facilities, training needs of alcohol, drug abuse, mental health workers, alternative drug abuse service facilities and mainstreaming drug abuse care with primary care.
- ADAMHA has underway in FY 1988 five regional training sessions targeted to ethnic minorities and another five sessions on reaching hard-to-reach audiences. State and community leaders will be included in these conferences.

Other conferences--particularly ones on restrictive measures and criminal statutes, and neighborhood resistance that involve subjects of concern to other departments--are being planned in the context of Interagency Working Group on AIDS. A conference plan should be ready by September 27, with revisions to be made after the November conference discussed above.



### C. COMMUNITY-BASED EDUCATION PROGRAMS

Requirement: Increase the number of community-based educational programs, especially programs directed to those women and members of minority groups who are at highest risk of HIV infection. These programs, especially those directed to youth, should place greater emphasis on the Principles for AIDS Education, for their efforts to prevent the spread of HIV infection. Please collaborate with the Department of Education in developing youth-oriented programs.

#### Response/Status

HHS has substantial continuing efforts, as well as a number of new initiatives, for community-based educational programs.

The general educational effort has been under the aegis of the Centers for Disease Control. Within the National Public Information Campaign, at-risk and special population groups have been emphasized, i.e., women, children, and minorities. This Campaign is expanding existing support to 54 state and 16 local education agencies and 20 national organizations that serve American youth. The CDC has augmented community-based programs through support of 30 national and regional minority organizations in FY 1988 which will be continued in FY 1989. Further expansion of minority education will be achieved through direct funding of minority community-based organizations in FY 1989.

In addition, a number of PHS efforts address special populations:

- o The Indian Health Service and the CDC are developing culturally relevant prevention and education programs for Indian community groups and Bureau of Indian Affairs school teachers.
- o HRSA has community-based education programs in each of the 20 AIDS Service Demonstration Grant projects primarily focused on youth and women; HRSA coordinates with CDC in this effort. Most of HRSA's 13 Pediatric AIDS Health Care Demonstration projects have community education components. CDC will be investigating effective means of preventing perinatal HIV infection in these and other pediatric programs.
- o ADAMHA has developed educational programs for young people informing them how intravenous substance abuse results in an increased risk of HIV infection. Fifteen national organizations will be funded to implement 8-10 community based programs each through their local affiliates. Four special studies (general youth, hard-to-reach youth, Hispanic youth and Native Americans) are to be conducted in



1989 on risk assessment and effective community-based intervention. These studies have implications for HIV infection control measures through community-based efforts. Within NIDA's AIDS outreach demonstrations emphasis is placed on educating intravenous drug abusing women, pregnant drug abusers, female sexual partners of IV drug abusers, and prostitutes about HIV infection.

Wherever pertinent, these efforts have involved consultation with the Department of Education, and utilize the Principles for AIDS Education.

#### D. PROTECTION OF THE BLOOD SUPPLY

Requirement: Implement actions within the next 45 days (by September 20, 1988) that address the blood safety issues raised by the Commission. This plan should address: (a) the prompt notification of transfusion recipients who are at increased risk of HIV infection; (b) steps to improve HIV laboratory quality and HIV screening tests; and, (c) ways to encourage the use of autologous transfusions in appropriate circumstances.

##### Background

Currently, a three-tiered system is in place to ensure that contaminated blood or blood products are not transfused. First, since 1983, when blood-borne transmission of AIDS seemed likely, the Public Health Service issued recommendations that individuals who practiced recognized high-risk behaviors for AIDS voluntarily refrain from donating blood or plasma. These recommendations have been modified over time as our knowledge of the epidemiology of the disease has expanded. The application of these guidelines has proven to be very effective in eliminating at-risk donors from the donor pool. Second, in 1986, a method earlier adopted in several centers for donors to exclude their units from the blood supply in a confidential manner was instituted nationwide. Finally, the third level of protection, which was initiated in 1985, is testing of all units of blood and plasma for antibodies to HIV. By implementing all three levels of protection, the risk of HIV transmission by blood transfusion is exceedingly small. The small number of transfusion-associated infections which have been reported since 1985 probably occurred because HIV antibodies had not yet formed in infected donors when the screening was done and thus were not detectable by the screening tests used. This is a rare event, with published estimates of risk ranging from a high of 1 in 40,000 to a low of 1 in 250,000.

##### Response/Status

HHS has several ongoing efforts that address blood safety issues raised by the Commission. Two agencies of the Public Health Service, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), are working collaboratively on this effort. A detailed plan to address the requirements is under development and should be completed by September 23 or sooner.



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E. ACCELERATING DRUG AND VACCINE DEVELOPMENT

Requirement: Implement actions within the next 60 days (by October 5, 1988) to improve and accelerate further the process for development, evaluation, approval, and distribution of HIV-related vaccines, drugs, and devices. This plan should draw upon research of Federal and State governments, the private sector, academia, and national laboratories.

Background

The development, evaluation and approval of new vaccines and therapies for AIDS occurs in two major phases: (1) research/development, for which the NIH has primary responsibility; and (2) approval of new products, which is FDA's responsibility. Both agencies work closely together to ensure that the new therapies and vaccines are being rapidly developed, and are reviewed for approval expeditiously.

Response/Status

NIH has developed a Plan for AIDS Vaccine Development and Evaluation which describes a multidisciplinary framework for a cooperative effort among government-industry-academia to expedite AIDS vaccine development. The primary goal of the plan is to utilize innovative strategies to maximize interaction of public and private sector components for resource allocation, reagent distribution, technology transfer, and information exchange. The Vaccine Plan currently is being reviewed by the NIH AIDS Program Advisory Committee. Based on its review, the Committee will develop a priority listing of the recommendations contained in the Plan.

NIH has also made a major commitment to the development of rational drug models for potential AIDS therapies by establishing the National Cooperative Drug Discovery Groups (NCDDG). These groups are comprised of scientists from government, academia and industry who are working together to discover, develop and move new AIDS therapies rapidly through the stages of preclinical testing.

FDA has developed a proposal, as directed by Vice President Bush, designed to expedite approvals for therapies that are intended to treat life-threatening illnesses such as AIDS. The proposal, submitted to OMB on September 6, contains several key elements:

- o Early consultation by FDA with the sponsor to develop Phase 2 studies which could provide definitive data on safety and effectiveness, warranting marketing approval. This will, in effect, compress Phase 2 and Phase 3 studies, shortening the approval time.

- o Focused FDA research when the sponsor is, itself, unable to conduct all necessary research or when FDA can contribute special research expertise (e.g., pharmacokinetics).
- o Risk-benefit analysis to assess the risks of the disease balanced against the identified benefits and risks of the product.
- o Treatment IND status for appropriate drugs which will serve as a bridge between completion of Phase 2 testing and marketing approval.
- o Phase 4 studies may be requested following expedited approval of the product to develop additional information about the product's risks and benefits after marketing.
- o Proactive involvement of the Commissioner and other Agency officials with sponsors will assure that product review is proceeding on schedule.
- o Safeguards will be included to assure the safety and effectiveness of products approved through the expedited process.



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F. INCENTIVES FOR DEVELOPING AND MARKETING  
OF HIV PRODUCTS

Requirement: Provide within 120 days (December 5, 1988) an assessment of private incentives for development and marketing of HIV products, including an evaluation of the need, if any, to have Federal authority to offer increased incentives in exchange for royalties, licenses, or pricing concessions. This assessment should take into consideration solutions proposed in the February 1986 report of the Tort Policy Working Group. In doing this assessment, please consult with the Departments of Justice and Defense.

Response/Status

The Department has several ongoing efforts that address appropriate incentives for private sector development of drug products discovered with Federal funding, and intends to complement these existing efforts with new initiatives.

Many existing efforts help promote rapid technology transfer of HIV-related products, particularly the granting of commercial incentives to private sector companies in exchange for development and marketing resources. For example, various forms of collaborative agreements, including those under the Federal Technology Transfer Act of 1986, between Federal laboratories, (e.g., NIH) and commercial research-based companies, have brought about rapid progress towards new AIDS-related products. Mechanisms such as exclusive grants of marketing rights and waivers of royalty or patent licensing rights permit Federal laboratories to provide more successful incentives for rapid commercialization.

Over and above these existing efforts, the Department has asked the Technology Management Advisory Board of the Public Health Service to consider the extent to which these incentives to private industry might be refined, expanded, or improved. This Board will also consider the appropriate Federal role in encouraging reasonable pricing for HIV-related products, such as AZT, developed in part with Federal funds. This Board will also consider recommendations that might improve the quality of the technology transfer program generally. The Board has appointed a Working Group to address these issues on a priority basis. The Working Group first met on August 31 and intends to draft its recommendations in October. Findings will be available to meet the time requirement directed by the President.

One factor that may be inhibiting rapid development of some HIV-related products, particularly vaccines, is the manufacturers' fears of liability suits. Although it is difficult to know if there exists any actual and serious risk of liability, the Department recognizes that the very perception of significant risk could delay important research and development efforts,

particularly in the area of vaccines. Secretary Bowen directed on April 27, 1988, an examination of this potential problem.

Accordingly, HHS is investigating the parameters of liability issues for HIV-related products, in consultation with groups that have addressed liability issues. The findings, which will also be coordinated with the Departments of Justice and Defense, will be available by December 5, 1988.



## G. EVALUATE THE HEALTH CARE FINANCING SYSTEM

Requirement: Undertake an evaluation of our current system of health care financing to be completed within 1 year.

### Response/Status

HHS currently is completing its plans for the evaluation which will be coordinated by the Health Care Financing Administration. It (as suggested by the President's HIV Commission) will focus on access to care by the American public, both the uninsured and the underinsured. Although theoretically access could involve such matters as facilities, outreach programs, specialized disease or health problem initiatives, personnel recruitment and training, and the special problems of long-term care, the study will not extend to these areas because of concerns with scope and manageability. The evaluation will concentrate instead on financing and insurance issues.

Particular attention will be paid to the experience of low-income disabled individuals (e.g., with the SSI Medicaid eligibility process) in keeping with the President's request that ways be studied to increase the responsiveness of the system to that group (see summary H(4)).

The evaluation will use the wealth of information we have collected in responding to the President's directive on catastrophic health care, plus other studies concerning access to health care in this country.

There are also several related activities. First, PHS is working with HCFA to plan a series of regional conferences regarding the financing of health care services for HIV patients. The specific topics, dates and locations of these conferences are still to be determined, but they will deal with financing-related recommendations of the Presidential Commission on the HIV Epidemic and PHS' Charlottesville Conference. Conferences will cover such topics as promoting private sector involvement in paying for services, exploring ways to finance non-traditional services (including housing-related services), and encouraging states to adopt risk pools.

Second, PHS also will study the financing of services provided in the networks of care supported by the AIDS Service Demonstration Grants. A data collection survey which will gather information on the demographics of the patients being served by the grantees and on the primary source of payment for each of the broad categories of care provided for in the networks is being submitted for OMB clearance.



H(1). SPECIFIC STUDIES ON HEALTH CARE--OUT OF HOSPITAL  
AND CASE MANAGED CARE

Requirement: Conduct specific studies of ways to promote better out-of-hospital and case managed care.

Response/Status

HCFA is coordinating efforts to respond to the requirement. These include --

- o HCFA is encouraging states, under the home and community-based services waiver program to provide more cost-effective care for persons who would otherwise be at-risk of institutionalization, focusing particular attention on persons with AIDS. Overall, there are 46 States with currently active waivers, with 7 states specifically identifying AIDS/ARC patients as a category of patients being served under their waiver programs. The seven states are: New Jersey, New Mexico, North Carolina, Ohio, Hawaii, Illinois, and South Carolina. HCFA will continue to encourage additional states to avail themselves of this optional waiver program as a means of promoting out-of-hospital and case-managed care.
- o HCFA has been encouraging states and other organizations to conduct studies of the effectiveness of out-of-hospital and case-managed care through the annual solicitation for research and demonstration proposals. In both the FY 1988 and the proposed FY 1989 solicitations, HCFA has solicited projects that assess the effects of innovative state, local, and private programs in promoting such care for AIDS patients. (Although no application was funded in this area in FY 1988.) In the FY 1989 notice, HCFA has included a solicitation for studies that examine the use of Medicaid waivers, hospice care, home health and other ambulatory services in providing cost-effective alternatives to inpatient care for AIDS patients.
- o NCHSR has developed a program announcement to stimulate investigator-initiated research. One priority area is research that involves analysis of the effectiveness and efficiency of health-care delivery for HIV-infected persons. NIH has other program announcements for investigator-initiated biomedical research.
- o HRSA is conducting an evaluation of patterns of utilization and costs in four AIDS Service Demonstration Grant projects. This evaluation, which is being performed by Project HOPE, will concentrate on out-of-hospital care and is scheduled for completion late next summer. An additional study of these demonstration grants is preparing descriptions of the



range of services provided in each city, and of the relationships among service providers in the network. HRSA also has a contract for evaluating the results of a small scale study of ambulatory care costs of AIDS patients in the San Francisco area.

- o This fall, HRSA will begin a two-year evaluation of Regional AIDS Education and Training Centers. This evaluation will identify ways to improve the effectiveness of the Centers in preparing health professionals to care for HIV-infected people and will begin to assess their impact on this objective.

## H(2). SPECIFIC STUDIES ON HEALTH CARE -- STATE RISK POOLS

Requirement: Conduct specific studies on ways to encourage states to establish insurance risk pools for medically uninsurable persons.

### Background

About one percent of the United States population is estimated to be medically uninsurable due to pre-existing medical conditions, including AIDS. When private insurance is available, the price is often prohibitive or the pre-existing conditions are excluded from coverage for the first year or longer. Without insurance, many of these people are unable to pay the high medical bills they often incur. This results in financial strain on health providers. It also means financial hardship for the individuals and their families and the depletion of resources until the individual qualifies for government-subsidized care. Risk pools are legislatively established health insurance programs intended to make insurance available to people considered otherwise uninsurable. The resulting coverage can reduce the impact on personal finances and the dependency on Medicaid.

Fifteen states have enacted legislation establishing subsidized risk pools; of these, 13 are active. Some 20 states considered (but none enacted) risk pool legislation in 1987-88. According to a GAO report, all existing pools appear to cover AIDS, and four (Indiana, Iowa, Minnesota and Nebraska) specifically include AIDS among the diagnoses that are grounds for presumptive pool eligibility.

### Response/Status

- o HHS has proposed, and will repropose, to OMB that the Administration support enactment of S. 1634 proposed by Senator Durenberger which would encourage states to establish risk pools, would establish very limited Federal requirements (which should be further modified), and would provide \$30 million in "seed money" spread over 3 years.
- o HHS will promote state enactment of risk pools in several forums, including the consensus conferences required in the action plan, and through speeches, letters, and other interactions with the National Governors' Association and the National Conference of State Legislatures.
- o Through the evaluation of existing risk pools and the development of several model risk pool statutes, HHS will act as a resource center to help states wishing to consider enactment of legislation to establish risk pools. We will communicate this to all states.



H(3). SPECIFIC STUDIES ON HEALTH CARE--HIV-  
INFECTED INFANTS AND CHILDREN

Requirement: Conduct specific studies on ways to increase the responsiveness of the public health and health services system to HIV-infected infants, children, and adolescents.

Response/Status

In February 1988 Secretary Bowen established a special initiative on pediatric HIV infection to focus and develop HHS-wide efforts to address this problem.

A Departmental work group was formed under the leadership of the PHS. That group has completed its report and provided it to the Assistant Secretary for Health on August 31. It is now under review by PHS and other components of the Department. It includes many recommendations, including ones concerning resources, provision of health care services, financing of such services, and prevention of HIV infection. HHS agency review should be completed by late September, and particular implementation actions will be identified and included in the plan discussed in the summary of item I.

There also are a number of ongoing activities aimed at pediatric AIDS, such as HRSA's recent award of 13 grants totalling \$4.4 million to states and communities for the funding of projects demonstrating innovative approaches for intervention in pediatric AIDS, particularly to reduce perinatal transmission of AIDS and develop family centered services; several evaluations to assess problems in foster care for children with HIV infection and identify potential solutions; and NIH will be working with FDA to revise that agency's guidelines to permit early testing of promising agents in infants, children and adolescents--simultaneous with testing in adults.

H(4). SPECIFIC STUDIES ON HEALTH CARE -- DISABLED

Requirement: Conduct specific studies to increase the responsiveness of the health care system to low-income disabled individuals.

Response/Status

Responsiveness of the health care system to the needs of low-income, disabled persons will be addressed in the overall evaluation of the health care system summarized in item G.



## I. NATIONAL PLAN FOR COMBATTING HIV

Requirement: Provide an update by December 15, 1988, of the 1986 PHS plan for combatting HIV infection, reflecting, in part, both the Commission Report and the recent Public Health Service Charlottesville Planning Conference.

### Background

The PHS has led the effort to control the human immunodeficiency virus (HIV) infection since 1981. Many of the salient contributions by the various Agencies of the PHS have been developed within the context of an ongoing planning process.

### Response/Status

The Assistant Secretary for Health (ASH) convened a meeting in June 1986 to develop a comprehensive plan for the entire PHS. That plan was used to coordinate efforts through 1988, but new developments necessitated a major update. In response, the ASH convened a second PHS AIDS Prevention and Control Conference in early June 1988 in Charlottesville, Virginia, to develop a new PHS coordination plan. The report of the meeting contains an assessment of the last two years' effort, the major issues facing PHS, 222 goals, and 554 specific objectives as priority areas. The report is expected to be published in October 1988.

The Department is developing an implementation plan which will identify the major goals to be carried out in FY 1989 with specific objectives and dollars allotted. It will include implementation of Commission recommendations, as appropriate. The PHS Charlottesville report/plan discussed above will serve as the major component of this implementation plan, with components added by other HHS agencies. The final plan is expected to be ready simultaneously with the Charlottesville Report.

Similar implementation plans will be prepared for future years.

In addition, we plan to use both the Charlottesville Report/HHS implementation plan, and the President's Commission Report, to establish a tracking and monitoring system for HHS activities combatting HIV infection.

J. ESTABLISH AN AIDS EMERGENCY FUND

Requirement: Seek a special HIV emergency fund in the FY 1990 budget for unanticipated problems and opportunities.

Response/Status

The FY 1990 budget request sent to OMB on September 1 includes \$25 million for an AIDS emergency fund.



## K. IMPLEMENT OPM GUIDELINES

Requirement: Every Federal agency is to adopt a policy based on OPM guidelines for AIDS information and education and personnel management.

### Proposed Response/Status

In response to OPM's Guideline of March 24, 1988, the Assistant Secretary for Personnel (ASPER) issued Personnel Manual Instruction 792-4, AIDS in the Workplace, which provides HHS policy on employment issues concerning AIDS in the HHS workplace. ASPER is also preparing a memorandum for the Secretary to send to all HHS employees regarding AIDS in the workplace.

In addition, ASPER has developed continuing education programs for the Employee Counseling Service. A videotape entitled "One of Our Own - A story About AIDS in the Workplace" and accompanying educational materials are available for Employee Counseling Service personnel. A report, AIDS: The Facts - A Special Report, was prepared and distributed in 1987.

Finally, Employee Counseling Service personnel are encouraged to utilize available programs and informational materials as they work to educate HHS employees about AIDS. Brochures of these materials are displayed in Employee Counseling Service centers for distribution. Counseling Service staff members also attend workshops, conferences and/or seminars on AIDS education whenever possible, as part of their in-service training.

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# FDA Looks to Speed Up Drug Approval Process

*Bush wants the FDA to accelerate approval for drugs to treat life-threatening illnesses; more risks are okay, given the alternative; some clinical trials may be eliminated*

TO APPEASE AIDS PATIENTS and others clamoring for access to experimental drugs, Vice President George Bush recently asked the Food and Drug Administration to look for ways to cut some corners and to speed approval for drugs to treat life-threatening illnesses for which there are no alternative therapies.

FDA Commissioner Frank Young responded to Bush's charge with a proposal that would allow the FDA to approve a drug without knowing everything there is to know about the agent's long-term toxicity or long-term effectiveness. To answer these lingering questions, Young's proposal states that the agency may require additional studies on drugs after they have been approved. Whether the FDA can demand the additional studies without new legislation is uncertain. How the agency would yank drugs after it approved them is also problematic.

To hurry up the process for drug approval, Young sees the FDA taking a far more active role in helping drug companies design their early clinical trials. The FDA might even offer to do some of the research itself, especially in cases where the company sponsoring the drug is either too small or too inexperienced to do the job alone.

In the past few weeks, Young has been briefing interested parties on his proposal, which is winning mixed results, even within the FDA. Most everyone agrees that getting truly promising drugs into very sick patients as quickly as possible is a noble goal. But critics contend that the proposal is only a public relations gesture. Says Jeff Levi of the National Gay and Lesbian Task Force in Washington: "I suspect the whole thing is just a political exercise to boost the vice president's popularity."

Levi's dislike of the proposal comes from a basic disagreement between the regulatory agency and AIDS patients and their advocates concerning access to experimental or alternative treatments. Many AIDS patients want to be able to get their hands on drugs immediately after they've shown the slightest hint of efficacy, if only in a test tube. The FDA, however, maintains that drugs must not only prove to be relatively safe, but effective according to rigid scientific criteria.

And it is here, over the government's insistence that it protect desperately ill patients from drugs that might not work, that the battle lines have been drawn.

"We believe that there are adequate provisions for protection, but not for access to drugs. The FDA is deeply rooted in consumer protection, not saving lives," says Martin Delaney of Project Inform, an AIDS information group in San Francisco.

Even some members of the Administration would like to see new regulations that give patients and their physicians greater access to drugs that might ultimately prove ineffective.



Frank Young: A more active role

"Historically, the FDA has felt that it's better to deny approval to a drug than approve one too quickly. But in this case, you're not talking about headache remedies or cosmetics, you're talking about a drug for someone who is threatened with imminent death," says Jay Plager, executive director of the Presidential Task Force on Regulatory Relief, the group chaired by Bush which instigated the new proposal.

As the system currently operates, an investigational new drug is put through three phases of clinical trials in humans after first showing biological activity and safety in test tubes and lab animals. The first phase concerns the safe dosage range of the drug and examines how the drug is absorbed and

metabolized. Only a handful of people are needed for the first trial. The second phase, which involves several hundred patients and may last 2 years, asks the more pressing question: does the drug work? The third phase involves thousands of patients and several more years, and is designed to further test efficacy and to search for adverse reactions that might occur in only a few patients.

Young's proposal for accelerated approval would eliminate the need to do the large Phase 3 study before approval. Instead, Young would call for a mandatory meeting between the drug sponsor and the FDA following the completion of the Phase 2 clinical trial. At this meeting, the company and the government would agree on the design of the Phase 2 trial, so as to answer as many questions as possible concerning efficacy and possible side effects. This would probably mean larger and more elaborate Phase 2 trials. But if the drug proves to be safe and effective after the completion of the Phase 2 trial, FDA would approve the drug at that time.

Some potential stumbling blocks remain. One concern is the so-called treatment protocol for investigational new drugs, or the treatment IND. In June 1987, under pressure from AIDS patients, the FDA decided to allow people greater access to experimental drugs outside of the carefully controlled clinical trials. Under the treatment IND system, a company can release an experimental drug to patients after it completes a Phase 2 clinical trial, but before it completes its Phase 3 trial. According to Young's proposal to accelerate approval for drugs, the treatment IND system could be used to make a drug available to patients during the window of time between the completion of the Phase 2 trial and approval by the FDA to market the drug.

Unfortunately, the treatment IND system has been a great disappointment to AIDS patients. To date, only one AIDS drug has been released under the new protocol. Plager believes that a manufacturer has no reason to offer his product through the treatment IND process because the company is not allowed to actively market the drug, nor is it allowed to reap profits only to recoup manufacturing costs.

But Deborah Katz of the AIDS Program at the National Institutes of Health thinks the problem is not the treatment IND system itself, but "the fact that we haven't had enough promising drugs."

The proposal by Young does not deal with producing promising drugs, only moving drugs through the system with greater speed. Producing promising drugs is another problem entirely. ■ WILLIAM BOOTH



## MEDICINE & HEALTH

September 19

### Bowen May Back AIDS Anti-Bias Law

HHS Secretary Bowen may be ready to drop his resistance to a federal ban on bias against people with AIDS and those infected with HIV. The evidence: a draft letter to Attorney General Richard Thornburgh in which Bowen calls an AIDS bias ban "critical to ensure the success of our efforts to protect the public health." The letter was drafted for Bowen by HHS Assistant Secretary for Health Robert Windom, MD; the HHS chief has not yet signed it. Absent a vaccine or cure, the letter says HIV testing and counseling is key to controlling the epidemic. Success in that effort "will be greatly affected by the extent to which persons at risk for HIV infection understand themselves to be protected from discrimination. . . . Where current law provides adequate protections, we need to clarify and enforce those protections. Where current law is inadequate, we must seek change."

### VHA Chiefs Depart; HCA Going Private

Changes at the helm of one major hospital industry player and a leveraged buyout bid for another illustrate how sharply competition continues to alter the profile of the health industry. Sept. 14 news of the sudden departure of Voluntary Hospitals of America Chairman and CEO Donald Arnwine and Thomas Reed, president and CEO of for-profit subsidiary Voluntary Hospitals of America Enterprises, was followed by Sept. 15 announcements of a leveraged buyout attempt involving Hospital Corp. of America. Arnwine and Reed cleaned out their desks immediately; McGraw-Hill's *Health Business* reports that the turmoil at VHA may stem from growing too fast. "Worse than expected" financial results include a \$5.7 million net loss for the quarter ending June 30; a year ago, that figure was \$7.4 million. On Sept. 15, management at HCA, a major for-profit chain, announced plans to take the firm private. HCA Chairman and CEO Thomas Frist and members of his team have offered \$47 a share.

### IG Reviews Medicare Kickback Regs

Hospitals could waive Medicare cost-sharing if they did so for all beneficiaries, under rule revisions drafted by HHS Inspector General Richard Kusserow. The proposal follows HHS Secretary Bowen's override of Kusserow's earlier plan to ban cost-sharing waivers (*M&H* 8/29/88). There "would ap-

pear to be no substantial federal harm resulting from this practice," says the draft, a copy of which was obtained by *Medicine & Health*. Under the rules, hospitals would have to offer the waiver regardless of diagnosis or length of stay. The IG also has softened his earlier proposal to limit discounts by supply companies. The new rules would allow suppliers to give price breaks or additional items for free as long as it is spelled out on the invoice or statement. The IG rejects a blanket "safe harbor" for preferred provider organizations (PPOs) but says the rules should cover "many relationships in PPOs."

### HCFA Signs New PRO Contracts

New three-year HCFA contracts with peer review organizations in seven states give the PROs significant increases. Existing contract-holders in Delaware, Nebraska, Montana, Wyoming, Rhode Island, Missouri, and Washington have gotten new pacts. New Jersey's PRO has gotten a two-month extension of its contract during negotiations. HCFA began replacing the old two-year cycle with staggered three-year deals to ease the renewal process. The PROs will get as much as 50 percent more per year under the new contracts, reports McGraw-Hill's *Utilization Review*. Additional work -- review of ambulatory surgery, HMOs, home health agencies, and nursing homes -- will up the cost of review, HCFA says. Payment for hospital photocopying costs also is factored in.

### Dukakis Aide Blasts Bush Health Policy

The Reagan Administration has pursued "cost containment at any price" with "irrational" cuts in health budgets, says the top health adviser to Democratic candidate Michael Dukakis. Republican candidate George Bush "hasn't displayed an interest in health care," says David Blumenthal, MD, senior VP at Boston's Brigham & Women's Hospital and an unpaid adviser to the Dukakis campaign. At a Sept. 15 debate sponsored by the American Hospital Assn, he pointed to Massachusetts' universal health insurance coverage law, expansive Medicaid program, and emphasis on prevention. Bush representative, hospital administrator David Jacobson, said his man is "truly compassionate" and will pursue "innovative" health policies. But Blumenthal kept up the offensive, accusing the Administration of pursuing a "let it burn" AIDS policy.





# STATEMENT OF ADMINISTRATION POLICY

September 13, 1988  
(House)

H.R. 5142 - AIDS Counseling, Testing, and Research Act of 1988  
(Waxman (D) California)

The President has taken decisive actions to advance the battle against AIDS through both his FY 1989 Budget -- which includes \$1.3 billion for Department of Health and Human Services' (HHS) AIDS-related research, prevention, and treatment programs -- and his recently-adopted 10 point action plan, which responds to the recommendations of the Presidential Commission on Human Immunodeficiency Virus (HIV) Epidemic. This plan orders a number of actions to focus the efforts of the Government and private sector on this tragic human problem. Additionally, staff resources will be added in FY 1989 to the already significant numbers of Federal staff assigned to work on HIV.

Any legislation in this area must be fashioned carefully to help, rather than hinder, Federal, State, local, and private research and actions to inhibit the transmission of HIV. For the reasons stated below, the Administration does not believe H.R. 5142 should be enacted at this time.

Specifically, H.R. 5142 would:

- provide Federal protections for confidentiality of records related to HIV testing and counseling. The Administration is looking carefully at the appropriateness of enacting Federal provisions on HIV confidentiality. H.R. 5142 also requires routine HIV antibody testing and counseling in certain settings, which the Administration has endorsed previously (e.g., in family planning clinics and clinics that regularly provide care for sexually transmitted diseases). The bill would also assure that counseling accompanies the testing. Although their goals are laudable, these efforts must not burden those dealing with this disease in the front lines with new Federal reporting and paperwork requirements, nor should they force uniform approaches on varying local HIV populations and problems.
- seek to clarify HIV research authorities and institute improved management practices, such as expedited grant awards. The Administration continually seeks ways to build upon management improvements already implemented, which include coordinated HIV planning in HHS and expedited grant awards. In this regard, care must be



taken not to overregulate the content and practice of HIV research and prevention. Impressive advances in HIV research and prevention have been achieved under broad statutory authorities which permit rapid and flexible responses to changing research opportunities.

\* \* \* \* \*

(Not to be Distributed Outside Executive Office of the President)

This draft of a position was developed by LRD (Pellicci) in consultation with HIMD (Kleinberg/Clendenin/Jacob), OIRA (Eisinger/Koss), the White House Office of Policy Development (per Bob Sweet), and the White House Drug Abuse Policy Office (Macdonald). HHS (per Kay Holcomb, Office of the Assistant Secretary for Legislation) and Justice (per Faith Burton, Office of the Assistant Attorney General for Legislative Affairs) agree with the position.

### Background

The Committee on Energy and Commerce report on H.R. 5142 is not available (H.R. 5142 was introduced on August 3, 1988). The information used to develop the proposed position was provided by HHS staff (Kay Holcomb).

H.R. 5142 is a new bill combining the provisions of H.R. 4757, the "AIDS Counseling and Testing Act of 1988," H.R. 4850, the "AIDS Research Act of 1988," and H.R. 2881, "National Commission on Acquired Immune Deficiency Syndrome Act."

The "Watkins" Commission report recommends additional support for research, prevention, and treatment from all levels of Government. It also recommends confidentiality provisions like those proposed in H.R. 5142. Moreover, provisions similar to H.R. 5142 are also contained in the Wright-Michel, "Omnibus Drug Initiative Act of 1988," H.R. 5210.

### Administration Policy

The Administration has not submitted any authorizing legislation pertaining to AIDS. The Administration has maintained that current authorities are sufficient to carry out the President's proposals to combat AIDS. The President's FY 1989 budget request of \$1.3 billion for HHS AIDS research and education (\$2 billion government-wide, including other agencies) represents an increase of \$349 million, or 37 percent, over FY 1988.

In remarks to the American Foundation for AIDS Research Awards Dinner on May 31, 1987, the President announced that the Federal Government will encourage routine AIDS testing for aliens and immigrants, prisoners, marriage license applicants, and potentially other groups. Regulations published on June 8, 1987, require AIDS antibody testing of aliens and immigrants.



A Statement of Administration Policy (SAP) opposing S. 1220, Senator Kennedy's "AIDS Research and Information Act of 1987," was sent to Congress on October 1, 1987, and a revised SAP also opposing the bill was sent on April 20, 1988 (S. 1220 was passed by the Senate on April 28, 1988, 87-4). Moreover, a SAP opposing H.R. 2881, a bill creating a National Commission on AIDS, was sent to Congress on August 4, 1987 (H.R. 2991 was passed by the House on August 4 by voice vote).

### Description of Bill

H.R. 5142 has three parts:

Counseling and Testing. This portion of the bill would:

- authorize appropriations of \$400 million per year for FY 1989 through FY 1991 for counseling and testing grants to States and to existing health care facilities serving persons with high-risk behavior (e.g., VD clinics, drug abuse clinics, family planning clinics, community and migrant health centers, public hospitals, etc.);
- guarantee confidentiality of test results (regardless of whether or not Federal funds are involved), with Federal, civil, and criminal penalties for willful or negligent disclosure;
- require States to establish procedures to notify emergency workers if an injured person they cared for had AIDS or tested positive for HIV;
- require States to test and counsel all persons convicted of prostitution, sexual assault, or crimes related to IV drug use; and
- provide civil and criminal penalties for individuals who knowingly transmit the HIV to another person.

Research. This part would authorize "such sums" for FYs 1989-1991 for various National Institutes of Health (NIH) research authorities; e.g., establishment of: (1) additional inpatient drug therapy evaluation units at NIH, (2) a research program to evaluate unlicensed treatments in current use by AIDS patients, (3) international AIDS research efforts, and (4) a program of long-term virus genetics research for development of AIDS treatments.

The bill would also require expedited review of AIDS research applications; authorize up to 780 additional FTEs for AIDS activities; require GSA and OPM to respond quickly to HHS requests for space and personnel; and establish CDC training fellowships for researchers in epidemic control services.



Establishment of a National Commission on AIDS. The Commission would consider and make recommendations on national policy and priorities with respect to AIDS research, testing, confidentiality of test results, treatment and care of AIDS patients, prevention of transmission, and education regarding AIDS. The Commission would be composed of 15 voting members including five appointed by the President (two of whom would be the Secretary of HHS and the Administrator of Veterans' Affairs), five by the Speaker of the House of Representatives, and five by the President Pro Tempore of the Senate. A final report would be required not later than two years after the date on which the Commission is fully constituted.

#### Current Status of H.R. 5142

On August 10, 1988, the House Rules Committee granted a modified open rule providing one hour of debate on H.R. 5142.

Twelve specific amendments will be in order. Among the amendments allowed are Dannemeyer proposals to: require testing for HIV of individuals convicted of a crime and sentenced to imprisonment and of hospital admittees aged 15-50 who will have blood tests or surgery; require that State public health officers be provided with information sufficient to locate individuals who are infected with HIV; and delete the bill's provision establishing an AIDS Commission.

The rule also makes in order Pelosi amendments to establish demonstration AIDS Monitoring and Treatment Centers that focus on early monitoring and intervention, and demonstration grants for follow-up counseling and mental health services for infected individuals. Mr. Madigan will offer an amendment to delete the bill's expedited processes for space and personnel requests and to make the hiring of new personnel (the 780 authorized positions) subject to the availability of appropriations. Mr. Waxman will offer an amendment to require the Secretary to encourage manufacturers of drugs that may be potential AIDS treatments to apply for research exemptions already available from the Food and Drug Administration.

LEGISLATIVE REFERENCE DIVISION DRAFT  
9/13/88



**A BEHAVIOR BASED MODEL OF THE INITIAL GROWTH  
OF AIDS IN THE UNITED STATES**

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**Los Alamos**





A BEHAVIOR BASED MODEL OF THE INITIAL GROWTH  
OF AIDS IN THE UNITED STATES

Stirling A. Colgate, E. Ann Stanley, James M. Hyman

Scott P. Layne, and Clifford Qualls

**Abstract**

The cumulative number of AIDS cases in the United States has grown as the cube of time rather than exponentially. We explain this as the result of partner choice and sexual frequency in a biased mixing, risk-behavior model. This leads to a saturation wave of infection among risk groups moving from high to low risk. The universally applauded decreasing growth rate is then not yet due to behavior changes, but instead due to the intrinsic epidemiology of the disease.

**Introduction**

Our objective is to understand the early growth of AIDS in the United States by defining an intuitive and plausible mathematical model. Because we feel the widespread acceptance and understanding of models can greatly accelerate progress in both individual as well as government policies, we have endeavored to simplify the mathematics and explain most equations in words as well as symbols. The confidence that any model explains the epidemic and predicts the future must come from comparison with known social behavior patterns and the available data. Confidence in our model rests on comparison with AIDS case data from the extensive compilation by the United States Centers for Disease Control (CDC)<sup>1</sup>. This data, because of the tragically large numbers involved, is statistically the most significant data available.

The cumulative cases of AIDS have grown as the cube of time rather than exponentially. The growth rate of a polynomial decreases inversely as time, whereas that of an exponential is constant. We construct a biased mixing model that reproduces the observed cubic

growth of AIDS when (1) the risk of behavior is distributed as an inverse cubic power of the number of individuals, (2) when either new partner frequency or sexual outlet frequency dominates the risk behavior separately or when both are positively correlated, and (3) when the probability of conversion to AIDS per unit time is approximately constant. The resulting polynomial model is then normalized to the data. From this we conclude (1) that the total number infected at the current time is roughly one million, (2) that the apparent mean time between infection and AIDS is an increasing function of time, (3) that as a consequence the decreasing growth rate of AIDS cases is not yet due to behavior change, and (4) that the mean risk behavior of those with AIDS at time of infection is a decreasing function of time, (5) that the model is consistent with the mean probability of infection per sexual contact presently being as small as 1/250 to 1/1000, (6) that a slow increase in infectivity during the progression from infection to AIDS can change the cubic growth rate to be greater than cubic in the future and that behavior modification could reduce it, (7) that partner exchange frequency is likely to be more important to the growth rate of the epidemic than sexual frequency, only if sexual frequency and partner exchange rate are strongly correlated, or that high infectiousness (100%) per sex act is restricted to a few percent of the population, (8) that most major subpopulations both demographic and geographic were infected with a few high-risk individuals early in the epidemic and that only small highly socially isolated groups may remain isolated from the epidemic. (9) The most likely path by which the initial infection reached the high risk groups was by an initial seeding in the average population which then progressed from a low-risk individual to the high-risk population in 1979 giving rise to the cubic saturation model. Simulation suggests that the first case of infection could have occurred in the average population in the late 1960's. Only somewhat less probable is that the first case of AIDS occurred in the higher-risk groups in the late 1970's. (10) After all in the highest risk group are infected, a saturation wave proceeds downwards to lower-risk groups, producing the cubic growth in total AIDS cases. (11) The growth of the epidemic within the purely heterosexual drug-free



population may be similarly polynomial and most likely cubic and that only by measuring prevalence in the high- risk groups adequately isolated from other known risk groups can such a question be answered.

### The Growth Functions

The total number of AIDS cases reported by the CDC for the U.S. population has grown as the cube of time<sup>2,3</sup>. A reasonable best fit function for the cumulative AIDS cases reported to the CDC (pre-1987.5 definition) is

$$A = 174.6(t_y - 1981.2)^3 + 340 \pm 2\%, \quad (1)$$

where the 2% error is a relative error in the total cases and where  $t_y$  is the date in years as shown in Fig. 1a. This fit is accurate for  $t_y$  greater than 1982.5 (July 1982). Hence, if we measure time,  $t$ , from 1981.2,

$$A = A_0 + A_1 t^3, \quad (2)$$

where  $A_0 = 340$  and  $A_1 = 174.6$  for  $t > 1.3$  years. Nearly cubic growth occurs in different geographic regions, sexual preference groups, in intravenous drug users, for all age (exclusive of children and old age) and racial groups (Figs. 1a, 1b, and 1c). This is in itself surprising since the fact that the sum is cubic, requires that the separate cubics be synchronized in time; in this case to less than 6 months (Figs c and d). We shall discuss this later in the context of the initial seeding process.

### The Expected Growth

In order to demonstrate why this power law growth is unexpected, we start by predicting that the initial growth rate of any infection in a homogeneous population where behavior remains constant in time will in itself be constant in time. We assume AIDS is the long-term result of an initial infection by a virus, HIV<sup>4,5,6</sup>. In contrast the cubic growth of AIDS implies that the growth rate is decreasing inversely as time. If  $A = A_0 + A_1 t^m$  then

$$\text{relative growth rate} = (dA/dt)/A = m/t, \quad (3)$$

where  $m$  is a constant. With a power law growth not only is the relative growth rate decreasing inversely as time, but also the doubling time,  $t_d$ , or the time for the number of people infected to double increases proportionally to  $t$ , or  $t_d = t(\ln 2)/m$  years. For AIDS cases observed so far,  $m = 3$ , and the next doubling time is given by  $t_d \simeq t/4$  years. We have observed the epidemic to start with  $t_d$  less than  $1/2$  year<sup>6</sup> and progress to the current value of 1.75 years<sup>1</sup>. This change in the doubling time by a factor of four is dramatically different from an epidemic with exponential growth.

**Growth Rate and Learning.** There is a perception in the press and resulting complacency that the increasing doubling time of AIDS cases is a reflection of the efficiency of education and a decreasing participation in risk behavior. Indeed, if learning modifies risk behavior inversely as a function of time, then the resulting power law growth would give this trend. However, infection precedes AIDS by many years so that the AIDS cases in the early to mid-1980s were infected with HIV in the late 1970s and early 1980s. We will quantify this delay later. However, this is long before learning affected a major fraction of the homosexual population. The behavior changes, if any, could not have been nearly enough to give a power law growth in infections in the late 1970's and early 1980's. Another possibility is that the growth in HIV infections is exponential, but that the transition times from infection to AIDS is highly variable. But this does not yield power-law growth because, in general, a continuing exponential growth of infection converting to AIDS within a finite time will, after an initial transient, reproduce the same exponential growth in AIDS cases.

We have looked with considerable diligence for other ways of producing such a constant power law growth and concluded that a risk behavior model best fits the observations. This model is an extension of an earlier risk-based model of May and Anderson<sup>6</sup>, where homogeneous mixing of the susceptible population was assumed and where an early exponential growth was inevitable. We have drawn much from this work, but it was the contradiction between a nearly inevitable early exponential and the observed growth that led us



to the following biased-mixing model. We explored some aspects of this model in Hyman and Stanley<sup>3</sup> with particular emphasis upon computational and mathematical consistency. We find no inconsistency with the simplified version presented here and instead carry the conclusions further.

### **A Risk-Based Model**

In our risk-based, biased mixing model, we assume that the susceptible population is divided into groups according to the behavior that puts them at risk of infection and that most of an individual's sexual partners belong to the same risk group. Conversely, an unbiased, risk-based model is one where partners are chosen independent of either's risk behavior. We shall discuss two risk behaviors which we believe are related to each other that can produce the power law growth.

The risk behavior most frequently correlated with HIV infection in the homosexual population (as suggested by the early work of the CDC<sup>10</sup>) is the number of new sexual partners per time interval.<sup>11-14</sup> The second behavior we consider is frequency of sexual contact. It is obvious that one without the other cannot spread HIV. The risk behavior determines the reproduction rate – that is, the probability that an infected person will infect a new partner within the doubling time.

For our model to agree with observation we must assume that groups of similar risk behavior,  $r$ , interact primarily, but not exclusively, within themselves, i.e. biased mixing. We also assume (and justify below) that risk behavior is distributed such that the number of individuals is a decreasing function of risk. Finally we assume the initial infection rate within a group of risk behavior,  $r$ , is proportional to  $r$ . We believe that these three assumptions are sufficient to explain the power law growth pattern of the AIDS epidemic. For the purposes of the model it makes no difference what the risk behavior actually is—only that such a behavior exists. However, because of past preconceptions and universal interest, we restrict our model to the two related risk behaviors, new partner rate and sexual frequency. In so doing we restrict ourselves to the homosexual epidemic or roughly

65% of the AIDS cases according to the data of Figs. 1a and 1b. This model can only be applied to IV drug users when additional risk behavior data is available.

**New Partner Rate Among Homosexual Men.** A number of studies of homosexual men have published data on the number of new sexual partners in some time interval<sup>13-16</sup>. Although most of this data is given in summary form (number of men with 20-40 partners in the past year, for example), and sample sizes tend to be small, all of the studies show a similar pattern. The standard deviation,  $\sigma$ , is larger than the mean,  $\langle p \rangle$ , sometimes much larger. For men with more than a few partners per year, the distribution  $p^\beta$ , where  $p$  is the number of new partners per year, and  $\beta$  is between 3 and 4, provides a good fit to all of the samples we have examined. In Fig. 2 we show combined data from two studies of homosexual men attending STD (sexually transmitted diseases) clinics in London<sup>15</sup> as well as the fit  $2 \langle p \rangle^3 / (\langle p \rangle + p)^3$ . These two studies are biased away from low-activity men; more randomly chosen samples<sup>14,16</sup> tend to have the same  $p^{-\beta}$  behavior for large  $p$ , but a larger fraction at low  $p$ .

In our model, the value of  $\beta$  determines the growth rate of the epidemic (AIDS cases increase as  $t^\beta$ ). However, either the data from the studies are published in too crude of a form (especially since the maximum value for the last bin tends to be omitted), or the sample sizes are too small to distinguish between  $\beta = 3$  and  $\beta = 4$ . We have chosen to use  $\beta = 3$  in this paper, to be consistent with the sexual frequency data of Kinsey (see below). One test of the hypothesis that  $\beta = 3$  for the male homosexual population as a whole is to note that a distribution which decreases as  $p^{-3}$  has an infinite variance. Any finite sample taken from this distribution will have a finite variance, but  $\sigma / \langle p \rangle$  will continue to increase as the sample size increases. A distribution which decreases as  $p^{-4}$  will have a limiting value of  $\sigma / \langle p \rangle$  as the sample size increases. Of course, there is also some physical limit to the partner-change rate, so that the  $p^\beta$  distribution will be effectively truncated above this limit, and even when  $\beta = 3$ ,  $\sigma / \langle p \rangle$  will approach a limiting value.

(May and Anderson have pointed out<sup>6,7,17</sup> that a model in which partners are haphaz-



ardly chosen from all partner change rates according to their availability (which we term unbiased mixing), the initial growth rate is proportional to  $\langle p \rangle (1 + \sigma^2 / \langle p \rangle^2)$ . Since not only the very high activity, but also the very low activity people, strongly influence  $\sigma$ , the initial behavior of the epidemic will be heavily influenced by the distribution of both the low-risk and high-risk individuals when mixing is unbiased. In contrast, for our biased mixing model, only the shape of the distribution at high risk influences the behavior of the saturation wave until it reaches low-risk individuals.)

**Average Male Sexual Outlet.** Next we note the similarity between the distribution of new partner rate among homosexuals and the distribution of sexual outlet frequency among the total male population. Figure 3 shows the male sexual outlet frequency data from Kinsey<sup>18</sup> for a sample of 11,467 males from adolescence to 30 years old. The data are plotted as log (number of people) versus log (frequency per week). The straight line in Fig. 3 has a slope -3 corresponding to a power law distribution of  $N \propto f^{-3}$ . The distribution superimposed on the figure

$$N/N_0 = (f / \langle f \rangle)^{-3} \quad f \geq (\langle f \rangle) \quad (4a)$$

and

$$N/N_0 = 1 \quad f < (\langle f \rangle) \quad (4b)$$

provides an excellent fit to the data where  $(3/2)N_0$  is the total sample size and  $\langle f \rangle$  is the population mean. Thus the distribution of sexual outlet frequency among the U.S. male population clearly resembles the distribution of new partner risk behavior within the limited population of homosexuals.

**Risk Groups.** In our biased mixing model we divide the population into groups of individuals with similar risk behavior, and let  $r$  denote the rate of this risk behavior divided by the mean rate at this risk behavior. This normalizes  $r = 1$  to be the risk value for the average risk group. We assume that the similarity in behavior causes the individual members of a risk group to interact primarily among themselves, i.e. intragroup preference.

The infection will grow in each group as if it mixed homogeneously within itself. Thus, after a risk group is first seeded, i.e. one individual is infected, the number of infected in this group will grow exponentially due to the unbiased mixing within the group, where the growth rate of the group primarily depends upon  $r$ , its mean risk behavior.

Partner exchange rates probably determine the social structure of an unbiased mixing group, and partner exchange rate and sexual frequency together determine the growth rate within a group. The amount that each determines the growth rate depends upon the degree of correlation between them and the distribution of infectiousness within the group. Regardless, whichever is the causative risk, both lead to the same risk behavior distribution provided we assume infectiousness is not correlated with risk behavior. If infectiousness rate is correlated with the assumed partner rate and sexual frequency, we would have to define a new risk behavior including a correlated infectiousness with presumably a different distribution than Eq. (4). For high-risk behavior,  $r \geq 1$ , we therefore assume a risk behavior distributed as  $N \propto r^{-3}$ .

Although this risk behavior is associated with sexual contact and partner exchange rate of the homosexual population, in what follows it could just as well apply to intravenous drug users or the heterosexual population provided only that the primary risk is distributed as Eq. 4.

**Growth Within a Group to Saturation.** The assumption that the relative growth rate in infections will be proportional to the risk behavior implies that the time for the epidemic to grow to saturation within each risk group will be inversely proportional to the average risk behavior,  $r$ , of the group. Hence, high risk groups saturate much more quickly than low risk groups.

The fact that higher risk groups have fewer members decreases the saturation time still further. The saturation time with exponential growth is proportional to  $r^{-1} \log N(r)$  and the logarithm is a slowly varying function, and so the change in group size has a negligible effect on the time to saturation. Therefore the  $r^{-1}$  dependence dominates the



time to saturation. Thus, after a member of the highest risk group is infected, that group quickly saturates; then the next lower risk-behavior group saturates, and so on.

**The Saturation Wave.** Figure 4 shows a saturation wave with biased mixing of infection progressing from high risk to low risk groups. To the right of the wave front, all high-risk individuals are infected and conversely all lower risk groups to the left of the front have just a few infected. It is only within the group comprising the wave front that the infections primarily are taking place. The doubling time of the epidemic at any given time is primarily the doubling time of this group. There will be some out-of-group contacts, a fraction  $F$ , that will both reduce the growth rate within a group by  $(1 - F)$  and increase the growth rate in the neighboring risk groups. We have also shown in the figure what happens if unbiased mixing is assumed, i.e.  $F \rightarrow 1$ . The growth then occurs primarily in the low-risk population.

**The Calculation of the Saturation Wave.** Once the saturation wave starts, the total number of infected,  $I$ , is roughly the sum of all individuals from the highest risk individual down to individuals with risk behavior  $r_*$  at the front of the wave. If, for the moment, we ignore the few infected individuals that were "seeded" throughout the population before the saturation wave started, then the sum of the saturated groups is the integral of all individuals with risk behavior  $r \geq r_*$ :

$$I(r_*) = \int_{r_*}^{\infty} N(r) dr = (N_0/2)r_*^{-2}. \quad (6)$$

Here  $r_*$  is the risk behavior of the group when most of the individuals are infected and  $N(r)$  is the number of individuals with risk behavior,  $r$ , as defined in Eq. (4).

The time required to infect all members of the group with risk behavior,  $r_*$ , i.e. to saturate the group of  $N(r_*)$  individuals at the front of the wave, can be calculated from the assumption that within that group the number of infected has an exponential growth rate  $\alpha r_*$ . That is, the number infected initially grows as  $I_s e^{\alpha r_* (t-t_s)}$  where  $I_s$  are the number "seeded" at  $t = t_s$ , the start of the saturation wave. We now define  $t$  to correspond to the

time of the start of the saturation wave, or when the highest risk individual was infected so that  $t_s = 0$ . Here  $\alpha$  is assumed a constant relating the probability of infectious transfer per unit time to the average risk behavior  $r_*$ .

At saturation  $N(r_*)$  approaches the number infected:

$$N(r_*) \cong I_s e^{\alpha r_* t_*}. \quad (7)$$

Here  $t_*$  is the time to saturate the  $r_*$  group. Solving Eq. (10) for  $t_*$  gives

$$t_* \cong (1/\alpha r_*) \ln(N_*/I_s). \quad (8)$$

We assume that all groups were seeded at the same time and so we can replace  $t_*$  by  $t$ . Also to the accuracy of this model, we will consider the logarithm of group size to seed ratio,  $\ln(N_*/I_s)$  to be constant. Then Eq. (11) says that the time,  $t$ , to saturate a group with risk  $r_*$  is proportional to  $1/r_*$ . This implies that the time to saturate a group increases, on the average, inversely as risk behavior.

We can then replace  $1/r_*$ , with a constant times  $t$ , or  $I_1 t$ . Then in Eq. (6) we obtain  $I(t) \cong I_1 t^2$ , where  $I_1$  has yet to be determined. In addition some few individuals,  $I_0$ , were probably infected before a member of the highest risk group started the saturation wave, so we add an unknown constant  $I_0$  to Eq. (5) and obtain

$$I = I_0 + I_1 t^2 \quad t \geq 0. \quad (9)$$

Thus after an initial transient the infection grows as the square of time.

**The Progression to AIDS from Infection.** Given the number infected, we need to estimate the resulting number of AIDS cases. The most extensive study of the development from HIV infection to the syndrome AIDS, defined by the CDC for reporting purposes is the San Francisco Health Department hepatitis B study as first reported by G. Lemp et al.<sup>19</sup> and by Hessol et al.<sup>20</sup>.

We define the probability of conversion to AIDS  $\tau$  years after infection as  $C(\tau)$ . The San Francisco data for the first 7 years following infection indicates that the differential



probability of developing AIDS per unit time,  $dC/dt$ , after HIV infection is near zero for two years, followed by a constant of roughly 6% probability per year of converting to AIDS for the next five years. Figure 6 shows the cumulative probability as a function of time for the first 8 years after infection, which is now consistent with the data for 9 years after infection<sup>20</sup>.

This description of a progressive conversion to AIDS is consistent with the steady decrease of the T-4 cell count with time from infection<sup>21-28</sup> resulting in a progressive destruction of the immune system. The different rates of destruction are correlated with different times to convert to AIDS, but the destruction is steady. It is reasonable to assume that this process always proceeds to AIDS. As evidence we refer to a study of seropositive individuals in Frankfurt, Brodt et al.<sup>29</sup> during which more than 90% progressed from one stage of immune destruction to the next. The Frankfurt data suggest that at least 90% of those infected will convert to AIDS. Thus, even though the hepatitis B study presently only covers 9 years of experience, we suggest that a reasonable extrapolation of the data is to assume a constant conversion probability per unit time of 6% per year starting 2 years after infection. Using this distribution the cumulative probability of converting to AIDS is 50% within 10 years and 100% within 18 years since the time of infection.

Because conversion to AIDS has a probability of happening at any time within a period 2 to 18 years after infection, the growth in the number of AIDS cases,  $dA/dt$  at any given  $t$  is the sum of the rate of newly infected at  $t - \tau$  years,  $dI(t - \tau)/dt$  multiplied by their differential probability of conversion to AIDS  $\tau$  years later or at time  $t$ , which is  $dC(\tau)/d\tau$ . The sum is written as a convolution integral over past times  $\tau$ :

$$\frac{dA}{dt} = \int_0^t \left[ \frac{dI(t - \tau)}{dt} \right] \left[ \frac{dC(\tau)}{d\tau} \right] d\tau. \quad (10)$$

Here the probability of conversion to AIDS is

$$\frac{dC(\tau)}{d\tau} = 0 \quad \tau \leq 2 \quad \text{negligible for the first 2 years;}$$

$$\frac{dC(\tau)}{d\tau} = 0.06 \quad 2 < \tau < 18 \quad \text{constant 6\% per year thereafter;}$$

$$\frac{dC(\tau)}{d\tau} = 0 \quad \tau > 18 \quad \text{until all have gotten AIDS.} \quad (11)$$

Then Eq. (9) and (10) reduce to

$$dA(t)/dt = 0.06 \int_2^t [dI(t-\tau)/d\tau] d\tau, \quad 2 \leq t \leq 18y \quad (12).$$

Evaluating  $dI/dt$  from Eq. (9),  $dI(t)/dt = 2I_1 t$ , and at the time  $(t - \tau)$  is  $2I_1 \times (t - \tau)$ , and so

$$dA(t)/dt = 0.12I_1 \int_2^t (t - \tau) d\tau = 0.06I_1(t - 2)^2. \quad (13)$$

We can integrate this to obtain the cumulative AIDS cases,  $A(t)$ ,

$$A(t) = \int_0^t [dA(\tau)/d\tau] d\tau = 0.02I_1(t - 2)^3 + A_0. \quad (14)$$

Provided we shift the time later by 2 years, this result has the same form as the data in Eq. (1), i.e. the cumulative AIDS cases grow as the cube of time. This time shift just reflects our approximation that very few AIDS cases develop during the first two years following infection. We associate the growth factor  $[0.02I_1]$  multiplying  $(t - 2)^3$  of the model with the constant  $A_1$  of the data of Eq. 1 and so we determine  $I_1$  by

$$0.02I_1 = A_1 = 174.6 \quad \text{or} \quad I_1 = 8700. \quad (15)$$

With the value of  $I_1$  of the model determined, we can evaluate the number infected as a function of time in Eq. 9, which becomes

$$I(t) = 8700t^2 + I_0 \quad \text{for } t \geq 0. \quad (16)$$

The model predicts a quadratic growth of the saturation wave of infection starting 2 years before the cubic term in the data of the growth of AIDS. From Eq. (1) this time is 1981.2,



so the quadratic term of the model of the infection wave started in 1979.2. Hence for the date of 1988.2, or 9 years after  $t = 0$ , an estimate of the number of infected is

$$I = 8700(9)^2 + I_0 = 705,000 + I_0. \quad (17)$$

The constant  $I_0$  is the number of "seed" cases infected before the saturation wave started at  $t = 0$  or at 1979.2. This number must be small enough not to give rise to a larger number of AIDS cases in 1982.5 than the error in the fit (Fig. 1) to the data at that time which was  $\pm 2\%$ . The leading term in the quadratic growth of infection gives rise to the cubic term in AIDS. A generous error is fraction of  $A_0$  like 100 cases. In 1982.5 the mean time since  $I_0$  were infected was approximately 4 years (including one year for seeding process). According to Eq. (14) the cumulative probability of conversion to AIDS 4 years after infection is 12%, so the number of seed cases can not be much larger than 800. We will therefore choose  $I_0 = 400 \pm 400$  consistent with both this argument and a later model to be published.

Therefore we estimate that the number infected is

$$I = 8700t^2 + 400 \quad (18)$$

where  $t = 0$  at the start of the infection saturation wave, or in 1979.2. The estimate of 700,000 infected in 1988.2 from Eq. (18) is then not changed significantly due to the addition of  $I_0$ .

To summarize our biased risk based model shows a cubic growth of AIDS independent of learning and predicts that the infected population initially grew as the square of time. Both have a doubling time increasing linearly with time.

### III. Consequences of the Model

(1) **The Present Number Infected.** The estimate of 700,000 infected in 1988.2 is significantly less than the estimate of 1.5 million<sup>30</sup> made several years ago, but agrees more closely with current CDC estimates of 1 to 1.5 million<sup>31</sup>. The estimate of Eq. (18) neglects

several factors as discussed in Hyman and Stanley<sup>3</sup>. Under-reporting amounts to  $\simeq 10\%$  of the cases, Hardy<sup>31</sup> and cases falling outside the pre-1987 CDC definition, amounts to  $\simeq 20\%$ <sup>32</sup>. Then the estimate Eq. (18) must be adjusted by  $1/(0.9 \times 0.8)$  or one million infected at 1988.2. This assumes that learning has not reduced the growth of infection below the square of time in the last four years. If it has, the number of infected could be less. Time-dependent infectivity which we discuss later could make the number greater.

**(2) Time Since Infection.** So far we have assumed that the epidemic growth has been unaffected by learning, which has and will modify the risk behavior. We must ask how long ago was the average present AIDS case infected and then question whether learning was likely to have been significant at that time. The most likely time since infection,  $\bar{t}$ , of the present cases of AIDS is

$$\bar{t} = \frac{\int_0^t [dI(t-\tau)/dt] \tau [dC(\tau)/d\tau] d\tau}{\int_0^t [dI(t-\tau)/dt] [dC(\tau)/d\tau] d\tau} = \frac{1}{3} \frac{(t^3 - 12t + 16)}{(t-2)^2} \cong t/3 + 4/3 \text{ years.} \quad (19)$$

For the present where  $t = 9$  years, the mean time since infection of the current AIDS cases is approximately 4.3 years ago or 1983.9. The rapid growth of the number infected relative to the conversion time biases the age of the present AIDS cases much closer to the present.

### **(3) Learning and Decreasing Growth Rate.**

We emphasize that 4.3 years ago is just about when learning started on a large scale, i.e. when the bath houses in San Francisco were closed, safer sex practices began to be accepted, etc. Therefore, we may expect that a decrease in the growth of AIDS among homosexual men below the current cube law has already started. The change in the AIDS case definition makes this difficult to see in the data. Our estimate of 1 million currently infected is based on extrapolating the cubic growth of AIDS cases into the future, so the actual number infected may be considerably less than a million due to learning. In any case the decreasing growth rate due to the polynomial behavior of the epidemic cannot so far be ascribed to learning.

**(4) Risk Behavior as a Function of Time.** We can use Eq. (9) to estimate the risk behavior of those becoming infected or developing AIDS as a function of time provided we



have estimates of the total number in the host and the present number infected. For this estimate we will consider one sector of the population, the total population of homosexuals in the principal cities with active homosexual behavior. We estimate this population  $N$  as roughly 10% according to Kinsey<sup>18</sup> of 40 million young males, i.e.  $\simeq 1/7$  the U.S. population ages 20-40, or 4 million. From Eq. (8a,b) the size of the cohort, i.e. the integral of the total distribution over risk, is  $3N_0/2$  and so  $N_0 = 2.7 \times 10^6$  in the case of active homosexual males. We then equate  $I$  from Eq. (6) to  $I$  from Eq. (16) and deduce the infected fraction by the ratio of homosexuals to the total cumulative AIDS cases,  $\simeq 65\%$  from Figs. 1b and 1c. Then

$$(N_0/2)r_*^{-2} = 0.65 \times I_1 t^2, \quad (20)$$

or the risk behavior of the homosexual group just being infected is

$$r_* \cong \left(\frac{N_0/2}{0.65I_1}\right)^{1/2} \cong 15t^{-1}. \quad (21)$$

Recall that  $r$  and  $r_*$  were normalized so that they are multiples of the average risk behavior and  $t$  is the time since 1979.2.

Thus, our model suggests, for example, that most of the present AIDS cases were infected 4.3 years ago when  $t = 4.7y$ , that 200,000 were infected at that time, and that their risk behavior was  $\cong 3$  times the average behavior. More generally the model predicts that the risk behavior of those being infected is a continuously decreasing function of time and that the earliest infected, which in general were the earliest cases of AIDS, were those with the highest risk behavior. This last point correlates with the original CDC findings<sup>10</sup>, and others<sup>11,12,13,14</sup>. In contrast, unbiased mixing models do not predict this time-dependent behavior, since at any time most of those being infected are members of the average and not the higher risk groups. The observation of the high average risk behavior at the time of infection characteristic of the early cases of AIDS is a strong argument for the importance of including behavior in any AIDS epidemic model.

**(5) Mean Probability of Infection.** We can calculate the mean probability of

transferring infection per sexual contact in this model. For example those developing AIDS today on the average were infected 4.3 years ago in 1983.9 and had a risk behavior of approximately three times the population mean. The risk behavior of three times the mean for the 1984 infected homosexual cohort implies  $\cong 72$  new partners a year if we use the mean of 24 partners per year in the studies shown in Fig. 2. (This mean may be considerably larger than the population mean, but does not affect what follows if it is 1/10 as great.) If the sexual frequency is correlated with new partner frequency, then three times the mean from Fig. 3 is 450 sexual outlets per year, the major fraction of which can be considered possible infectious contacts, Kinsey<sup>18</sup>. The growth rate,  $\alpha$ , of the infection at that time was

$$\alpha = ((1/I)dI/dt) = 2/t = 0.43 \text{ per year at } t = 4.7y, \quad (22)$$

(or a doubling time  $t_d = (1/\alpha)(\ln 2) = 1.6$  years). Since on the average each infected member of the group must infect only one new partner per doubling time, then with 10 to 100 partners per doubling time, the probability of infecting any one partner must be very small. Therefore the probability of infecting just one partner is dependent upon the total number of sexual contacts in the doubling time and not on the number of new partners. If  $i$  is the probability of infection per sexual contact, then after  $ft_d$  sexual contacts,  $ift_d = 1$  or the infectiousness, per contact,  $i = 1/ft_d = 1.4 \times 10^{-3}$ . If the sexual contact frequency is uncorrelated with partner frequency then the sexual frequency will be 1/3 as great, and then the infectiousness per contact must be three times larger or  $4 \times 10^{-3}$ . These estimates are comparable to the estimates of Grant et al.<sup>33</sup> of 0.003 to .1 per sex act.

These estimates for an average infectivity must be viewed in relation to the large variability in infectivity seen in the extraordinary Australian case reported by Stewart<sup>34</sup>, where four out of eight women were infected from one donor sample of cryo-preserved semen split ten ways, and yet the 90 cases of artificial insemination in New York from infected individuals which gave rise to no case of infection (Stewart, private communication).



**(6) Time-Dependent Infectivity.** If instead of an episodic infectivity, there were different strains of virus as would be consistent with the Australian case being 400 times more infectious than the mean infectivity, then this strain would have rapidly eclipsed all others and the growth would have been 400 times faster since the Australian incident in 1982. Since this clearly has not happened, if there are large variabilities in infectivity, then they must occur either (1) in just a few individuals permanently for a period longer than the doubling time, (2) for a given individual for very short episodes of time, (3) or because an infectious mutation quickly mutates to a less infectious one. One possible explanation according to Stewart is that the Australian donor was in the active pre-mononucleosis phase of the infection before the characteristic debilitating lymphoma illness<sup>35</sup>. Also according to Stewart, three women have not yet (in 6 years) infected their unprotected partners. This long delay is consistent with the slow infection of the majority of monogamous partners of transfusion-related HIV infection<sup>19,20</sup>. On the other hand the very rapid spread in the Kagera region of Tanzania with few seropositive in 1984 and 43% of urban adults infected today<sup>36</sup> may indicate that a more virulent strain has emerged.

Our model tacitly assumed a constant infectivity per unit time so that the probability of infection was proportional to risk behavior. However, a short period of days to weeks of greater than 50% infectiousness per sex act just before antibodies develop could have driven the early phase of the epidemic when partner change rates were high and the apparent growth rates would have been the same. Provided a subsequent return to infectiousness did not occur for roughly two years, the cubic growth rate would not be affected. A return to infectiousness episodically as a function of time, roughly two years after infection, would then lead to an additional infectiousness. Finally an increasing infectivity, as for example, correlated with decreasing T-4 cell count<sup>37</sup> would change the cubic growth to a higher power of time or at least tend to maintain the current growth rate despite lower risk behavior from learning or from the progression of the saturation wave to lower risk groups.

**(7) Partner Exchange Rate and Risk.** There is a strong perception that partner

exchange rate rather than sexual frequency was the primary risk factor at the start of the epidemic. We pointed out earlier that if the probability of an infected person infecting any given partner is small, that is the mean infectiousness per sex act  $i$  times the number of sex acts per partner,  $f/p$ , where  $f$  is sexual frequency and  $p$  is partner exchange rate or  $i(f/p)$ , is small and one doubles  $p$ , then the probability of infection per partner halves and the sum of the partners in a doubling time  $2pt_d$  times this probability remains nearly constant. In this case sexual frequency drives the net reproductive rate, not partner exchange frequency. Only if partner exchange frequency is highly correlated with sexual frequency will partner exchange rate be indicative of risk behavior.

However, another way that the partner exchange rate within a group can be the dominating risk factor is if there are a small percentage of very infectious individuals within each group. Then if such an individual has more partners with the same number of sex acts, he or she will infect more individuals. We have argued above that the average infectiousness must be small so most of the infected individuals must have low infectiousness. If the superspreaders infected almost every partner and the others infected very few, the fraction of such highly infectious individuals must also be small.

Thus for partner exchange rate to drive the epidemic, the fraction of highly infectious individuals must be no larger than a few percent and have an average infectiousness greater than  $\simeq 60$  times the average. The singular Australian case supports this possibility. Because of this possibility, an understanding of the biological mechanism of high infectivity and the means for identifying such individuals becomes important to the control of the epidemic.

**Conclusions** We believe that the AIDS epidemic has grown as the cube of time because of biased mixing in choosing partners. Several results of the ensuing model agree with observations, e.g. decreasing risk behavior with time, number infected, and a decreasing growth rate. Learning may have only recently affected the growth of number infected and barely affected the current growth of AIDS cases. The unknown correlation of partner



exchange rate and sexual outlet frequency, and the possible distribution of infectiousness among individuals make it difficult to identify the current dominant risk behavior. A time-dependent infectiousness may lead to greater growth than a simple projection of the past.

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### Figure Captions

Fig. 1a. The cumulative AIDS cases in thousands as reported by the CDC is shown as a function of dates in years. The kink at the end of the curve at 1987 is due to reporting delay.

Fig. 1b. The cumulative AIDS cases are plotted at the cube root versus time. The best fit is

$$A = 174.6(t - 1981.2)^3 + 340,$$

showing that the AIDS cases are growing as a cubic polynomial.

Fig. 1c. The data in Fig. 1b are broken down into subgroups according to sex and plotted as the cube root versus time. Curve 1 = homosexual male, 2 = bisexual male, 3 = heterosexual or pediatric male, 4 = female. The dotted straight lines are an extrapolation of the cube root term and indicate that the various sexual preference groups were seeded nearly simultaneously within six months. This is equivalent to the statement that at least one individual of all four sexual preferences was a member of the original high-risk group that had approximately a six months doubling time.

Fig. 1d. The data in Fig. 1b are broken down into racial subgroups. 1 = white, 2 = black, 3 = hispanic, and 9 = unknown. The near straight lines indicate that the cubic growth of AIDS has occurred for sexual preference as well as race. Here also an extrapolation of the cube root behavior indicates universal seeding within a roughly six months period. Regional categories follow the same behavior.

Fig. 2. The distribution of homosexual men attending STD clinics in London obtained by combining the data of McManus (partners per year) and of Carne and Waller (partners



per month). The dotted line shows the inverse cubic with the same mean as the data. (Data reported in May and Anderson<sup>6</sup>).

Fig. 3. The distribution of males (adolescent to 30) versus sexual outlet frequency plotted as logarithm of number of individuals versus log of frequency,  $f$ , per week. The line is drawn with a negative slope of  $-3$  showing that the distribution is inverse cubic. The data is from Kinsey, Pomeroy, and Martin<sup>18</sup> from a sample of 11,467. The small peak at  $f = 7$  and 10 are to be expected and do not significantly affect the inverse cubic relation. The 12 cases with  $f > 29$  per week are to be compared to 9 expected for an inverse cubic.

Fig. 4a. Shows a calculation of the progressive saturation of infected in a population  $I(r, t)$  versus risk behavior at various times for biased mixing. The out-of-group mixing was modeled with a gaussian where full width at half maximum was 40% of the risk. After the highest risk behavior group  $r = 100$  is infected at  $t = 0$ , the progressively low-risk groups grow in infection to saturation, which is close to the distribution bound, at progressively later times 5, 10, 15, etc. The sum of all those infected grows at the square of time,  $t^2$ , when the total population,  $N(r)$ , is distributed as an inverse cubic,  $r^{-3}$ . The difference between the total population,  $N$ , and the infected is due to AIDS and death. The units in the example are arbitrary.

Fig. 4b. Shows a similar calculation for unbiased growth where again the initial infected were in the highest risk group. Here, in contrast to biased mixing, the fastest growth in the total infected occurs in the average risk behavior or lowest risk group. The early growth is also nearly exponential and the total infected at a given time larger than in the biased mixing case, since a smaller fraction of the population is saturated.

Fig. 5. The probability of cumulative conversion to AIDS as a function of time in years since seroconversion, which is assumed to be the time of infection. The plot is from Lemp et al.<sup>19</sup> as derived from the San Francisco hepatitis B study. One notes the near zero probability of conversion for the first two years and then the linear increase in cumulative

probability of conversion corresponds to a differential probability of 6% per year after two years. An extrapolation as a constant slope or probability gives 50% conversion in 10 years and 100% after 18 years. The data has recently been extended to 10 years in agreement with this extrapolation.<sup>19,20</sup>



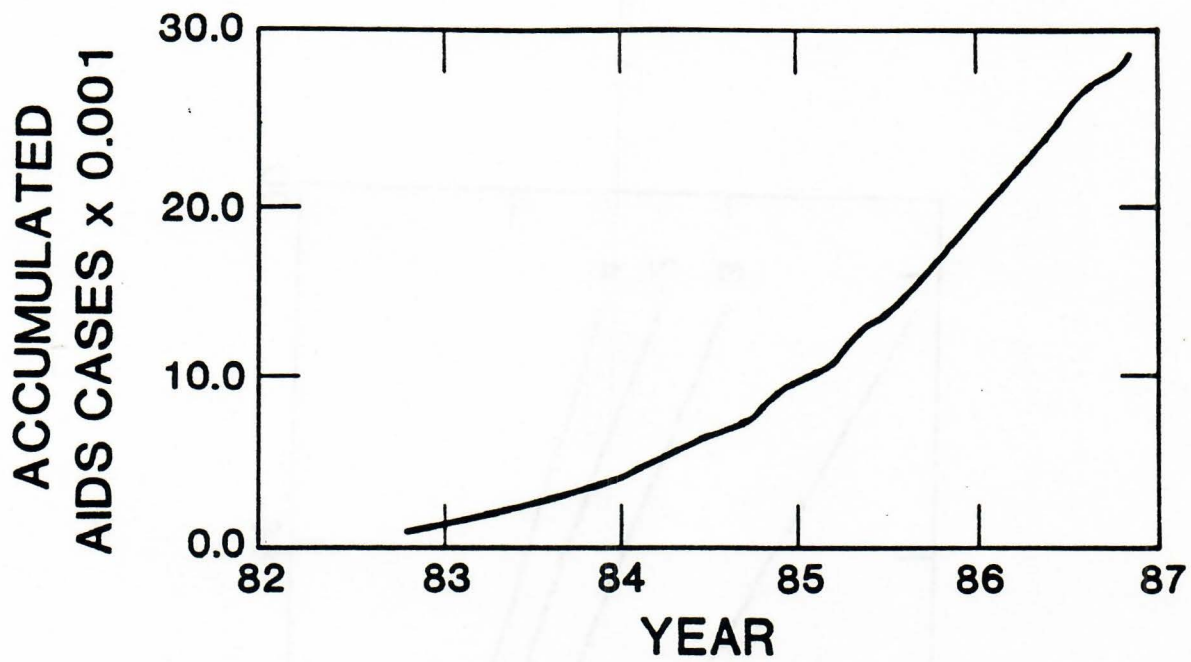


Figure 1a

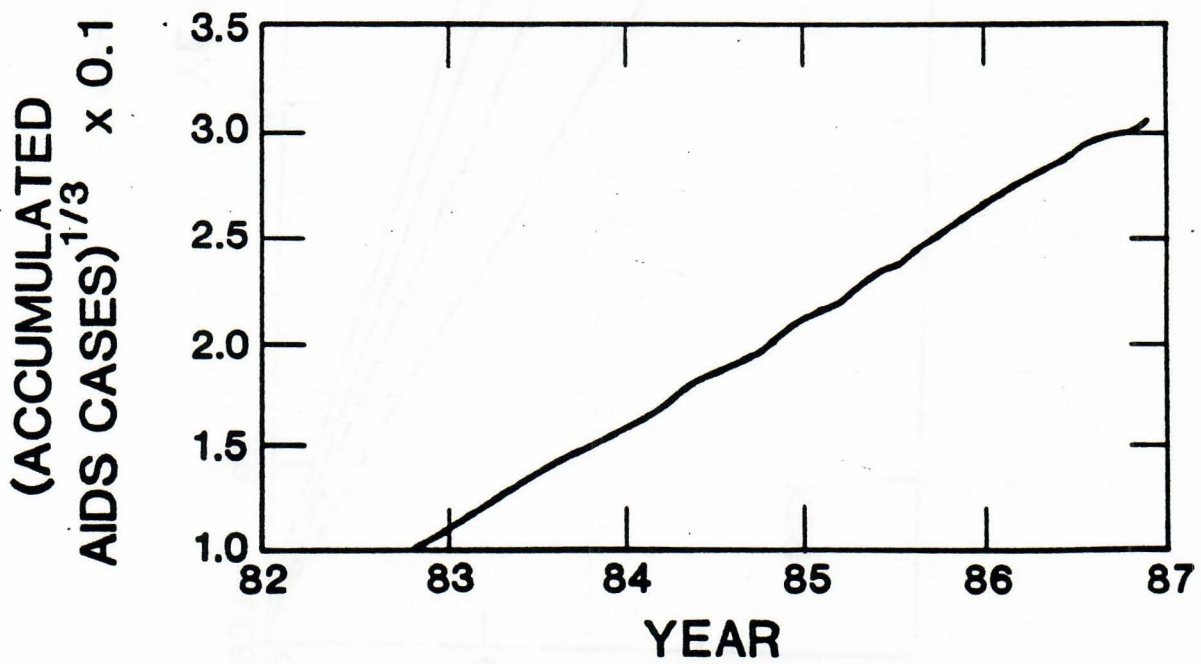


Figure 1b

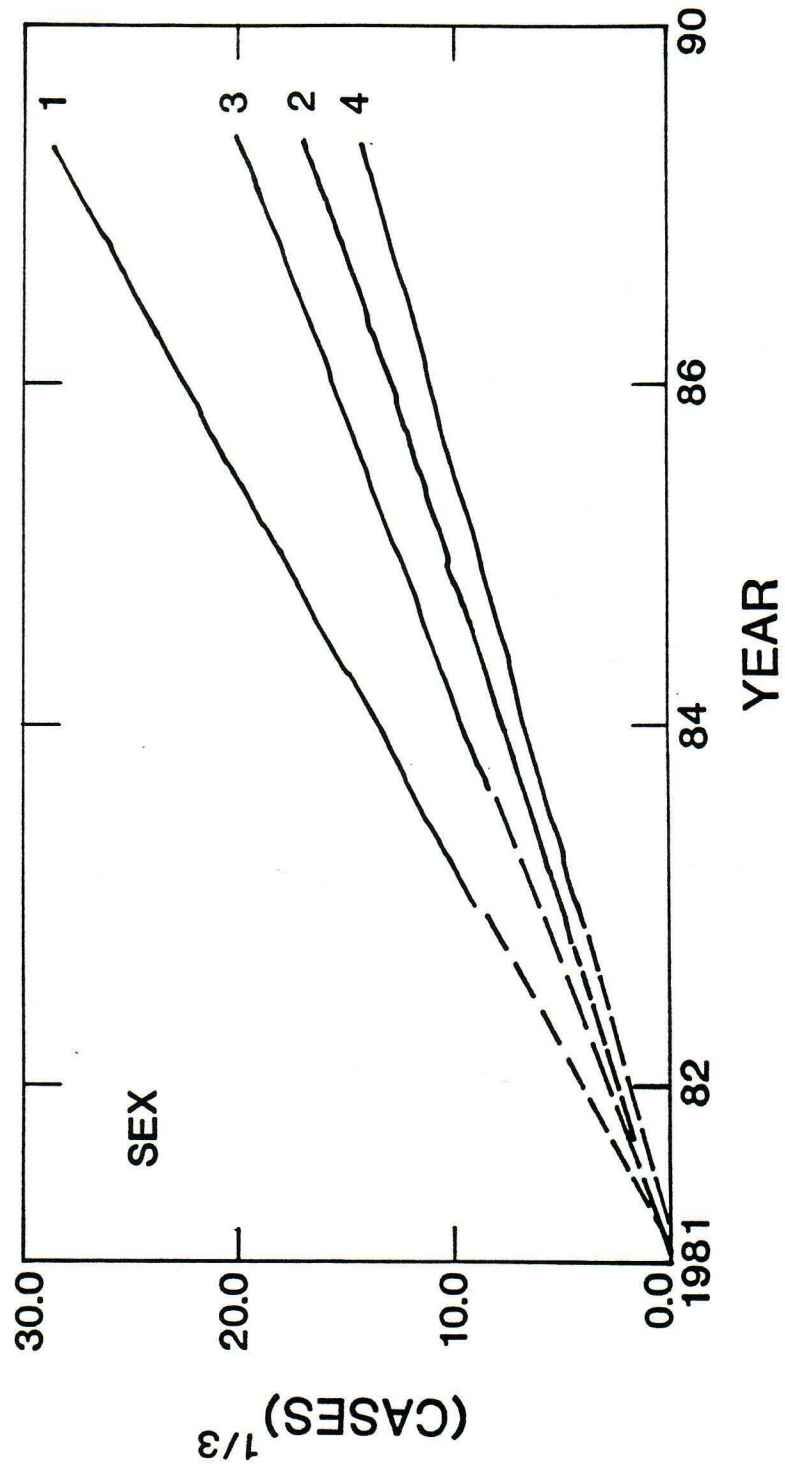


Figure 1c



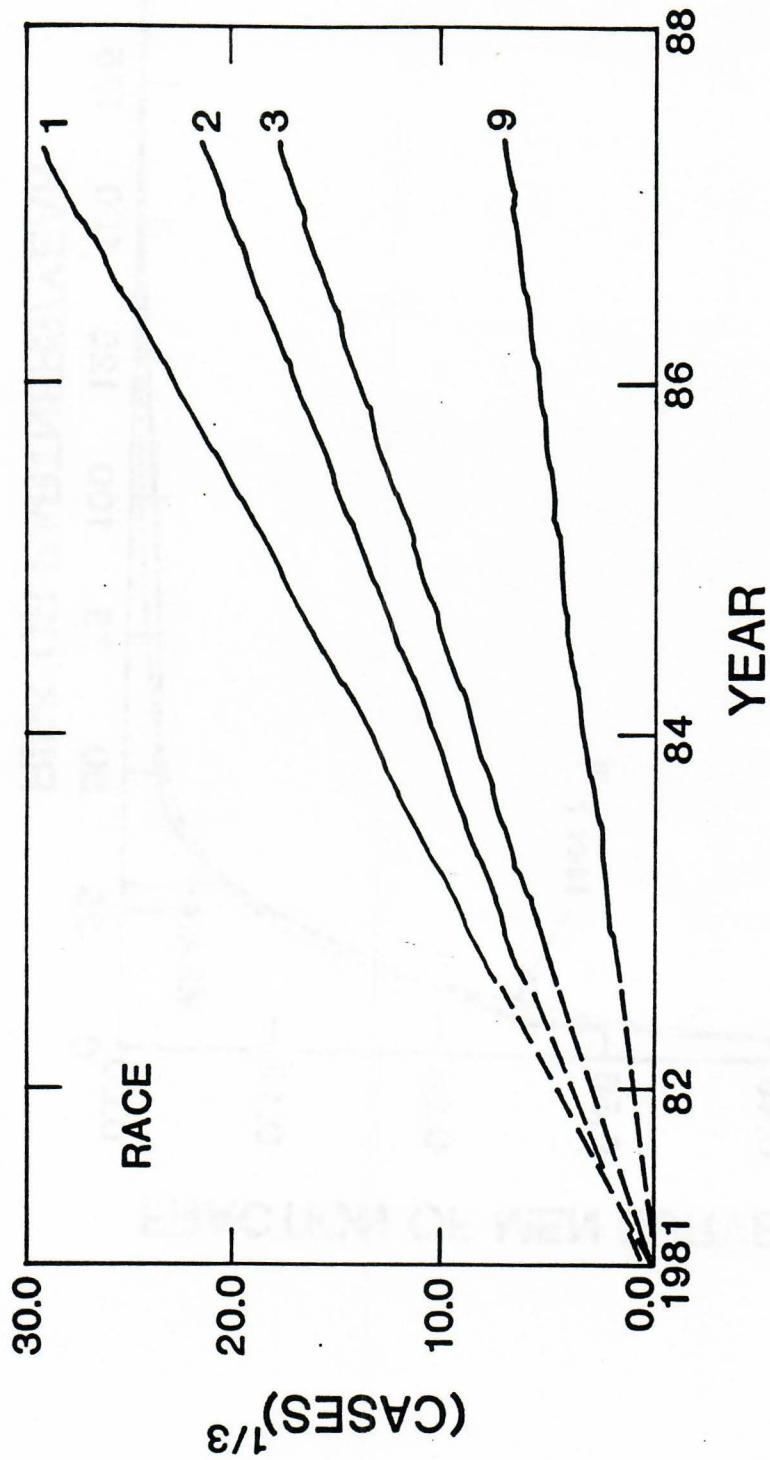


Figure 1d

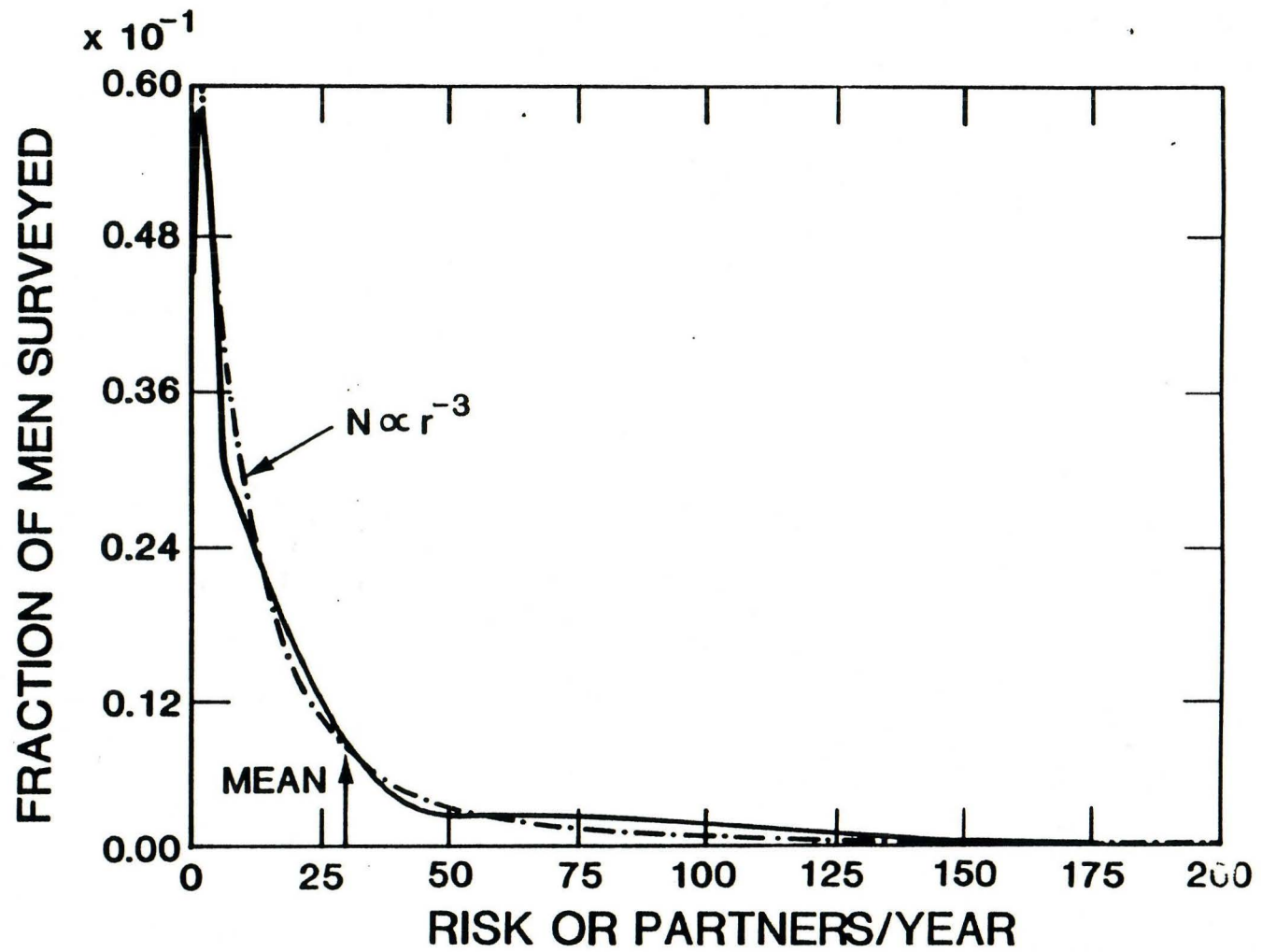


Figure 2



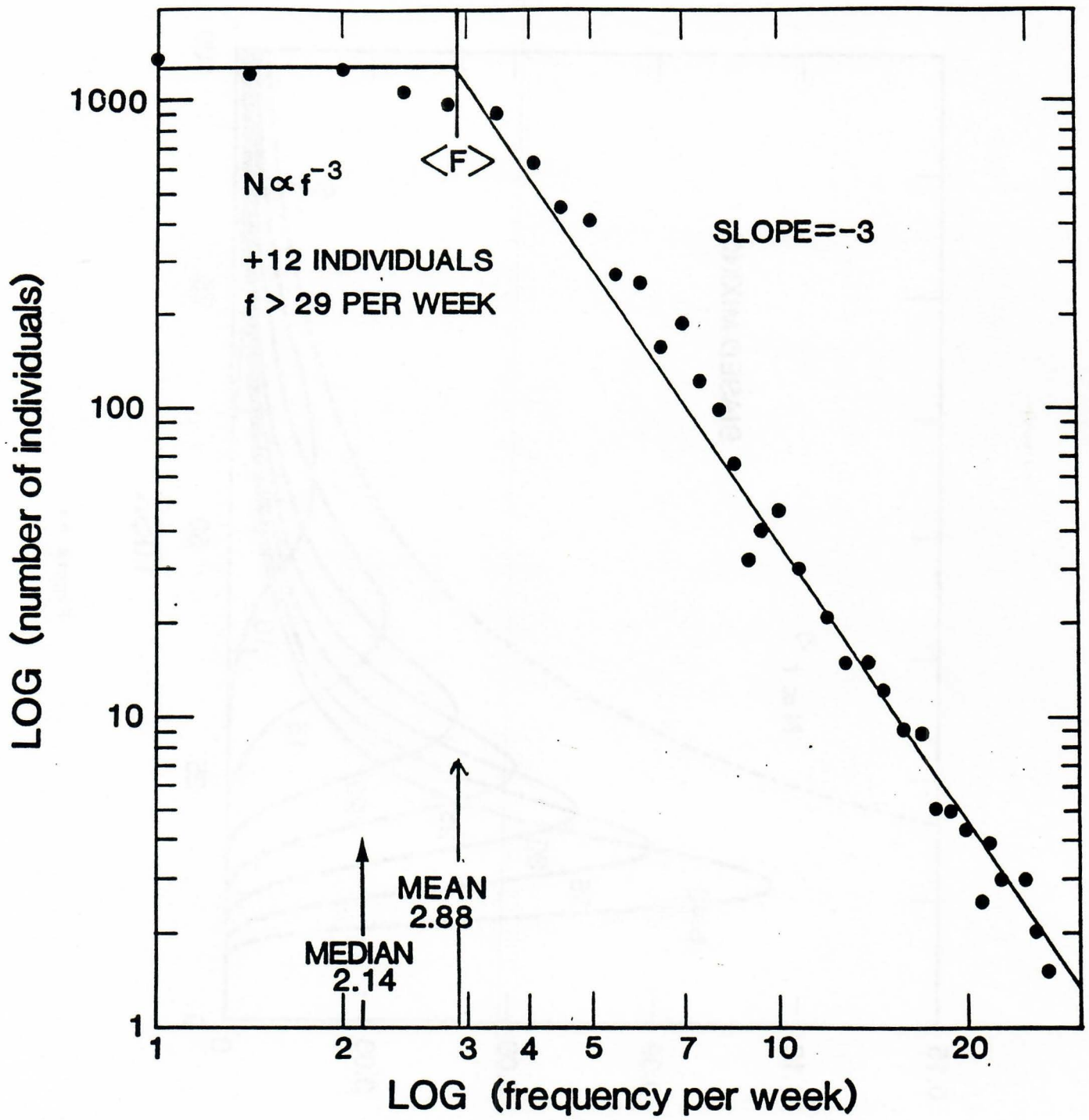


Figure 3

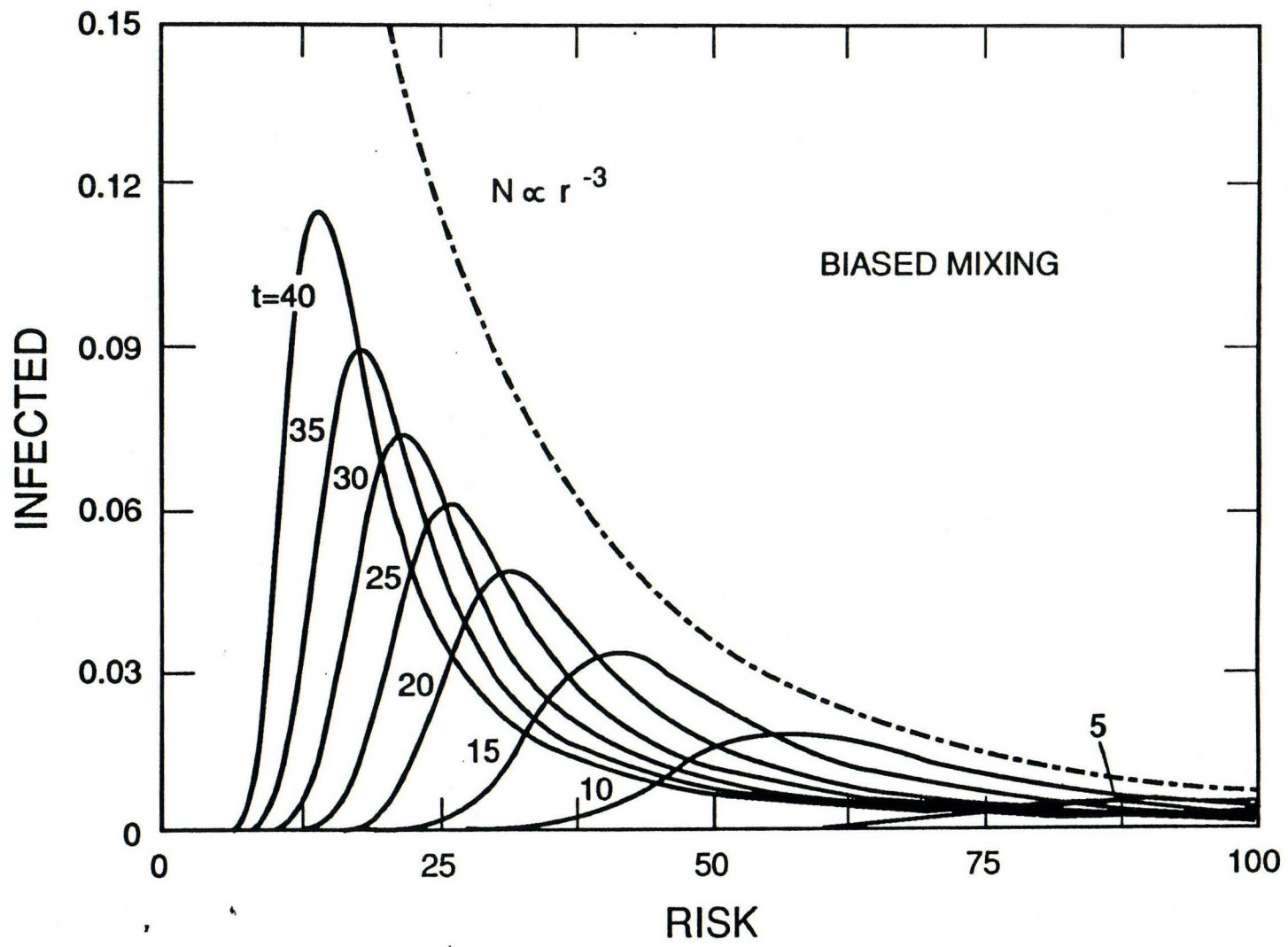


Figure 4a



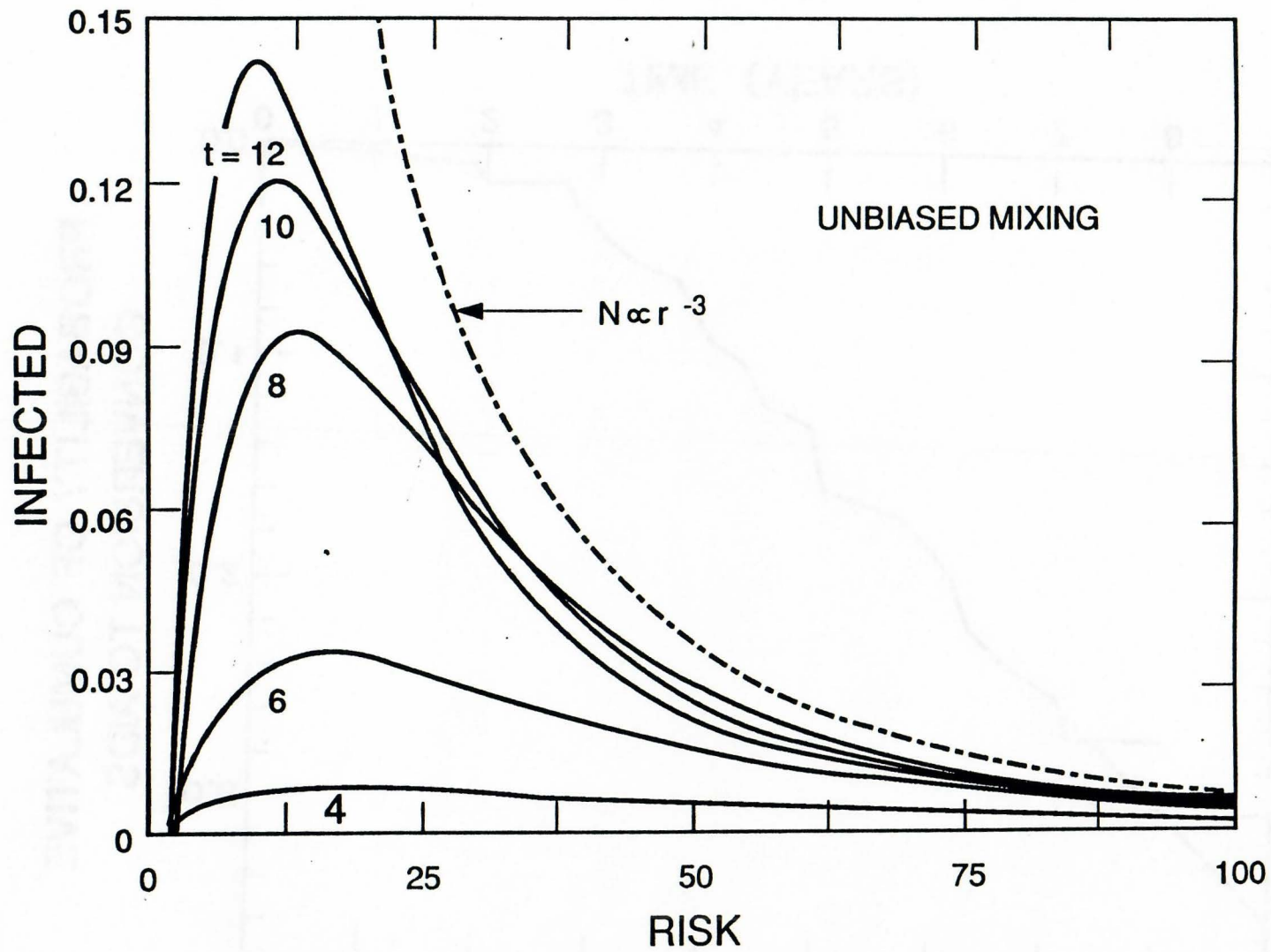


Figure 4b

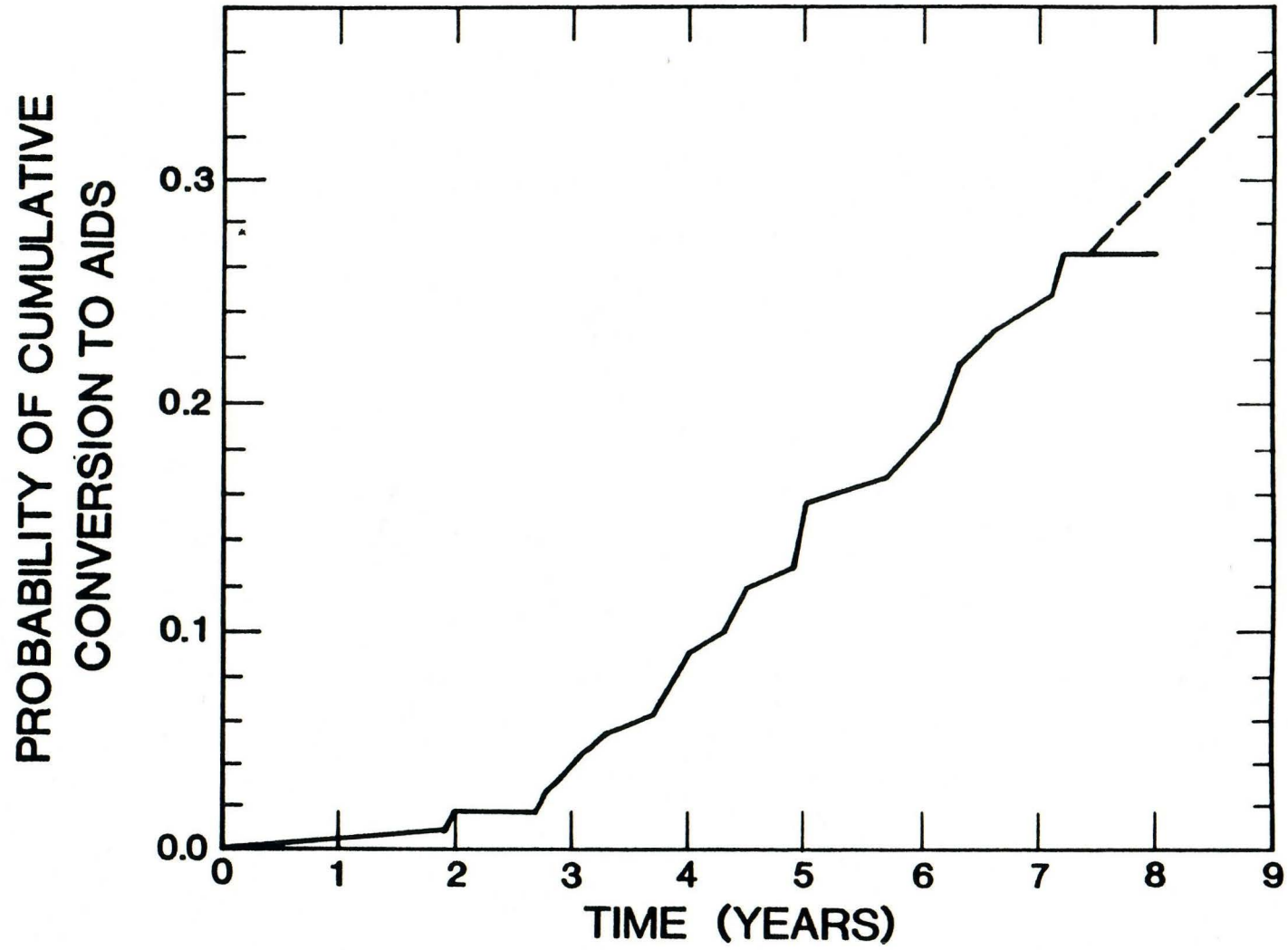


Figure 5





DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

SEP 13 1988

MEMORANDUM FOR: Steven Grossman  
Deputy Assistant for Health  
Planning and Evaluation

FROM: Gerald *(initials)* Britten  
Deputy Assistant Secretary  
for Program Systems

SUBJECT: President's Directives on HIV Commission

Per our conversation, attached are the preliminary responses of HHS to the President's directives concerning implementation of the AIDS Commission report, per Dr. Macdonald's request. As you know, these will be reviewed by the Policy Council tomorrow; we will send you updated versions subsequently.

Attachments  
a/s

*For Policy Council* *Sue*

*Rec'd 11/14*

REQUIREMENTS AND PRINCIPAL RESPONSIBILITY

President's Requirements for HHS

- A. Review budgets for FY 1989-90 (MB)
- B. Hold consensus conferences on public health protection (PHS)
- C. Increase community-based education programs (PHS)
- D. Improve protection of national blood supply (PHS)
- E. Accelerate drug and vaccine development (PHS)
- F. Assess private incentives for development and marketing of HIV products (PHS and P)
- G. Evaluate the national health care financing system (HCFA)
- H. Conduct special studies:
  - 1. Out of hospital care and case management (HCFA/PHS)
  - 2. State risk pools (P)
  - 3. Children with AIDS (PHS)
  - 4. Low-income disabled with AIDS (HCFA)
- I. Update national plan for combatting HIV epidemic (PHS)

Other Requirements

- J. Establish an AIDS emergency fund (PHS and MB)
- K. Implement OPM guidelines (ASPER)



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A. REVIEW FY 1989 AND FY 1990 BUDGETS (MB)

Requirement: The President directed the Secretary of HHS to review FY 1989 spending plans to incorporate relevant recommendations of the HIV Commission. In addition, the Secretary said, in a letter to Dr. Macdonald, that HHS would review the Commission recommendations in developing our FY 1990 budget.

Background

FY 1989 Conference action provides \$1.29 billion (assumes FDA at Senate level) for AIDS activities in PHS. This represents a 1.2% decrease from the President's budget request.

The FY 1990 Budget Request for HHS was submitted to OMB on September 1 and includes almost \$3 billion for AIDS; \$1.94 billion for the Public Health Service activities, \$710 million for Medicaid and Medicare and \$305 million for Disability Insurance. PHS indicated that its FY 1990 request to the Department reflected both the recommendations of the President's AIDS Commission as well as the Charlottesville AIDS Planning Conference held in June.

Proposed Response/Status

As a follow-up to the Commission report, all components of the Department have been asked to review their FY 1989 AIDS spending plans to incorporate the recommendations of the AIDS Commission. Additionally, components have been asked to identify all FY 1989 and FY 1990 resources devoted to each of the Commission recommendations to which the Department has no disagreement.

The AIDS component of the FY 1990 budget request to OMB has been developed taking into account the AIDS Commission recommendations.

Specifically for the PHS, the FY 1989 spending plans of each of the PHS agencies have been reviewed within the context of the recommendations proffered by the Presidential Commission on the Human Immunodeficiency Virus Epidemic. The fact that the Commission released an interim report several months earlier which addressed many substantive issues related directly to various agencies' budgets was very helpful for fiscal planning for FY 1989.

A second element is represented by the development of the Charlottesville Report and the HHS Implementation Plan for AIDS which collectively represent the major departmental planning exercise relative to the control of the HIV epidemic. Many of the goals and objectives of the report and plan are congruent with the recommendations of the Commission, and have therefore

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already been considered in the formulation of the FY 1990 budget.

Accordingly, no PHS agency identified any Commission recommendations which have not been taken into account already during the budget formulation process. The only exception to the above deals with the implementation of actions to protect the blood supply. The final format of the notification of transfusion recipients that may be at risk for HIV infection may have an impact on the FY 1989 budget (see summary D later in this package). Alternatives range from those with no impact on the budget to ones that are expensive. FDA will present its recommendation(s) within several days.

HCFA has not budgeted specifically for the cost (\$400-\$500 thousand) of the required evaluation of the health care system (see summary G), although the FY 1989 Conference agreement includes \$42 million for HCFA research and evaluation.



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**B. CONSENSUS CONFERENCES ON HEALTH PROTECTIONS (PHS)**

**Requirement:** Convene a series of consensus conferences over a 12-month period involving state, local, and private groups to encourage them to adopt the specific public health measures discussed in the Commission's Report, such as increased counseling and testing, reporting of HIV infection, partner notification, and health care worker safety. One conference should address restrictive measures and criminal statutes directed to HIV-infected persons who knowingly persist in maintaining behaviors that transmit their infection. Another possible topic is the serious problem of neighborhood resistance to facilities for the care of HIV patients, drug abusers, and group homes for HIV-infected infants and children.

**Proposed Response/Status**

HHS has already initiated a series of conferences which partially fulfill this directive. A U.S. Health Summit on HIV Infection is scheduled for November 28-29, 1988, in Washington, D.C. Participants will include State Health Commissioners, gubernatorially appointed AIDS Coordinators, representatives of State Medical Societies, and local health officers. The purpose of the meeting is to strengthen public health measures to reduce the spread of AIDS. The conference will provide a forum for public/private sector collaboration on efforts to reduce the spread of HIV infection and an opportunity to share information about HIV-policies, programs and further needs. Workshops will be included where participants will develop recommendations for the conduct and content of the future consensus conferences.

Numerous other conferences, either held recently or planned by the PHS during the next 12 months, meet the definition of consensus conferences.

- The CDC, together with NIMH and other PHS agencies, sponsored the National Conference on Prevention of HIV Infection and AIDS in Racial and Ethnic Minorities in August 1988; over 2,000 participants attended. Follow-up PHS regional conferences involving all PHS Agencies and the Office of Minority Health are expected in fiscal year 1989.
- CDC will jointly support, with the Department of Labor, a conference to be held in January 1989 on the OSHA workplace standards for blood-borne diseases.
- HRSA is planning a second national conference on the planning and management of health care services for HIV-infected patients, following the conference held in Charleston, S.C. on August 4-6, 1988. One major topic will be the health care facilities and housing needs of HIV patients.
- In October, HRSA will co-sponsor a conference on drugs and AIDS, organized by the New York State Hospital Association.



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The conference will address issues related to providing family oriented care for IV drug abusers.

- HRSA will sponsor a two-year followup to the April, 1987 Surgeon General's Workshop on Children with HIV Infection and Their Families in Los Angeles.
- HRSA is joining with NIDA and NIMH to sponsor a series of conferences on developing appropriate services for adolescents and youth at risk of HIV infection.
- The HRSA supported Regional Education and Training Centers will be conducting consensus conferences during FY 1989, addressing such topics as the safety of health care workers.
- OASH and ADAMHA are developing a Gubernatorial Consensus Conference on Federal-State strategies to overcome neighborhood resistance to drug abuse treatment facilities, training needs of alcohol, drug abuse, mental health workers, alternative drug abuse service facilities and mainstreaming drug abuse care with primary care.
- ADAMHA has underway in FY 1988 five regional training sessions targeted to ethnic minorities and another five sessions on reaching hard-to-reach audiences. State and community leaders will be included in these conferences.



C. COMMUNITY-BASED EDUCATION PROGRAMS (PHS)

Requirement: Increase the number of community-based educational programs, especially programs directed to those women and members of minority groups who are at highest risk of HIV infection. These programs, especially those directed to youth, should place greater emphasis on the Principles for AIDS Education, for their efforts to prevent the spread of HIV infection. Please collaborate with the Department of Education in developing youth-oriented programs.

Proposed Response/Status

The PHS has substantial continuing efforts as well as a number of new initiatives for community-based educational programs.

The general educational effort has been under the aegis of the CDC. Within the National Public Information Campaign, at-risk and special population groups have been emphasized, i.e., women, children, and minorities. This Campaign is expanding existing support to 54 state and 16 local education agencies and 20 national organizations that serve American youth. The CDC has augmented community-based programs through support of 30 national and regional minority organizations in FY 1988 which will be continued in FY 1989. Further expansion of minority education will be achieved through direct funding of minority community-based organizations in FY 1989.

In addition, a number of PHS efforts address special populations:

- o The Indian Health Service and the CDC are developing culturally relevant prevention and education programs for Indian community groups and Bureau of Indian Affairs school teachers.
- o HRSA has community-based education programs in each of the 20 AIDS Service Demonstration Grant projects primarily focused on youth and women; HRSA coordinates with CDC in this effort. Most of HRSA's 13 Pediatric AIDS Health Care Demonstration projects have community education components. CDC will be investigating effective means of preventing perinatal HIV infection in these and other pediatric programs.
- o ADAMHA has developed educational programs for young people informing them how intravenous substance abuse results in an increased risk of HIV infection. Fifteen national organizations will be funded to implement 8-10 community based programs each through their local affiliates. Four special studies (general youth, hard-to-reach youth, Hispanic youth and Native Americans) are to be conducted in

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1989 on risk assessment and effective community-based intervention. These studies have implications for HIV infection control measures through community-based efforts. Within NIDA's AIDS outreach demonstrations emphasis is placed on educating intravenous drug abusing women, pregnant drug abusers, female sexual partners of IV drug abusers, and prostitutes about HIV infection.

Wherever pertinent, these efforts have involved consultation with the Department of Education, and utilize the Principles for AIDS Education.



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**D. PROTECTION OF THE BLOOD SUPPLY (PHS)**

Requirement: Implement actions within the next 45 days (by September 20, 1988) that address the blood safety issues raised by the Commission. This plan should address: (a) the prompt notification of transfusion recipients who are at increased risk of HIV infection; (b) steps to improve HIV laboratory quality and HIV screening tests; and, (c) ways to encourage the use of autologous transfusions in appropriate circumstances.

**Proposed Response/Status**

The Department has several ongoing efforts that address blood safety issues raised by the Commission. Two agencies of the Public Health Service, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), are working collaboratively on this effort.

- a. **Notification of transfusion recipients.** FDA is in the process of formulating a plan for the prompt notification of transfusion recipients. First, the Department has sought and received an opinion from the General Counsel that the FDA has the authority to carry out this directive. To obtain comments from the blood community on the optional format to carry out this directive, FDA held a meeting on September 8, with the American Red Cross, the American Association of Blood Banks, members of the Blood Subgroup of the PHS AIDS Task Force, the American Medical Association and the American Hospital Association.
- b. **Improve HIV laboratory quality and testing.** FDA is in the process of preparing an integrated strategy that will include: (1) proficiency testing, (2) surveillance of blood bank facilities, (3) enhanced training of FDA investigators who inspect blood banks, and (4) training programs for blood establishment staff. FDA will report at the Policy Council meeting when the plan will be completed and actions initiated.  
  
NIH is conducting research in FY 1989 aimed at the development and evaluation of new tests to detect HIV in infected individuals. This research includes development of improved assays to detect or confirm the presence of antibody to the virus utilizing more pure viral antigens, or the use of specific viral components including genetically engineered peptides, proteins, or glycoproteins. Further research will be conducted on the approaches to detect HIV antigens and to assess wide-scale applicability of the Polymerase Chain Reaction test, which detects viral nucleic acid. NIH is also funding research in FY 1989 to develop tests to detect other HIV-related retroviruses that cause human disease.
- c. **Encourage autologous transfusion.** NIH is in the process of developing a major educational effort, the National Blood Resources Education Program, to promote a safe supply of

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blood and the more effective utilization of blood and blood products. One of the initial thrusts of this campaign be an effort to promote autologous donation as a means of increasing the blood supply and assuring safety. In addition to a public service message campaign for radio, television and print media, informational brochures and publication will be widely disseminated. Funding for this effort began in FY 1988 and will continue into FY 1989. In addition to this NIH activity, FDA is preparing an article for its Drug Bulletin on red blood cell transfusion that will, among other topics, present information to health professionals on the appropriate use of autologous transfusions.



**E. ACCELERATING DRUG AND VACCINE DEVELOPMENT (PHS)**

**Requirement:** Implement actions within the next 60 days (by October 5, 1988) to improve and accelerate further the process for development, evaluation, approval, and distribution of HIV-related vaccines, drugs, and devices. This plan should draw upon research of Federal and State governments, the private sector, academia, and national laboratories.

**Background**

The development, evaluation and approval of new vaccines and therapies for AIDS occurs in two major phases: (1) research/development, for which the NIH has primary responsibility; and (2) approval of new products, which is FDA's responsibility. Both agencies work closely together to ensure that the new therapies and vaccines are being rapidly developed, and are reviewed for approval expeditiously.

**Proposed Response/Status**

NIH has developed a Plan for AIDS Vaccine Development and Evaluation which describes a multidisciplinary framework for a cooperative effort among government-industry-academia to expedite AIDS vaccine development. The primary goal of the plan is to utilize innovative strategies to maximize interaction of public and private sector components for resource allocation, reagent distribution, technology transfer, and information exchange. The Vaccine Plan currently is being reviewed by the NIH AIDS Program Advisory Committee. Based on its review, the Committee will develop a priority listing of the recommendations contained in the Plan.

NIH has also made a major commitment to the development of rational drug models for potential AIDS therapies by establishing the National Cooperative Drug Discovery Groups (NCDDG). These groups are comprised of scientists from government, academia and industry who are working together to discover, develop and move new AIDS therapies rapidly through the stages of preclinical testing.

FDA has developed a proposal, as directed by Vice President Bush, designed to expedite approvals for therapies that are intended to treat life-threatening illnesses such as AIDS. The proposal, submitted to OMB on September 6, contains several key elements:

- o Early consultation by FDA with the sponsor to develop Phase 2 studies which could provide definitive data on safety and effectiveness, warranting marketing approval. This will, in effect, compress Phase 2 and Phase 3 studies, shortening the approval time.

- o Focused FDA research when the sponsor is, itself, unable to conduct all necessary research or when FDA can contribute special research expertise (e.g., pharmacokinetics).
- o Risk-benefit analysis to assess the risks of the disease balanced against the identified benefits and risks of the product.
- o Treatment IND status for appropriate drugs which will serve as a bridge between completion of Phase 2 testing and marketing approval.
- o Phase 4 studies may be requested following expedited approval of the product to develop additional information about the product's risks and benefits after marketing.
- o Proactive involvement of the Commissioner and other Agency officials with sponsors will assure that product review is proceeding on schedule.
- o Safeguards will be included to assure the safety and effectiveness of products approved through the expedited process.



F. INCENTIVES FOR DEVELOPING AND MARKETING  
OF HIV PRODUCTS (PHS/P)

Requirement: Provide within 120 days (December 5, 1988) an assessment of private incentives for development and marketing of HIV products, including an evaluation of the need, if any, to have Federal authority to offer increased incentives in exchange for royalties, licenses, or pricing concessions. This assessment should take into consideration solutions proposed in the February 1986 report of the Tort Policy Working Group. In doing this assessment, please consult with the Departments of Justice and Defense.

Proposed Response/Status

The Department has several ongoing efforts that address appropriate incentives for private sector development of drug products discovered with Federal funding, and intends to complement these existing efforts with new initiatives.

Many existing efforts help promote rapid technology transfer of HIV-related products, particularly the granting of commercial incentives to private sector companies in exchange for development and marketing resources. For example, various forms of collaborative agreements, including those under the Federal Technology Transfer Act of 1986, between Federal laboratories, (e.g., NIH) and commercial research-based companies, have brought about rapid progress towards new AIDS-related products. Mechanisms such as exclusive grants of marketing rights and waivers of royalty or patent licensing rights permit Federal laboratories to provide more successful incentives for rapid commercialization.

Over and above these existing efforts, the Department has asked the Technology Management Advisory Board of the Public Health Service to consider the extent to which these incentives to private industry might be refined, expanded, or improved. This Board will also consider the appropriate Federal role in encouraging reasonable pricing for HIV-related products, such as AZT, developed in part with Federal funds. This Board will also consider recommendations that might improve the quality of the technology transfer program generally. The Board has appointed a Working Group to address these issues on a priority basis. The Working Group first met on August 31 and intends to draft its recommendations in October. Findings will be available to meet the time requirement directed by the President.

One factor that may be inhibiting rapid development of some HIV-related products, particularly vaccines, is the manufacturers' fears of liability suits. Although it is difficult to know if there exists any actual and serious risk of liability, the Department recognizes that the very perception of significant risk could delay important research and development efforts, particularly in the area of vaccines. Secretary Bowen directed on April 27, 1988, an examination of this potential problem.

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Accordingly, HHS is investigating the parameters of liability issues for HIV-related products, in consultation with groups that have addressed liability issues, such as the Keystone Group and the Institute of Medicine. The findings, which will also be coordinated with the Departments of Justice and Defense, will be available by December 5, 1988.



G. EVALUATE THE HEALTH CARE FINANCING SYSTEM (HCFA)

Requirement: Undertake an evaluation of our current system of health care financing to be completed within 1 year.

Proposed Response/Status

HCFA plans to take the following approach:

- o Scope and Focus of the Evaluation -- The evaluation (as suggested by the President's HIV Commission) will focus on access to care by the American public, both the uninsured and the underinsured. Although theoretically access could involve such matters as facilities, outreach programs, specialized disease or health problem initiatives, personnel recruitment and training, and the special problems of long-term care, the study will not extend to these areas because of concerns with scope and manageability. The evaluation will concentrate instead on financing and insurance issues.

Particular attention will be paid to the experience of low-income disabled individuals (e.g., with the SSI Medicaid eligibility process) in keeping with the President's request that ways be studied to increase the responsibility of the system to that group (see summary H(4)).

- o Outcome -- The evaluation will assemble thorough and comprehensive information on the current situation in regard to access under the current system of health care financing in this country. That information will be of use to Congress and to the next Administration for policymaking.
- o Action Steps (Tentative)

1988

September

- o Assemble HCFA staff.
- o Establish HHS liaison group.
- o Develop draft study design.

October

- o Bring together a blue-ribbon group of consultants to further formulate study design.
- o Finalize study design.
- o Write and publish request for contract with outside group for research support.

November/December

- o Work and communicate with other Federal agencies.
- o Evaluate proposals developed in response to RFC.

1989

January

- o Award contract for research assistance.

January - September

- o Conduct and complete study.
- o Cost (Tentative) - 3-5 FTEs; \$400-\$500,000
- o Departmental Cooperation

The success of the evaluation will depend on the following specific assistance from HHS components:

- o ASPE cooperation and expertise in addressing certain issues outside the Medicare/Medicaid area, particularly those involving outside agencies such as the Departments of Labor and Treasury.
- o PHS cooperation in making available preliminary data from the National Medical Expenditures Survey (NMES) at the earliest possible time.

PHS is working with HCFA to plan a series of regional conferences regarding the financing of health care services for HIV patients. The specific topics, dates and locations of these conferences are still to be determined, but they will deal with financing-related recommendations of the Presidential Commission on the HIV Epidemic and PHS' Charlottesville Conference. Conferences will cover such topics as promoting private sector involvement in paying for services, exploring ways to finance non-traditional services (including housing-related services), and encouraging states to adopt risk pools.

PHS will also study the financing of services provided in the networks of care supported by the AIDS Service Demonstration Grants. A data collection survey which will gather information on the demographics of the patients being served by the grantees and on the primary source of payment for each of the broad categories of care provided for in the networks is being submitted for OMB clearance.



H(1). SPECIFIC STUDIES ON HEALTH CARE--OUT OF HOSPITAL AND CASE MANAGED CARE (HCFA/PHS)

Requirement: Conduct specific studies of ways to promote better out-of-hospital and case managed care.

Proposed Response/Status

HCFA is coordinating efforts to respond to the requirement.

- o HCFA is encouraging states, under the home and community-based services waiver program to provide more cost-effective care for persons who would otherwise be at-risk of institutionalization, focusing particular attention on persons with AIDS. Overall, there are 46 States with currently active waivers, with 7 states specifically identifying AIDS/ARC patients as a category of patients being served under their waiver programs. The seven states are: New Jersey, New Mexico, North Carolina, Ohio, Hawaii, Illinois, and South Carolina. HCFA will continue to encourage additional states to avail themselves of this optional waiver program as a means of promoting out-of-hospital and case-managed care.
- o HCFA has been encouraging states and other organizations to conduct studies of the effectiveness of out-of-hospital and case-managed care through the annual solicitation for research and demonstration proposals. In both the FY 1988 and the proposed FY 1989 solicitations, HCFA has solicited projects that assess the effects of innovative state, local, and private programs in promoting such care for AIDS patients. (Although no application was funded in this area in FY 1988.) In the FY 1989 notice, HCFA has included a solicitation for studies that examine the use of Medicaid waivers, hospice care, home health and other ambulatory services in providing cost-effective alternatives to inpatient care for AIDS patients.
- o NCHSR has developed a program announcement to stimulate investigator-initiated research. One priority area is research that involves analysis of the effectiveness and efficiency of health-care delivery for HIV-infected persons. NIH has other program announcements for investigator-initiated biomedical research. -New?
- o HSRA is conducting an evaluation of patterns of utilization and costs in four AIDS Service Demonstration Grant projects. This evaluation, which is being performed by Project HOPE, will concentrate on out-of-hospital care and is scheduled for completion late next summer. An additional study of these demonstration grants is preparing descriptions of the range of services provided in each city, and of the relationships among service providers in the network. HSRA also has a contract for evaluating the results of a small

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scale study of ambulatory care costs of AIDS patients in the San Francisco area.

- o This fall, HRSA will begin a two-year evaluation of Regional AIDS Education and Training Centers. This evaluation will identify ways to improve the effectiveness of the Centers in preparing health professionals to care for HIV-infected people and will begin to assess their impact on this objective.



**H(2). SPECIFIC STUDIES ON HEALTH CARE -- STATE RISK POOLS (P)**

**Requirement:** Conduct specific studies on ways to encourage states to establish insurance risk pools for medically uninsurable persons.

**Background**

About one percent of the United States population is estimated to be medically uninsurable due to pre-existing medical conditions, including AIDS. When private insurance is available, the price is often prohibitive or the pre-existing conditions are excluded from coverage for the first year or longer. Without insurance, many of these people are unable to pay the high medical bills they often incur. This results in financial strain on health providers. It also means financial hardship for the individuals and their families and the depletion of resources until the individual qualifies for government-subsidized care. Risk pools are legislatively established health insurance programs intended to make insurance available to people considered otherwise uninsurable. The resulting coverage can reduce the impact on personal finances and the dependency on Medicaid.

Fifteen states have enacted legislation establishing subsidized risk pools; of these, 13 are active. Some 20 states considered (but none enacted) risk pool legislation in 1987-88. According to a GAO report, all existing pools appear to cover AIDS, and four (Indiana, Iowa, Minnesota and Nebraska) specifically include AIDS among the diagnoses that are grounds for presumptive pool eligibility.

**Proposed Response/Status**

- o HHS has proposed to OMB that the Administration support enactment of S. 1634 proposed by Senator Durenberger which would encourage states to establish risk pools, would establish very limited Federal requirements (which should be further modified), and would provide \$30 million in "seed money" spread over 3 years. We will follow up with OMB.
- o HHS will promote state enactment of risk pools in several forums, including the consensus conferences required in the action plan, and through speeches, letters, and other interactions with the National Governors' Association and the National Conference of State Legislatures.
- o Through the evaluation of existing risk pools and the development of several model risk pool statutes, HHS will act as a resource center to help states wishing to consider enactment of legislation to establish risk pools. We will communicate this to all states.



H(3). SPECIFIC STUDIES ON HEALTH CARE--HIV-  
INFECTED INFANTS AND CHILDREN (PHS)

Requirement: Conduct specific studies on ways to increase the responsiveness of the public health and health services system to HIV-infected infants, children, and adolescents.

Proposed Response/Status

In February 1988 Secretary Bowen established a special initiative on pediatric HIV infection to focus and develop HHS-wide efforts to address this problem.

A Departmental work group was formed under the leadership of the PHS. That group has completed its report and provided it to the Assistant Secretary for Health on August 31. It is now under review by PHS and other components of the Department. It includes many recommendations, including ones concerning resources, provision of health care services, financing of such services, and prevention of HIV infection. HHS agency/PHS review should be completed by late September.

There also are a number of ongoing activities aimed at pediatric AIDS, such as HRSA's recent award of 13 grants totalling \$4.4 million to states and communities for the funding of projects demonstrating innovative approaches for intervention in pediatric AIDS, particularly to reduce perinatal transmission of AIDS and develop family centered services; several evaluations to assess problems in foster care for children with HIV infection and identify potential solutions; and NIH will be working with FDA to revise that agency's guidelines to permit early testing of promising agents in infants, children and adolescents--simultaneous with testing in adults.



H(4). SPECIFIC STUDIES ON HEALTH CARE -- DISABLED (HCFA)

Requirement: Conduct specific studies to increase the responsiveness of the health care system to low-income disabled individuals.

Proposed Response/Status

The principal questions to be addressed concern the Commission's recommendations to consider decreasing the waiting period for Medicare from 24 to 12 months, and to extend the coverage period of employer's health insurance. These solutions and others are addressed in the evaluation of the health care system summarized in item G.

I. NATIONAL PLAN FOR COMBATTING HIV (PHS)

Requirement: Provide an update by December 15, 1988, of the 1986 PHS plan for combatting HIV infection, reflecting, in part, both the Commission Report and the recent Public Health Service Charlottesville Planning Conference.

Background

The PHS has led the effort to control the human immunodeficiency virus (HIV) infection since 1981. Many of the salient contributions by the various Agencies of the PHS have been developed within the context of an ongoing planning process.

Proposed Response/Status

The Assistant Secretary for Health (ASH) convened a meeting in June 1986 to develop a comprehensive plan for the entire PHS. That plan was used to coordinate efforts through 1988, but new developments necessitated a major update. In response, the ASH convened a second PHS AIDS Prevention and Control Conference in early June 1988 in Charlottesville, Virginia, to develop a new PHS coordination plan. The report of the meeting contains an assessment of the last two years' effort, the major issues facing PHS, 222 goals, and 554 specific objectives as priority areas. The report is expected to be published in October 1988.

The Department is developing an implementation plan which will identify the major goals to be carried out in FY 1989 with specific objectives and dollars allotted. It will include implementation of Commission recommendations, as appropriate. The PHS Charlottesville report/plan discussed above will serve as the major component of this implementation plan, with components added by other HHS agencies. The final plan is expected to be ready simultaneously with the Charlottesville Report.

Similar implementation plans will be prepared for future years.

Plans are under development to use both the Charlottesville Report/HHS implementation plan, and the President's Commission Report, to establish a tracking and monitoring system for HHS activities combatting HIV infection.



J. ESTABLISH AN AIDS EMERGENCY FUND (MB)

Requirement: Seek a special HIV emergency fund in the FY 1990 budget for unanticipated problems and opportunities.

Proposed Response/Status

The FY 1990 budget request sent to OMB on September 1 includes \$25 million for an AIDS emergency fund.

K. IMPLEMENT OPM GUIDELINES (ASPER)

Requirement: Every Federal agency is to adopt a policy based on OPM guidelines for AIDS information and education and personnel management.

Proposed Response/Status

In response to OPM's Guideline of March 24, 1988, ASPER issued Personnel Manual Instruction 792-4, AIDS in the Workplace, which provides HHS policy on employment issues concerning AIDS in the HHS workplace. ASPER is also preparing a memorandum for the Secretary to send to all HHS employees regarding AIDS in the workplace.

In addition, ASPER has developed continuing education programs for the Employee Counseling Service. A videotape entitled "One of Our Own - A story About AIDS in the Workplace" and accompanying educational materials are available for Employee Counseling Service personnel. A report, AIDS: The Facts - A Special Report, was prepared and distributed in 1987.

Finally, Employee Counseling Service personnel are encouraged to utilize available programs and informational materials as they work to educate HHS employees about AIDS. Brochures of these materials are displayed in Employee Counseling Service centers for distribution. Counseling Service staff members also attend workshops, conferences and/or seminars on AIDS education whenever possible, as part of their in-service training.



Revised  
9/13/88

**Presidentially Directed Evaluation of  
Health Care Financing**

o Action Steps (tentative)

September 1988

- o Assign HCFA staff.
- o Designate HHS liaisons.
- o Develop draft study design.

October/November

- o Bring together a group of consultants to review the study design.
- o Finalize plans and timetable for conducting the study.
- o Draft a request for contract to solicit outside group for research support.

November/December

- o Continue liaison with other Federal agencies.
- o Publish request for contract for research support.

January/February 1989

- o Award contract for research support.

January - September 1989

- o Conduct and complete study.