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OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT
THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: **Robert Pellicci** FROM: **Todd Summers**
COMPANY: **OMB** DATE: **July 7, 1999**
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NOTES/COMMENTS:

Bob - Please see handwritten correction
on page 5 - it's not in the version
I emailed you - this makes Fanci's
testimony consistent with President's
comments on 12/1/98 and 6/9/99 regarding
level of vaccine research funding. Todd

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement of
Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Field Hearing on AIDS
Senate Appropriations Committee
Subcommittee on Labor, HHS, and Education
The Honorable Arlen Specter, Chairman

San Francisco, California

July 9, 1999

I am pleased to appear before you today to discuss the human immunodeficiency virus (HIV) epidemic, recent developments in HIV research, and the many challenges that remain in the fight against HIV and the acquired immunodeficiency syndrome (AIDS).

The Scope of the Epidemic

AIDS was recognized eighteen years ago this summer, and continues to exact an enormous toll here and throughout the world, in both human and economic terms. In the United States, an estimated 650,000 to 900,000 people are living with HIV, more than 200,000 of whom are unaware of their infection. In this country, 688,200 cumulative cases of AIDS and 410,800 AIDS-related deaths were reported to the Centers for Disease Control and Prevention (CDC) through 1998.

Despite an encouraging downturn in the overall number of new AIDS cases and AIDS-related deaths in the United States during the past three years, the rate of new HIV infections in this country – approximately 40,000 per year – continues at an unacceptably high level. Of these newly infected individuals, the CDC estimates that half are people younger than 25 who were infected sexually.

Unlike the early days of the HIV/AIDS epidemic in this country, the virus now affects minority populations disproportionately. The rates of AIDS cases (per 100,000 population) reported in 1998 in the United States were 66.4 for African-Americans, 28.1 for Hispanics, 8.2 for Whites, 7.4 for American Indians/Alaska Natives and 3.8 for Asian/Pacific Islanders. Women are increasingly affected: the proportion of U.S. AIDS cases reported among adult and adolescent females more than tripled from 1985 to 1998, from 7 percent to 23 percent.

In the developing world, the HIV/AIDS epidemic continues to accelerate, notably in sub-Saharan Africa, southeast Asia and on the Indian sub-continent. There are also signs of burgeoning epidemics in Russia and the Former Soviet Union nations. As of the end of 1998, more than 33

million people worldwide were living with HIV/AIDS, 43 percent of them female, according to estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS). An estimated 5.8 million new HIV infections occurred worldwide during 1998 – approximately 16,000 new infections each day. More than 95 percent of these new infections occurred in developing countries. In 1998, HIV/AIDS was the fourth leading cause of mortality worldwide, resulting in an estimated 2.3 million deaths.

Beyond the human tragedy of HIV/AIDS, the economic costs of the epidemic are staggering, posing a significant impediment to the growth and stability of many countries. A 1999 WHO publication *Removing Obstacles to Healthy Development* estimates the annual economic burden of HIV to be \$14 billion in prevention and health care costs alone. In many countries, the epidemic is decimating a limited pool of skilled workers and managers, and will likely wipe out gains in development by slashing life expectancy. According to UNAIDS, life expectancy in the nine countries in Africa with the highest HIV prevalence rates will fall, on average, 17 years by 2015.

HHS Spending on HIV/AIDS

Clearly, HIV remains one of the greatest threats to global health, and requires a sustained commitment by the many partners in AIDS research and prevention, including federal, state and local health agencies, foreign governments, UNAIDS, the World Bank, non-governmental and philanthropic organizations, academia, industry, and the activist community. In this regard, overall funding for AIDS-related programs within the U.S. Department of Health and Human Services (HHS) has increased by 122 percent under the current Administration. The FY 2000 President's Budget includes \$8.2 billion in total HIV/AIDS funding within HHS.

The Ryan White CARE Act, which helps states and highly impacted communities provide primary and supportive services to people living with HIV and AIDS, was funded at over \$1.4 billion in Fiscal Year 1999. President Clinton has proposed an increase of approximately \$100

million for FY2000 in recognition of the critical role that the CARE Act continues to play in helping people access and maintain themselves in care.

_____At the National Institutes of Health (NIH), HIV/AIDS funding increased 67.5 percent from FY 1993 to FY 1999; the FY 2000 President's budget includes \$1.834 billion in HIV/AIDS research funding at the NIH.

The Success – and Limitations – of Antiretroviral Therapy

In the United States and other developed countries, new AIDS diagnoses and deaths have fallen significantly during the past three years. In the United States, the age-adjusted death rate from AIDS declined 47 percent from 1996 to 1997, according to the National Center for Health Statistics; similar decreases have been noted in western Europe and Australia. These trends are probably due to several factors, particularly the increased use of potent, albeit expensive anti-HIV drugs, generally administered in combinations of three or more agents. Such combinations are known as "highly active antiretroviral therapy" or HAART. Sixteen anti-HIV drugs are now licensed by the Food and Drug Administration, 10 of which are approved for pediatric use.

Consensus guidelines have been developed for the use of HAART in adults and adolescents; separate treatment guidelines have been formulated for pediatric patients, as well as for the use of antiretroviral drugs in HIV-infected pregnant women. These guidelines are regularly updated on the World Wide Web (see <http://www.hivatis.org>) and when appropriately applied have greatly improved the prognosis for HIV-infected individuals and markedly reduced the risk of HIV transmission from mother to baby.

Unfortunately, many HIV-infected individuals have not responded adequately to current medications, cannot tolerate their toxicities, or have difficulty complying with treatment regimens that involve extremely complicated and demanding dosing schedules, large numbers of pills, and myriad interactions with other drugs and foods. This can be particularly difficult for those who are

struggling to maintain the basic necessities of life like housing and food, which are the very people in the path of this epidemic.

_____ Even in patients who are successfully treated with HAART and have extremely low bloodstream levels of HIV, the virus persists in sanctuaries where the drugs cannot reach it or in a latent form upon which drugs have no effect. In addition, the emergence of HIV strains resistant to current drugs is a ~~widespread~~ and growing problem. Although there is evidence of immune system reconstitution in certain patients who receive combination antiretroviral therapy, the goals of completely "rebuilding" the immune system or eradicating the virus from its hiding places in the body appear unlikely with current approaches to treatment.

Therefore, the development of a next generation of therapies remains a priority. Currently, all licensed antiretroviral medications are directed at one of two viral enzymes, reverse transcriptase or protease. Many new drug targets and novel treatment strategies are now being pursued, including drugs that prevent the virus from entering a cell, approaches to "purging" the virus from its hiding places in certain cells and tissues, and methods to boost an infected person's immune response.

The Critical Role of HIV Prevention

In developing countries where *per capita* health care spending may be only a few dollars a year, anti-HIV therapies are frequently beyond the reach of all but the privileged few, underscoring the urgent need for effective, low-cost tools of HIV prevention that can be used in these settings as well as in the United States.

Researchers have shown that several approaches to HIV prevention can reduce the number of new infections when properly executed, including education and behavior modification, the social marketing and provision of condoms, treatment of other sexually transmitted diseases, drug abuse treatment (for example, methadone maintenance for injection drug users), and the use of antiretroviral drugs to interrupt the transmission of virus from mother to infant.

For example, in one of the true "success stories" of HIV research, the rate of mother-to-child transmission of HIV in the United States has been cut to negligible levels among women and infants treated with an extended regimen of AZT therapy developed by NIH-supported investigators. Subsequent studies by CDC, NIH and others have shown that substantially shorter regimens of antiretroviral drugs, which would be more feasible in resource-poor settings, can also reduce perinatal HIV transmission significantly.

Other methods of preventing HIV transmission may also help slow the HIV/AIDS epidemic. For example, researchers are developing and testing topical microbicides, substances that a woman could use in her vagina before sex to prevent the transmission of HIV and other sexually transmitted diseases. UNAIDS and others also have facilitated the widespread use in Africa of the female condom. These interventions may help empower women to protect themselves in situations where they are unable to avoid sex with HIV-infected partners, and/or cannot persuade their partners to use a condom.

HIV Vaccine Development

Historically, vaccines have provided safe, cost-effective and efficient means of preventing illness, disability and death from infectious diseases. The development of a safe and effective vaccine for HIV infection remains the "holy grail" of AIDS research, and a necessary tool to bringing the HIV epidemic under control. To speed the pace of HIV vaccine discovery, many public and private agencies have dramatically increased the resources devoted to HIV vaccine research. For example, at the NIH, HIV vaccine funding rose from \$100.5 million in FY 95 to ~~an~~ ^{nearly \$200} ~~estimated \$194.1~~ million in FY 1999. As part of this expanded effort, NIH has awarded numerous grants to foster innovative research on HIV vaccines and to conduct clinical trials of candidate HIV vaccines. To date, more than 3,000 non-infected volunteers have enrolled in more than 50 NIH-supported HIV vaccine studies (including two "phase II" intermediate-sized trials), involving 27

vaccines. In addition, NIH has established the Dale and Betty Bumpers Vaccine Research Center within the NIH intramural research program to stimulate multidisciplinary vaccine research.

As part of a broad portfolio of research, recent NIH-supported studies have assessed so-called "vectored vaccines": harmless viruses (e.g. canarypox) which are genetically altered to make HIV proteins. These vaccines have been administered to volunteers in combination with a separate vaccine made of a purified HIV protein. Results have been encouraging: in phase I and phase II studies, the combination approach has appeared safe and evoked several types of immune responses that may have a role in protection from HIV. NIH-funded researchers are now comparing three different vectors, as well as other HIV proteins to determine which combination produces the most vigorous immune response.

Meanwhile, a large-scale study of a vaccine based on the surface proteins of two HIV strains was recently undertaken in the United States by a private company, with an additional phase III study to be conducted in collaboration with CDC in Thailand. NIH will collaborate with the company in evaluating the immunological responses to the vaccine.

Conclusion

As we work to contain the global HIV/AIDS epidemic, it is essential to sustain and enhance our commitment to HIV prevention, to caring for HIV-infected people, to developing the next generation of HIV therapies and prevention tools, and to producing a safe and effective HIV vaccine. Though we have been battling against AIDS for nearly 20 years, we are in no position to let down our guard. On the contrary, if we are ever to hope for a day without AIDS, we will need to sustain and increase our efforts both here in the United States and across the globe.

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