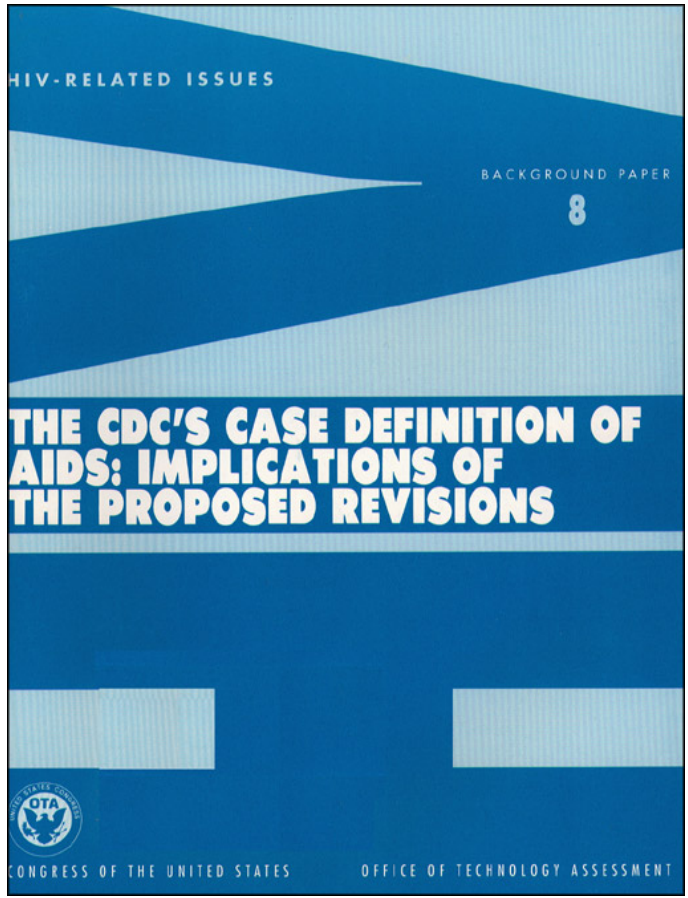
The CDC's Case Definition of AIDS: Implications of Proposed Revisions

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OTA PROJECT STAFF--THE CDC'S CASE DEFINITION OF AIDS: IMPLICATIONS OF THE PROPOSED REVISIONS

BACKGROUND PAPER

Roger C. Herdman, *Assistant Director, OTA, Health and Life Sciences Division*

Clyde J. Behney, Health *Program Manager*

Project Staff

Robert S. McDonough, *Study Director*
Jacqueline A. Corrigan, *Senior Analyst*

Sharon Y. Hamilton, *Research Assistant*
Kerry B. Kemp, *Senior Analyst*
Michelle Odom, *Research Assistant*
Sarah Sa'adah, *Research Assistant*[1]

Administrative Staff

Marian Grochowski, *Office Administrator*
Kimberly Holmlund, *Word Processor Specialist*
, Eileen Murphy, *P.C. Specialist*
Kelly Faulks, *Secretary*

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1 Until June 1991.

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WASHINGTON D C. 20510

FOREWORD

The Centers for Disease Control's (CDC) AIDS case definition is used to monitor trends in the number and distribution of AIDS cases in the United States. The AIDS case definition measures severe morbidity due to infection with the human immunodeficiency virus (HIV). This information is then used in formulating Federal and State policies for the prevention, treatment, and control of AIDS. In addition, the AIDS case definition has been used in disability determinations by the Social Security Administration.

Congress has been concerned about recent reports that the present AIDS case definition does not include some severe manifestations of HIV infection that occur in women and injection drug users. This is of particular concern because most HIV-infected women and injection drug users are African Americans or Hispanics. The CDC proposes to implement a revised definition of AIDS in the summer of 1992. The CDC believes that this revised definition of AIDS will adequately capture severe manifestations of HIV infection in these populations.

This background paper examines the epidemiologic evidence used by the CDC in deciding to revise the AIDS case definition and the impact the proposed definition will have on surveillance. The paper also explores the logistical consequences and other implications of the revised definition, including its impact on Social Security disability determinations. The issues discussed in this paper were the subject of a workshop conducted by OTA on October 22, 1991.

This background paper was prepared in response to a request by the Subcommittee on Human Resources and Intergovernmental Relations of the House "Committee on Government Operations.

This background paper is the eighth in OTA's series of studies on HIV-related issues. The preceding papers in this series were: Do Insects *Transmit AIDS? (9/87); AIDS and Health Insurance: An OTA Survey (2/88); How Effective is AIDS Education? (6/88); The Impact of AIDS on the Kaiser Permanence Medical Care Program (Northern California Region) (7/88); How Has Federal Research on AIDS/HIV Disease Contributed to Other Fields (4/90); The Effectiveness of Drug Abuse Treatment: Implications for Controlling UDS/HIV Infection (9/90);* and *HIV in the Health Care Workplace* (11/91).

Previous OTA reports addressing AIDS-related issues include: 1) *Blood Policy and Technology* (1/85); 2) *Review of the Public Health Service's Response to AIDS* (technical memorandum, 2/85); 3) *The Costs of AIDS and other HIV Infections: Review of the Estimates* (staff paper, 5/87); and 4) *Medical Testing and Health Insurance (8/88).*

JOHN H. GIBBONS
Director

The Definition of AIDS: Epidemiological, Clinical, and Policy Implications

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Office of Technology Assessment

Workshop Participants

Robert S. McDonough, M.D., J.D., Study Director
Jacqueline A. Corrigan, J.D., Senior Analyst
Workshop Moderators

Ruth Berkelman, M.D.
Acting Director, Division of HIV/AIDS
Centers for Disease Control
Atlanta, GA

G. Steve Bowen, M. D:, M.P.H.
Acting Associate Administrator for AIDS
Health Resources and Services Administration
Bureau of Health Resources Development
Rockville, MD

Mary Ann Chiasson, Ph. D., M. P.H., M.S.
Acting Assistant Commissioner
Disease Intervention Research
New York City Department of Health
New York, N.Y.

Judith Cohen, P.h.D., M. P.H., M.A.

San Francisco, CA

Elizabeth Cooper, J.D.

ACLU AIDS Project
New York, NY

Judith S. Currier, M.D.
Clinical Director for AIDS
Associate in Medicine
Beth Israel Hospital
Boston, MA

Jack DeHovitz, M.D.
Director, AIDS Prevention Center
SUNY Health Science Center at Brooklyn
Brooklyn, NY

Don Des Jarlais, Ph.D.
Direcor of Research

Chemical Dependency Institute
New York, NY

Karen M. Ezrine, M.D.
Chief, Medical Evaluation Branch
Office of Disability
Social InSecurity Administration
Baltimore, M D

Dave Fleming, M.D.
Deputy State Epidemiologist
Oregon Department of Human Resources
Portland, OR

Howard Foard
Assistant Deputy Commissioner for Policy and External Affairs
Office of Disability
Social Security Administration
Baltimore, MD

Philip Fornaci, J.D.
Staff Attorney
Whitman-Walker Clinic Inc.
Washington, DC

Jeff Jones, M.D., M.P.H.
Director, Disease Control and Epidemiology
Communicable Disease Division
South Carolina Department of Health
Columbia, SC

George Lemp, Ph.D., M.P.H.
Chief, AIDS Surveillance Branch
San Francisco Department of Public Health
San Francisco, CA

Jeff Levi, M.A.
Director of Government Affairs
AIDS Action Council
Washington, DC

Carol Levine, M.A.
Executive Director
The Orphan Project: The HIV Epidemic and New York City's Children
Fund for the City of New York
New York, NY

Theresa M. McGovern, J.D.
Project Director, MFY Legal Services, Inc.
New York, NY

Janet Mitchell, M.D., M.P.H.
Chief of Perinatology
Harlem Hospital Center
New York, NY

Alfred J. Saah, M.D., M.P.H.
Director, Infectious Disease Program
School of Hygiene and Public Health
Johns Hopkins University
Baltimore, MD

Rand Stoneburner, M.D., M.P.H.
Surveillance Officer
Global Programme on AIDS
World Health Organization
Geneva
Switzerland

Pauline Thomas, M.D.
Director, Office of AIDS/HIV Surveillance
New York City Department of Health
New York, NY

Sten Vermund, M.D., Ph.D.
Chief, Epidemiology Branch
Clinical Research Program
Division of AIDS
National Institute of Allergy and Infectious Diseases
National Institute of Health
Bethesda, MD

THE CDC'S CASE DEFINITION OF AIDS: IMPLICATIONS OF THE PROPOSED REVISIONS

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Executive Summary

The surveillance case definition for acquired immunodeficiency syndrome (AIDS) developed by the Centers for Disease Control (CDC) in the U.S. Department of Health and Human Services (DHHS) is the primary public health surveillance tool for determining the scope of the AIDS epidemic. The CDC's case definition of AIDS in use as of April 1992 was developed in 1987. This complex case definition specifies 23 AIDS-defining conditions that are strongly associated with severe immune deficiency caused by the human immunodeficiency virus (HIV). In addition to being used for surveillance, the CDC's case definition of AIDS has been used as a clinical definition by physicians, in research protocols, in the allocation of Federal funds under the Ryan White Comprehensive Resources Emergency Act of 1990, and as a measure of disability in benefit programs administered by the Social Security Administration within the DHHS.

The CDC's existing case definition of AIDS has been criticized because some of the severe manifestations of HIV infection found in women and injection drug users are not encompassed by the current case definition, and therefore, the impact of the epidemic in these populations may be underestimated. This is of particular concern because a disproportionate number of HIV-infected women and injection drug users are African Americans or Hispanics.[1,2] In particular, several small studies and case reports have

1 These groups are not mutually exclusive. The majority of HIV-infected women are injection drug users or the sexual partners of injection drug users.

2 Some estimates of the number of HIV-infected persons by race/ethnicity, sex, and exposure category are extrapolated from the reported number of AIDS cases in these groups; but other corroborating methods are also used (122).

found that gynecological conditions--cervical dysplasia, pelvic inflammatory disease, and recurrent vulvovaginal candidiasis--occur more commonly in HIV-infected women than in other women. There is also evidence that HIV-infected injection drug users are more likely to have pulmonary tuberculosis, endocarditis, sepsis, and bacterial pneumonias.

A controversy has also arisen over the use of the CDC surveillance case definition of AIDS as a disability definition by the Social Security Administration, a purpose that the case definition was not intended to serve. The concern was that some HIV-infected women and injection drug users were being denied disability benefits because their illnesses were not included in the AIDS case definition.

This OTA background paper is one in a series of papers on issues relating to HIV and AIDS that OTA has published since 1987, under a general authority from the OTA's Technology Assessment Board. This particular paper was requested by the Subcommittee on Human Resources and Intergovernmental Relations, House Committee on Government Operations.

OTA was asked to examine the CDC's 1987 surveillance definition of AIDS in light of the criticisms discussed above. In the fall of 1991, however, the CDC proposed *to* change its AIDS case definition and this paper focuses on *the* proposed definition. The remainder of this chapter provides a summary of the main findings of this report. Chapter 2 discusses the purpose of the CDC definition of AIDS and describes how the definition has changed over the course of the AIDS epidemic. It also examines the proposed change in the definition of AIDS, including the major criticisms of the proposed definition. Finally, it examines issues surrounding the implementation of the new

definition, including its impact on AIDS surveillance, the States, allocation of Federal resources, and individual privacy rights. Chapter 3 examines the controversy over the use of the CDC definition in Social Security disability determinations and recent changes in the Social Security disability process for HIV-infected persons.

SUMMARY OF THE FINDINGS

In November 1991, the CDC proposed to expand its AIDS case definition. Under the new definition, a person has AIDS if: 1) he or she has one of the 23 AIDS-defining conditions included in the 1987 definition of AIDS, or 2) he or she is HIV-positive and his or her $CD4^+$ lymphocyte count is below 200 cells per cubic millimeter ($/mm^3$) of blood. The CDC plans to implement the new case definition in 1992, but has not set a specific date for implementation. According to the CDC, there are several objectives for these changes in the case definition of AIDS: to more accurately reflect the number of persons with severe HIV-related immunosuppression; to simplify the AIDS case reporting process, in part by making the AIDS case definition consistent with standards of medical care for HIV-infected persons; and to make possible laboratory-based reporting of AIDS cases, which will help State and local health departments to more efficiently identify persons who are likely to have AIDS.

Several critics of the CDC's current case definition of AIDS have argued that the definition should be expanded to include HIV-associated conditions that commonly occur in women and injection drug users because these conditions are associated with profound immunosuppression and poor prognosis. In addition, critics argue that, unless these conditions are included in the AIDS case definition, physicians may not consider the possibility of HIV infection

in patients presenting with these conditions, or physicians may fail to look for some of these HIV-associated conditions in patients that are known to be HIV infected. Other observers argue that physicians should have a much broader view of severe manifestations of HIV infection than is appropriate for inclusion in an AIDS case definition designed for survillance purposes.

The CDC has opposed adding new HIV-related conditions to the AIDS case definition for several reasons. One is that doing so will add to the complexity of that definition, and this complexity will present an obstacle to reporting. The CDC has also opposed adding any infections and cancers to the AIDS case definition that do not appear to be specific for HIV infection or whose relationship to HIV infection is not adequately established. The current CDC AIDS case definition only includes opportunistic infections and cancers that rarely occur in persons whose immune systems are not compromised. The CDC believes that a profoundly depressed $CD4^+$ lymphocyte count in an HIV-positive patient is more specific for HIV-induced immunosuppression than are non-opportunistic infections and cancers. Finally, the CDC believes that the $CD4^+$ lymphocyte count cutoff is a more objective marker of HIV-induced immunosuppression than is the diagnosis of certain non-opportunistic illnesses, such as pelvic inflammatory disease. The CDC also argues that many of the concerns about the proposed definition would conceptually apply to alternative approaches to expanding the AIDS case definition, such as adding more diseases to the list of AIDS-defining conditions.

There is a considerable amount of variability in $CD4^+$ lymphocyte counts, although the amount of variability is within the range of other commonly used diagnostic tests. Moreover, the accuracy of $CD4^+$ tests is less important when interpreting population-based survillance data than for clinical care of individual patients.

The Impact of the New CDC Definition on AIDS Surveillance

In the long term, the increased efficiency of laboratory-based reporting of AIDS cases may enable some State and local health departments to save money in AIDS surveillance. Health departments, however, will need additional money to handle the initially larger AIDS case load, to establish new systems to more efficiently identify cases, and to provide $CD4^+$ lymphocyte testing to uninsured individuals who cannot afford it. According to the CDC, a typical $CD4^+$ lymphocyte test costs about $50 plus personnel costs to perform, and the average charge to the patient is $150.00 per test. The CDC's appropriations for 1993 do not provide additional funds for $CD4^+$ lymphocyte testing; however, the CDC will allow States to use money allocated for HIV testing and counseling to fund $CD4^+$ lymphocyte testing.

In the first years after implementation of the proposed case definition of AIDS, epidemiologists anticipate that the CDC will lose its ability to follow trends in the incidence[3] of AIDS. Once all prevalent[4] cases (i.e., those persons who currently have a $CD4^+$ lymphocyte count below 200 cells/mm^3 but who do not meet the 1987 AIDS case definition) are reported, the CDC will regain its ability to monitor the incidence of AIDS. The CDC, however, will have more difficulty using AIDS case reports to track changes in the incidence of each of the 23 AIDS-defining conditions included in the 1987 definition of

3 Incidence is defined as the frequency of new occurrences of disease within a defined time internal.

4 Prevalence is the number of cases of disease present at a particular time and in relation to the size of the population. A prevalent case of a disease is a single case that exists at a particular time.

AIDS because many AIDS cases are likely to be reported on the basis of a positive HIV antibody test and a low $CD4^+$ lymphocyte count. The CDC may, however, be able to track these changes by having selected centers report on the incidence of AIDS-defining conditions as well as on the incidence of AIDS.

Although the proposed definition will increase the number of reported AIDS cases, the completeness of reporting will be difficult to assess, making interpretation of trends difficult. HIV-infected individuals with $CD4^+$ lymphocyte counts below 200 cells/mm^3 may not be counted as AIDS cases because they are either symptom free and do not seek health care, or they are symptomatic but they do not yet know they are infected with HIV. Availability of $CD4^+$ lymphocyte testing will also influence the accuracy of AIDS surveillance. Lack of access to $CD4^+$ lymphocyte testing would blunt the surge of new cases that would otherwise be anticipated under the proposed definition. In particular, poorer women and injection drug users, who generally have sporadic access to care, may have less access to $CD4^+$ lymphocyte testing. Populations of HIV-infected individuals with better access to $CD4^+$ lymphocyte testing will have proportionately greater increases in AIDS cases, and a distortion in the contribution of various risk groups to the pattern of the epidemic could result.

Estimates of the increase in the number of AIDS cases that will result from the change in the definition vary among jurisdictions. The CDC estimates that the proposed expansion in the AIDS case definition will result in a 52 percent increase in the total number of living AIDS cases in the United States, with an increase in the proportion of AIDS cases reported among women and injection drug users. Other States estimate that the increase in the number of prevalent AIDS cases will be in the range from 36 to 135 percent.

Federal Funding Allocations and the New Definition

The proposed change in the definition of AIDS will affect the distribution of funds under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (henceforth referred to as the Ryan White Act). Title I of the Ryan White Act provides Federal money to metropolitan areas for ambulatory medical and support services for low-income individuals infected with HIV. In order to receive Title I funding, a metropolitan area must have at least 2,000 cases of AIDS documented with the CDC (or a per capita cumulative AIDS incidence rate of 0.0025). With an increase in the number of AIDS cases under the proposed definition, more cities will become eligible for funds distributed under Title I. Appropriations under Title I may therefore need to increase if the current level of funding for each metropolitan area is to be maintained. In addition, some deserving metropolitan areas may not receive Title "I funds because they are not adequately prepared to identify AIDS cases under the new definition.

Title II authorizes the distribution of Federal funds to States and territories for health care and support services for poor HIV-infected individuals. The funds are distributed among States and territories based on the number of AIDS cases in each State (or territory) as a proportion of the number of AIDS cases reported in the entire United States. Although in theory the proposed change in the CDC's case definition of AIDS should not significantly influence the distribution of Title II funds among States (one would expect the number of AIDS cases in each State to increase by the same amount), in practice, the distribution of funds may not be proportional to the actual needs of each State if some States are much better able than others to identify AIDS cases. Approximately 50 percent of Title I funds are also

distributed by a similar formula and therefore metropolitan areas that are better able to identify AIDS cases may receive proportionately more Title I funds.

Privacy Issues and the New Definition of AIDS

The proposed change in the AIDS case definition raises privacy concerns because there will be an increased number of persons with AIDS reported by name to the State and local health departments. State and local health departments report information on AIDS cases, absent the individuals' names, to the CDC. Advocates are concerned that the States may not be adequately prepared for the increase in reported AIDS cases, and that inadvertent breaches of confidentiality are more likely to result. Although all States take measures to protect the confidentiality of the names of AIDS patients, and to date no unauthorized disclosure has taken place, the risk of unauthorized disclosure exists. In addition, most State laws authorize disclosure of an individual's HIV status to third parties who have, or may have been, exposed to the blood of HIV-infected persons (e.g., health care workers, emergency care providers, funeral directors, sexual assault victims, laboratory workers, and even schools). Advocates are concerned that States may expand the number of situations in which disclosure of an individual's HIV status is permissible in order to stem further transmission of the virus. With the expansion of the AIDS case definition, more HIV-infected persons will face this potential threat to confidentiality because more HIV-infected persons will be reported as AIDS cases to the State and local health departments.

On the other hand, any expansion of the CDC definition of AIDS would result in more names being reported to State health departments. In addition, as more States require name reporting of HIV-infection, more HIV-infected persons will have their names reported to the State and local health departments even before they develop AIDS.

With the change in the CDC definition of AIDS, laboratories that perform $CD4^+$ lymphocyte tests will become involved in AIDS case reporting, and thus there is an additional point at which confidentiality may be breached. Again, there is no evidence that laboratories cannot adequately maintain the confidentiality of $CD4^+$ lymphocyte test results; however, in planning to implement the new AIDS definition, State and local public health departments and clinical laboratories should reassess current laws and operational procedures that protect the confidentiality of $CD4^+$ lymphocyte test results.

Some advocates have suggested that special informed consent and counseling requirements should accompany $CD4^+$ lymphocyte testing, as is done for HIV antibody testing, but this counseling need not be of the same nature as the counseling that accompanies HIV tests. In addition, it has been suggested that anonymous $CD4^+$ lymphocyte testing should be made available so that people won't avoid seeking early medical treatment because of concerns about confidentiality. Nevertheless, people who know they are HIV positive have an incentive to seek medical treatment that may outweigh their fears about breach of confidentiality.

Social Security Disability Determinations and the CDC Definition of AIDS

The public debate over whether the CDC definition of AIDS adequately includes severe manifestations of HIV infection in injection drug users and women arose in large part because the Social Security Administration used the CDC definition of AIDS in evaluating disability under the Social Security Disability Insurance (DI) program and the Supplemental Security Income (SSI) program.

SSA regulations set forth a five-step process that is used by the SSA disability adjudicators to determine disability for SSI or DI. The first two steps are to determine (1) that the claimant is not working, and (2) that the claimant has a disabling condition that significantly limits the ability to work. The third step is to see if the claimant's condition is included in, or is equal in severity to, one of the medical conditions included in the SSA's "Listing of Impairments;" a list of medical impairments that the SSA has designated as so severe as to entitle that person to disability benefits. If the claimant's medical condition meets or equals, in terms of severity, one of the medical impairments from the "Listing of Impairments," the claimant is said to have met a Listing and is awarded disability. Claimants who do not have a listed impairment must demonstrate that they are unable to perform their previous job (step 4) or any other job in the national economy (step 5) (see app. G).

Since 1983, the SSA has treated AIDS, as defined by the CDC, as a Listing, and persons with CDC-defined AIDS were almost always awarded disability. Advocates claimed that SSA adjudicators denied disability benefits to other seriously ill HIV-infected claimants because their HIV-associated conditions were not included in the AIDS case definition. The

advocates argued that the SSA's disability adjudicators did not adequately evaluate the disabling effect of other HIV-associated conditions because they assumed that only persons with AIDS are disabled. The SSA strongly denied this was the case and the SSA's written instructions demonstrate their policies did not preclude other HIV-infected claimants from being awarded disability. In addition, their statistics show some HIV-infected persons who did not have AIDS were awarded disability. Nonetheless, a number of seriously ill HIV-infected claimants were denied disability and the reasons for these denials are not clear.

In December, 1991, the SSA published a ruling and proposed regulations that create a Listing for HIV infection (hereinafter 'HIV Infection Listing") . This new criteria for evaluating disability in persons with HIV infection changes the focus of the debate. First, the SSA will no longer tie its disability determinations to the CDC's definition of AIDS, and therefore the expansion of the CDC's definition of AIDS will not enable more HIV-infected persons to obtain disability. Second, the new disability criteria include a number of HIV-associated conditions that advocates previously claimed the SSA did not adequately consider in its disability determinations for HIV-infected women and injection drug users.

The "HIV Infection Listing" incorporates all of the conditions included in the 1987 CDC definition of AIDS as well as other non-AIDS-defining diseases and symptoms, including pulmonary tuberculosis, endocarditis, bacterial pneumonia, bacterial or fungal sepsis, and vulvovaginal candidiasis. However, the "HIV Infection Listing" also requires that, in combination with many of these HIV-related conditions, the claimant demonstrate marked functional limitations in performing activities of daily living and/or work-related activities.

The functional limitation test for the “HIV Infection Listing” was derived from a functional limitation test used by the SSA in evaluating the severity of mental disorders, and it is unclear whether this functional limitation test is appropriate for evaluating the medical disabilities of HIV-infected persons. Moreover, a number of advocates have questioned the need to demonstrate marked functional limitations in two separate areas given that HIV-infected persons have already demonstrated that they have severe HIV-related medical conditions. Documenting functional limitations to the degree required under the new ‘HIV Infection Listing” may be especially difficult for poor claimants because they often do not have access to a regular physician who can document the existence of their functional limitations based upon their treatment history.

It is too early to evaluate what impact the new “HIV Infection Listing” will have on disability determinations, and the final regulations will not be issued until the SSA reviews the approximately 3000 comments it has received. The SSA does not expect the new Listing will result in an increase in the overall number of persons awarded disability, but does believe it will shorten the time between filing an application for benefits and the receipt of those benefits. The new “HIV Infection Listing” does, however, separate the debate over the proper disability definition for HIV-infected persons from the debate over the AIDS case definition, which is a surveillance definition.

Chapter II

The CDC AIDS Definition: Implications of the $CD4^+$ Lymphocyte Count

INTRODUCTION

The surveillance case definition of acquired immunodeficiency syndrome (AIDS) developed by the Centers for Disease Control (CDC) in the U.S. Department of Health and Human Services (DHHS) is the primary public health surveillance tool for determining the scope of the AIDS epidemic (8). In all 50 States, the District of Columbia, Puerto Rico, and other territories, physicians and medical institutions are required to send information on new AIDS cases, including the names of persons with AIDS, to State or local health departments. The States then send information about each AIDS case to the CDC, absent the name of the individual, which is only retained by State or local health departments (34). The CDC uses this information to monitor trends in the number and distribution of AIDS cases and in the scope of severe morbidity due to infection with the AIDS virus, human immunodeficiency virus (HIV).

The CDC's case definition of AIDS in use as of April 1992 was developed in 1987 (208) (see app. B). This complex case definition specifies 23 AIDS-defining conditions, including *Pneumocystis carinii* pneumonia, Kaposi's sarcoma, esophageal candidiasis, toxoplasmosis of the brain, and HIV wasting syndrome. The AIDS-defining conditions are distinguishable from other HIV-associated illness because they are strongly associated with severe immunodeficiency, occur frequently in HIV-infected individuals and rarely in uninfected individuals, and cause serious illness or death. A person who has

any one of these AIDS-defining conditions and who meets other condition-specific criteria (e.g. , an age requirement, in some cases a requirement for a positive HIV test) is considered to have AIDS.

For some time now, the CDC's existing case definition of AIDS has been attacked by advocates and others (1,2,243). One of the criticisms has been that some of the severe manifestations of HIV infection in women and injection drug users are not encompassed by the current case definition. The critics claim that the 23 AIDS-defining conditions in the existing case definition are, for the most part, severe manifestations of HIV infection found most commonly in HIV-infected white men who have sex with men.[1] As a consequence, critics charge, the CDC's current case definition of AIDS probably leads to undercounting of AIDS-related morbidity among the growing population of HIV-infected women and injection drug users. This is of particular concern because most HIV-infected women and injection drug users are African Americans or Hispanics (223) .[2,3]

In November 1991, the CDC proposed to expand the surveillance case definition of AIDS to include as AIDS cases all HIV-positive persons with $CD4^+$ lymphocyte counts below 200 cells per cubic millimeter ($/mm^3$) of blood,

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1 These critics allow, however, that these AIDS-defining conditions are not limited in occurrence to white men who have sex with men; the AIDS-defining conditions occur in all groups of HIV-infected persons with late-stage HIV infection. They argue that in addition to the AIDS-indicator conditions, a broader spectrum of illness occurs, and the pattern of both AIDS-defining conditions and these other illnesses varies among different groups.

2 These groups are not mutually exclusive. The majority of HIV-infected women are injection drug users or the sexual partners of injection drug users (223).

3 Some estimates of the number of HIV-infected persons by race/ethnicity, sex, and exposure category are extrapolated from the reported number of AIDS cases in these groups; but other corroborating methods are also used (122).

regardless of whether they have any AIDS-defining conditions (219).[4] The CDC believes this revised AIDS case definition will more accurately and completely measure the extent of severe immunosuppression in the HIV-infected population. Moreover, the CDC believes this proposed revision to the AIDS case definition will more adequately capture severe HIV-induced immunosuppression in women and injection drug users than would addition of more HIV-associated conditions to the definition.

This chapter provides a history of the CDC definition of AIDS and describes the ways in which the definition has been used. It also examines the arguments for and against the CDC's proposed revision of the AIDS definition, focusing on the impact of the revision on AIDS surveillance and clinical care. Finally, this chapter evaluates the impact of the change in the definition on Federal funding for AIDS care -and services and the privacy implications of the change.

THE CASE DEFINITION OF AIDS: PURPOSE, HISTORY, AND PROPOSED CHANGES

In 1982, soon after the first cases of what is now known as AIDS were identified, the CDC developed a case definition to be used for AIDS surveillance (201). Based largely on illnesses noted in men who have sex with men,[5] the AIDS case definition included reliably diagnosed "opportunistic" diseases that are at least moderately indicative of an underlying defect in cell-mediated immunity in the absence of known causes of immune defects. The

4 A low $CD4^+$ lymphocyte count in an HIV-infected person is a sign of severe HIV-related immunodeficiency.

5 Over 90 percent of the first 159 cases that were documented by 1982 were found in men who had sex with men (119),

case definition of AIDS was revised in 1985 with the discovery of HIV as the etiologic agent of AIDS (203). It was revised again in 1987, as clinicians gained experience with opportunistic diseases associated with the end stages of HIV infection (208). The 1987 expansion resulted in proportionately more HIV-infected injection drug users, women, and minorities being diagnosed with AIDS (156,211).[6] As mentioned above, the 1987 definition, which is still in use, includes 23 AIDS-defining conditions; a person who has any of these 23 conditions and who meets other condition-specific criteria is considered to have AIDS.

The CDC's definition of AIDS has been used as a surveillance definition to monitor trends in the incidence and prevalence of AIDS over time, to characterize persons with end stage HIV disease, to identify risk factors and modes of transmission, and to predict the future course and impact of the AIDS epidemic (8). In addition to being used for surveillance, the CDC's case definition of AIDS has been used for other purposes. Specifically, it has been used as:

- a clinical definition by physicians,
- a definition for research, and
- a measure of disability in benefits and entitlement programs.

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6 A large part of the rationale underlying the 1987 definition was recognition of the pattern of care and types of illnesses seen in the increasingly diverse population of persons with HIV-associated conditions, particularly injection drug users (15). The 1987 definition allowed practitioners to make diagnoses of some AIDS-defining conditions presumptively (i.e. , on the basis of clinically observed signs and symptoms) rather than definitively (i.e. , with confirmation of the diagnosis by a laboratory test). One rationale for including presumptive diagnoses of certain conditions was to accommodate the practices of overburdened public hospitals, where the pressures of providing care to large numbers of patients precluded consistent use of definitive diagnostic tests. It also accommodated situations where the urgency of the patient's critical condition requires presumptive diagnosis and empirical treatment.

In addition, AIDS surveillance data have been used to allocate Federal resources for HIV-related care and services among the States and metropolitan areas (40,58,185).

Some physicians have used the CDC's case definition of AIDS as a *clinical definition.* It is argued that, particularly for those physicians with relatively little experience treating patients with symptomatic HIV infection, the AIDS case definition directs the physician to consider the possibility of HIV infection in individuals with conditions included in the AIDS case definition (72). It is not known, however, to what extent the AIDS case definition guides clinical care (i.e., whether physicians who treat HIV-infected patients focus only on identifying those manifestations of HIV infection that are included in the AIDS case definition). It is also not known to what extent physicians suspect HIV infection in patients who display HIV-associated conditions that are not included in the AIDS case definition. For some other diseases, such as Lyme disease or toxic shock syndrome, clinicians use-a broader definition in clinical practice than is used by the CDC for surveillance purposes (37).

The CDC's AIDS case definition has been used as a *research definition.* Some researchers have used CDC-defined AIDS as the outcome that is measured.[7] In some instances, the use of this outcome is appropriate, such as when a researcher wishes to measure the occurrence of late-stage HIV infection (68). In other instances, the use of other outcomes is appropriate. In one analysis of data from the Multicenter AIDS Cohort Study (MACS), for example, the

7 Researchers can select outcome variables depending on the clinical parameters they are measuring (231).

endpoints included both clinical symptomatology and $CD4^+$ lymphocyte counts (129). These endpoints were more appropriate because the current AIDS case definition does not accommodate the immunological component of the disease.[8]

The AIDS case definition has been used by the Health Resources Services Administration (HRSA) of the DHHS in *allocating benefits and resources* under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (Public Law 101-381). As discussed later in this paper, the distribution of Federal funds under three of the four titles of this act is tied to the number of reported AIDS cases in metropolitan areas and the States. Finally, the AIDS case definition has also been used by the Federal government in *determining eligibility for entitlement programs.* Perhaps, most notably, the AIDS case definition has been used in determining eligibility for Federal disability programs administered by the Social Security Administration (SSA) within the DHHS. Such programs include the Social Security Disability Insurance (DI) program and the Supplemental Security Income (SSI) program.

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8 Certain research protocols exclude participants who do not have CDC-defined AIDS, and critics have argued that this practice may cause underrepresentation of women and injection drug users in research protocols (13). Furthermore, some have argued that much of HIV research has focused on AIDS itself--opportunistic infections and cancers included in the **CDC's** current case definition, as well as on viral replication--and less emphasis has been placed on manifestations of HIV infection other than AIDS-defining conditions (100). It is important to note, however, that several factors other than the **CDC's** definition of AIDS may lead to the exclusion of injection drug users and women from research protocols (101,114). The failure to include these groups in clinical research protocols may be more related to lack of access to health care, and to the concerns of pharmaceutical manufacturers and researchers about liability with respect to women of reproductive age (116).

The Proposed AIDS Case Definition

In November of 1991, the CDC announced a proposal to expand its AIDS case definition (219) . HIV-infected persons diagnosed with any one of the 23 AIDS-defining conditions in the 1987 AIDS case definition will continue to be considered to have AIDS. In addition, the new definition will include all HIV-positive persons with $CD4^+$ lymphocyte counts below 200 cells/mm^3 (see app. B).[9] $CD4^+$ lymphocytes are the primary target cell for HIV, and $CD4^+$ lymphocyte counts are a recognized marker of the progression of HIV-related immunosuppression. The CDC plans to implement the new case definition in 1992, but has not set a specific date for implementation.

According to the CDC, there are several objectives for this change in the case definition of AIDS. One objective is to make the AIDS case definition consistent with standards of medical care for HIV-infected persons (39,219). Monitoring $CD4^+$ lymphocyte counts in HIV-infected patients has become a standard of clinical care,[10] and the proposed expansion of the AIDS case definition is based on this recognized clinical standard.

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9 The CDC's case definition of AIDS allows for the use of the $CD4^+$ percent of lymphocytes when the $CD4^+$ lymphocyte count cannot be obtained (219). HIV-infected persons with a $CD4^+$ lymphocyte percent below 14 will meet the proposed AIDS case definition.

10 $CD4^+$ lymphocyte counts are used to guide the initiation of antiretroviral therapy (224) and prophylaxis against *Pneumocystis carinii* pneumonia (210). Antiretroviral therapy is currently recommended for all persons with $CD4^+$ lymphocyte counts below 500 cells/mm^3 (224), and prophylaxis of *Pneumocystis carinii* pneumonia, the most common initial AIDS-defining condition, is recommended for all persons with $CD4^+$ lymphocyte counts below 200 cells/mm^3 (210).

Another objective of the new AIDS case definition is to simplify the AIDS reporting process (219). The CDC believes it will be both practical and simple for physicians to use $CD4^+$ lymphocyte counts in AIDS case reporting because monitoring $CD4^+$ lymphocyte counts in HIV-infected persons has become standard clinical care.[11]

The new AIDS case definition may also make it easier for State and local health departments to identify persons who are likely to have AIDS but who have not been reported (56).[12] The proposed AIDS definition, by incorporating a laboratory marker of immune suppression into the definition, makes possible laboratory based reporting of AIDS cases. Once a laboratory identifies a patient with a $CD4^+$ count below 200 cells/mm^3, the laboratory can report the name of the person and the test result to the State or local health department. The health department can then prompt the physician who ordered the test to report the patient to the health department if the patient meets the criteria for an AIDS diagnosis.

Another objective of these changes in the AIDS case definition is to more accurately record the number of persons with severe HIV-related immunosuppression (219).[13] Numerous conditions other than the 23 included in

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11 A simplified AIDS case definition is particularly important as a greater proportion of AIDS patients is reported from outpatient clinics, which have had less experience with AIDS case reporting (219).

12 Currently in each State, health departments have identified unreported AIDS cases through reviews of hospital records, outpatient records, and death certificates. Each of these mechanisms to "capture" additional AIDS cases requires a substantial commitment of State health department staff time (56).

13 Epidemiologists' ability to track trends in HIV infection and AIDS may have been compromised by recent advances in therapy (60,142). There is evidence that AIDS-defining conditions have appeared later in the course of HIV infection because of the use of prophylaxis for *Pneumocystis carinii* pneumonia and antiretroviral therapy (234), and the appearance of AIDS-defining conditions have therefore become a less reliable measure of severe immune suppression in HIV-infected persons.

the CDC's 1987 case definition of AIDS are diagnosed in HIV-infected persons (15). These conditions, which are also diagnosed in persons with normal immune function, tend to increase in frequency and severity among persons who are immunosuppressed. Under the CDC's proposed definition of AIDS, persons who are severe HIV-related immunosuppressed, as determined by measurement of $CD4^+$ lymphocyte counts, will be considered to have AIDS (219).

CDC's Decision Not to Increase the Number of AIDS-Defining Conditions

As mentioned earlier, the CDC's 1987 AIDS case definition currently in use has been criticized by individuals who claim that a significant proportion of HIV-infected persons have severe manifestations of HIV infection that are not included in the current AIDS case definition (1,2,243) . Excluded, in particular, critics argue, are some manifestations of HIV infection that occur in women and injection drug users. An increasing number of AIDS cases in the United States are occurring among women and injection drug users. The CDC reports that, through February of 1992, injection drug users accounted for 29 percent of all AIDS cases in the United States (223). Women accounted for 10.5 percent of AIDS cases reported through February 1992 (223). Approximately 50 percent of women with AIDS are injection drug users (223) . (See app. D.) Among men who have sex with men (excluding those who use injection drugs), the rate of increase in the number of AIDS cases began to decline in 1987; however, the rate of increase in the number of AIDS cases associated with injection drug use and heterosexual transmission has continued to rise. The rate of increase in the number of reported AIDS cases in women now exceeds that in men (124).

Many illnesses occur more frequently in HIV-infected persons compared to persons with normal immune function (15). At issue is whether all or some subset of conditions that are worse or more common in the presence of HIV

infection should be included in the AIDS case definition. Some observers have noted that several gynecological conditions--cervical dysplasia (23,52,74,81,96,103,104, 155,171,180,214,233) , pelvic inflammatory disease (75,148,155), and chronic and recurrent vulvovaginal candidiasis (26,27,82,140)--occur more commonly in HIV-infected women than in other women. Substantial evidence shows that HIV-infected women have an increased incidence of abnormal pap tests and cervical dysplasia (abnormal cells in the epitheliums of the cervix, thought to sometimes progress to cervical cancer) (52,104,133,151,233). There are also several cases where cervical cancer in HIV-infected women proceeded more rapidly than usual and where HIV-infected women were diagnosed with advanced disease (103). However, there are only 15 reported cases in the literature of cervical cancer in HIV-infected women (244).[14] Given the long incubation time of cervical cancer and the short survival time after reaching a $CD4^+$ lymphocyte count of 200 cells/mm^3, it is not surprising that an epidemic of cervical cancer among HIV-infected women has not developed or been documented (232). At present, an association between HIV infection and invasive cervical cancer has not been established (37,134,214).

Several reports provide evidence that pelvic inflammatory disease in women immunosuppressed by HIV infection is more likely to be chronic, recurrent, and more severe than pelvic inflammatory disease in women with normal immune function (75,148). The studies that have been done involve limited numbers of patients, and the results may not be applicable to other populations (114).[15]

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14 Also, there has been no increase in cervical cancer rates in States with the highest prevalence of HIV infection in women (135,214).

15 In addition, the diagnosis of pelvic inflammatory disease is often made imprecisely to explain pelvic pain or tenderness. This may lead to overdiagnosis of this condition (15).

There is some evidence that vaginal candidiasis (yeast infection of the vagina) is more common in HIV-infected women than in women without HIV infection (26,82,140). Although women not infected with HIV frequently contract vaginal candidiasis, studies suggest that the symptoms are often more severe in HIV-infected women. Vaginal candidiasis in an HIV-infected woman is not life-threatening, can occur in women with normal immune function or moderate degrees of immune dysfunction, and is usually well controlled with fungicides. In these respects, it differs from esophageal candidiasis, an AIDS-defining condition, which occurs in profoundly immunocompromised patients and is associated with a poor prognosis.

These conditions--cervical dysplasia, cervical cancer, pelvic inflammatory disease, and vaginal candidiasis--occur in women with normal immune function with and without HIV infection; hence, these conditions are not specific to HIV infection (114). By contrast, AIDS-defining conditions rarely occur among those who are not HIV-infected, except among persons who are severely immunocompromised for other reasons.

Several observers have noted that HIV-infected injection drug users, in addition to having AIDS-defining conditions, are more likely to have certain manifestations of HIV infection than men who have sex with men or those in other risk groups (159,160,174,209). In recent years, there has been an increase in the incidence of certain infections among injection drug users that has occurred coincident with the increased prevalence of HIV infection and AIDS (43,158,159,160,174, 209).[16] These infections include pulmonary

16 Much of these data, however, were collected prior to implementation of the 1987 expanded AIDS case definition (176). In New York City, the Department of Health is investigating whether many of the injection drug users who failed to meet the pre-1987 AIDS case definition would be counted with the 1987 AIDS case definition (181).

tuberculosis (33,79,130,131,179,204, 206,207), endocarditis (inflammatory alterations of lining of the heart cavities) (117), sepsis (the presence in the blood of pathogenic micro-organisms or their toxins) (105), and bacterial pneumonias (177). It is argued that this increase in infections among injection drug users is a consequence of the HIV epidemical'

Pneumonia, sepsis, endocarditis, and pulmonary tuberculosis occur more commonly in HIV-infected injection drug users than in injection drug users who are not infected with HIV. Although one would expect these nonopportunistic illnesses to occur more frequently in immunosuppressed persons and follow a more severe course, these clinical conditions have a much less specific relationship to profound immunosuppression caused by HIV infection than do the 23 AIDS-defining clinical conditions listed in the CDC's 1987 case definition of AIDS. Pulmonary tuberculosis, bacterial pneumonias, sepsis, and endocarditis are frequently seen among injection drug users who are not infected with HIV (67,138,178,230,239) ; hence" it is difficult to evaluate the extent to which these conditions are related to infection with HIV.

Several critics of the CDC's current case definition of AIDS have argued that the case definition should be expanded to include HIV-associated conditions that frequently occur in HIV-infected women and injection drug users because they are associated with profound immunosuppression and poor prognosis (175). In addition, they argue that physicians may overlook these HIV-associated conditions in HIV-infected patients or fail to suspect HIV infection in high-risk patients who exhibit these HIV-associated conditions

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17 Diseases such as bacterial pneumonia and sepsis are not conditions that occur exclusively in injection drug users, women, African Americans, and Hispanics. For example, Redd and colleagues documented an increase in **pneumococcal** septicemia in San Francisco, where the overwhelming majority of AIDS cases have occurred in men who have sex with men (137).

(243). (This latter argument has been made particularly with respect to gyecologic conditions, which are absent from the current AIDS case definition (72).) This argument assumes that physicians are informed by the CDC case definition. A number of observers, however, reject this assumption, arguing that physicians are educated from medical journals and other sources.[18] No study has examined the extent to which physicians' diagnostic practices are influenced by the CDC's case definition of AIDS. If the problem lies in physician education, however, then the most direct solution may be changes in physician education rather than in the CDC's case definition.

Some observers argue that clinicians should have a much broader view of severe manifestations of HIV infection than is appropriate for inclusion in an AIDS case definition designed for surveillance purposes (37,185). For a surveillance definition intended to monitor trends in the incidence and prevalence of disease, a limited definition encompassing only severe manifestations of end-stage HIV infection may be appropriate.[19] In contrast, a clinician needs to identify and treat the broad spectrum of manifestations of HIV infection, and hence a broad clinical definition is more useful.

The CDC has opposed adding conditions to the AIDS case definition for several reasons (219). One is that doing so will add to the complexity of that definition. The 1987 case, definition currently in use has 23 AIDS-

18 At an OTA workshop, several physicians argued that they were educated by medical journals and other sources (194). This, however, was not a representative sample of clinicians because physicians at the workshop were AIDS experts.

19 One expert notes that the CDC's HIV classification system (See app. E), which is being revised in parallel with the AIDS case definition, acknowledges and accounts for many of the HIV-associated conditions seen in women and injection drug users, which, although not deemed AIDS-defining, nevertheless receive recognition as serious HIV-associated illnesses (161). Clinical staging and social service disability determinations could more appropriately be linked to the HIV classification system, and not to the AIDS case definition itself.

defining conditions, each with its own set of criteria. The CDC argues that the complexity of the definition presents an obstacle to reporting, especially since clinical care and reporting have moved from inpatient settings to ambulatory settings. The CDC points out that there is a broad spectrum of conditions that can occur with increased frequency and severity in HIV-infected persons, ranging from necrologic manifestations, dermatologic manifestations, infections, and other organ system conditions (15,134,135). The CDC and other experts argue that adding such conditions would increase the complexity of the case definition.

The CDC has also opposed adding any infections and cancers to the AIDS case definition that do not appear to be specific for HIV infection or whose relationship to HIV infection is not adequately established (217). The CDC believes that a depressed $CD4^+$ lymphocyte count in an HIV-infected patient is more specific for HIV-induced immunosuppression than nonopportunistic infections and cancers (219). The CDC also believes that the $CD4^+$ lymphocyte count cutoff is a more objective marker of HIV-induced immunosuppression than nonopportunistic illnesses.[20]

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20 The CDC argues that the $CD4^+$ lymphocyte count is an objective marker of immunosuppression, whereas a clinician must use considerable subjective interpretation in determining whether clinical conditions such as recurrent vaginal candidiasis or pelvic inflammatory disease are present. Others have argued that, given the variability of the $CD4^+$ lymphocyte count, its interpretation is also subjective.

ISSUES SURROUNDING THE IMPLEMENTATION OF THE PROPOSED REVISION OF THE CDC DEFINITION OF AIDS

From an epidemiologic perspective, the $CD4^+$ lymphocyte count may appear to be a better measure of severe HIV-induced immunosuppression than the presence of nonopportunistic infections or cancers. The accuracy of AIDS surveillance will largely depend, however, upon the accuracy and accessibility of the $CD4^+$ testing. As is discussed below, there is substantial variability in $CD4^+$ testing. This variability, however, may be of more concern in clinical care than in AIDS surveillance. Accessibility of $CD4^+$ testing will depend upon the availability of test sites and the affordability of the test.

The new AIDS case definition is expected to increase the number of HIV-infected persons considered to have AIDS. This increase in the number of AIDS cases will affect allocations of Federal funds and will have implications for the privacy of the individuals with AIDS whose names will be reported to the State and local health departments. The following sections discuss these issues.

Accuracy of $CD4^+$ Testing

There is a considerable amount of variability[21] in $CD4^+$ counts, although the amount of variability seen in flow cytometry is within the range of other commonly used diagnostic tests (e.g. , serum thyroxine measurements to diagnose thyroid abnormalities, serum cholesterol measurements to diagnose hypercholesterolemia, and creatine kinase measurements to diagnose heart

21 The variability of a test refers to the accuracy and reproducibility of a test (141).

attack) (76). However, because $CD4^+$ counts require interpretation of results within a narrow range of values, variability must be more tightly controlled than with other tests where the diagnostic alternative covers a broad range of values (152).[22]

The variability in $CD4^+$ testing means that some HIV-infected individuals' $CD4^+$ test results are likely to be higher than their "true" value, and therefore these immunocompromised individuals will not be counted as AIDS cases. Conversely, some relatively immunocompetent persons will be diagnosed with AIDS because their $CD4^+$ test results are lower than the "true" value. The CDC states that the $CD4^+$ lymphocyte count that should be used for a diagnosis of AIDS should be the one that the physician considers the most accurate (219). A physician who suspects that a $CD4^+$ lymphocyte count is not accurate could validate the reading with a separate determination on a separate sample (78). The accuracy of $CD4^+$ tests is far less important in interpreting population-based surveillance data than in clinical care of individual patients (17,162).[23] Confirmatory repeat testing, therefore, is not required under the new AIDS definition for the identification of cases of AIDS for surveillance.

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22 One cannot compare the analytic variability of different tests without considering the clinical use of tests and associated diagnostic variability that can be tolerated. The amount of variability that can be tolerated for a clinical test, however, depends on the need to distinguish among diagnostic alternatives. If the diagnostic alternative covers a broad range of values (e.g., creatine **kinase**), the amount of analytic variability that can be tolerated is wide. However, if diagnostic alternatives require interpretation of results in a narrow range of values, such as with $CD4^+$ lymphocyte counts, analytic variability must be more tightly controlled (152).

23 Others believe that confirmatory repeat testing is important from an **epidemiological** standpoint (77). Populations of individuals who receive $CD4^+$ testing frequently will on average qualify as AIDS cases more rapidly than populations of individuals who are tested less frequently. Confirmatory repeat testing makes it less likely an individual who is frequently tested will qualify as an AIDS case on the basis of one spuriously low $CD4^+$ count.

Accessibility of $CD4^+$ Testing

States' capacity to perform $CD4^+$ lymphocyte testing of HIV-positive patients is related both to the availability of flow cytometry capacity (equipment and personnel) and to the costs of $CD4^+$ tests. Some critics have argued that the CDC's new AIDS case definition should not be implemented until adequate resources are available to accomplish the $CD4^+$ testing that needs to be done (99).[24]

Clinical flow cytometers cost approximately $80,000 to $100,000 each (123). Most small hospitals and clinics do not have a flow cytometer and therefore must send a patient's blood sample to a laboratory with flow cytometry equipment to obtain the $CD4^+$ percent of lymphocytes. Nearly 1,000 laboratories in the United States have capabilities to perform $CD4^+$ testing (229). According to a CDC survey, in most of these labs, flow cytometry capacity exists to perform additional tests. Although the number of flow cytometers may be sufficient for additional testing, new personnel will probably need to be trained to run the tests.[25]

The extent to which flow cytometry can be performed at central facilities is limited because $CD4^+$ lymphocyte percents are affected by the storage time and temperature of a blood sample. The CDC recommends running $CD4^+$ lymphocyte percents within 24 hours after a blood sample is collected, and recommends rejecting samples that are over 48 hours old (109).

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24 Many HIV-infected persons are either uninsured or are receiving Medicaid. See discussion in Chapter III of this report.

25 In a CDC survey of flow cytometry laboratories, most responded that it would take 6 to 24 weeks for flow cytometer operators to become proficient at performing $CD4^+$ testing (229).

As of early 1992, only six State public health departments currently have an adequate number of flow cytometers to perform the $CD4^+$ testing of HIV-positive patients that would be required under the CDC's new case definition of AIDS (9,28). In many States, however, private and university laboratories may have sufficient available flow cytometry capacity to handle most or all of a State's flow cytometry requirements, and State health departments with adequate funds could contract with these laboratories to perform $CD4^+$ testing (152). According to the CDC, a typical $CD4^+$ test costs about $50, plus personnel costs, to perform, and the average charge to the patient is $150 for a $CD4^+$ test (108,152).

AIDS Surveillance Under the New Definition

In the long term, the increased efficiency of laboratory-based reporting of AIDS may enable some State and local public health departments to save. money in prompting physicians to report AIDS cases (56).[26] Health departments, however, will continue to need money to collect risk factor information and other information on AIDS cases from physicians. Also, as the

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26 Others anticipate that costs will increase over the long term. As one epidemiologist notes, "In New York City, I believe that exactly the opposite will occur. Patients with $CD4^+$ counts of less than 200 who are reported by laboratories will need to be investigated to obtain the bulk of the AIDS case report information. With the extensive hospital contacts of our present surveillance system, this will not present a great problem for patients whose $CD4^+$ tests were requested by hospitals. However, a $CD4^+$ count of less than 200 in patients whose $CD4^+$ tests are requested by private physicians will necessitate a large number of visits or telephone calls to literally hundreds of private physicians' offices that are not currently required" (70).

change takes place, public health departments may need additional money to handle the larger AIDS caseload, to establish new systems to more efficiently identify cases, and to provide $CD4^+$ testing to uninsured individuals who cannot afford these tests (56).

The CDC has not clarified whether additional monies will be made available to manage the additional AIDS cases that are identified under its new case definition. In the past, the CDC has provided States, the District of Columbia, and U.S. territories with $15 million for AIDS surveillance (15). Under cooperative agreements with the public health departments in the States, the District of Columbia, U.S. territories, and six metropolitan areas (New York, Houston, Los Angeles, Chicago, Philadelphia, and San Francisco), the CDC supports 65 HIV testing and counseling programs (220). The CDC has revised its agreement with the States to allow them to use some of the $120 million provided under these agreements to fund $CD4^+$ testing (56).

Some States will be placed in a dilemma over whether to provide additional funds to State public health departments for AIDS surveillance. On one hand, States will need to expend additional funds to identify a larger number of AIDS cases. In addition, although the expansion of the AIDS case definition will not increase the number of persons who need care, the surveillance system may identify more immunocompromised individuals who are in need of care. States may need additional funds to provide appropriate medical care for the immunocompromised individuals who are identified through $CD4^+$ testing. On the other hand, those States that are better able to identify AIDS cases will get proportionately more Federal funds. The reason is that Federal funding is divided among States, in part, based on the number of AIDS cases identified. This point is discussed in more detail below.

Concerns About the Accuracy of AIDS Surveillance Under the New Definition

In the first years after the CDC's case definition of AIDS is changed in 1992, there is likely to be a large increase in the reported number of new AIDS cases; this increase will reflect the identification and reporting of individuals who are diagnosed with AIDS on the basis of their $CD4^+$ lymphocyte counts, but who would not have been considered AIDS cases under the 1987 definition. After the initial large increase, the reporting rate of new AIDS cases is likely to return to a rate nearer to the rate of previous years (most of the individuals who are identified as AIDS cases under the new definition on the basis of their $CD4^+$ lymphocyte counts will eventually develop AIDS-defining conditions; with the development of such conditions, they would have been identified as AIDS cases under the 1987 definition) (32).[27]

In the first years after implementation of the CDC's proposed case definition of AIDS, epidemiologists anticipate that the CDC will lose its ability to use AIDS case reports to follow trends in the incidence of AIDS (50).[28] The reporting of prevalent cases that meet the criteria for AIDS under the proposed case definition but do not meet the criteria for AIDS under the 1987 case definition will obscure changes in the incidence of AIDS. Once the prevalent cases are reported, however, the CDC will regain its ability to monitor the incidence of AIDS.

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27 As HIV-infected persons are diagnosed with AIDS earlier in the course of infection, the number of persons living with AIDS will increase with implementation of the new definition.

28 The CDC could, however, create special studies to count cases meeting the 1987 definition as a subset of all reported cases. The CDC could also monitor trends in AIDS mortality as a substitute for AIDS incidence during the transition'period.

Following the implementation of the proposed case definition of AIDS, it will be more difficult for epidemiologists to use AIDS case reports to track changes in the incidence of each of the 23 AIDS-defining conditions that are included in the 1987 definition of AIDS. The change in the definition will also make it difficult to compare AIDS surveillance data before and after the change is implemented. The CDC may possibly be able to monitor trends in the incidence of AIDS-defining conditions after the case definition is changed by having selected centers report on the incidence of AIDS-defining conditions as well as reporting new AIDS cases (182).[29]

Not all of the HIV-infected persons with $CD4^+$ lymphocyte counts below 200 cells/mm^3 are likely to be counted as AIDS cases after the new case definition is put into effect. Severely immunocompromised individuals who are aware that they are HIV-infected and who receive $CD4^+$ testing will be counted as AIDS cases. But other HIV-infected individuals with $CD4^+$ counts below 200 cells/mm^3 may not be counted because they are either symptom free and do not seek health care, or because they are symptomatic but their symptoms are not recognized as HIV-related.

Although the proposed definition will increase the number of reported AIDS cases, the completeness of reporting will be difficult to assess (47,50). The completeness of reporting under the proposed system will depend on diagnosis of HIV infection and regular monitoring of $CD4^+$ lymphocyte counts. In contrast, completeness of reporting can more readily be assessed with the 1987 AIDS case definition. This is because almost all patients who develop an

29 In fiscal year 1991, the CDC awarded funds to five areas to test simplified methods of AIDS surveillance. In anticipation of implementation of the revised definition of AIDS; the CDC is planning to shift the focus of this project to the type of evaluation described here (15).

AIDS-defining condition seek medical care. Once they enter the health care system, persons with AIDS-defining conditions may be diagnosed and reported as AIDS cases.[30]

How many AIDS cases are identified after the new case definition is implemented will depend to some extent on the availability of $CD4^+$ testing. Lack of access to $CD4^+$ testing would blunt the surge of new cases that would otherwise be anticipated under the proposed definition. The size of the surge in case reports will also be related to the capacity of health departments to implement new surveillance procedures.

Differences in access to $CD4^+$ testing may make interpretation of trends difficult (47). Populations of HIV-infected individuals with better access to $CD4^+$ testing will have proportionately greater increases in AIDS cases, and a distortion in the contribution of various risk groups to the pattern of the epidemic could result. Critics of the case definition of AIDS argue that" injection drug users and the poor are more likely to be diagnosed with AIDS based on the presence of AIDS-defining conditions rather than on the basis of low $CD4^+$ counts (243). This is because persons of lower socioeconomic status and injection drug users have access to emergency rooms and hospitals when they are acutely ill, but they have much more limited access to outpatient care (10,25,62,164). Individuals with AIDS-defining conditions are likely to be diagnosed in an emergency room or when hospitalized. $CD4^+$ testing, however, is unlikely to be performed in an emergency room because typically only the emergent problem is addressed. Although $CD4^+$ counts may be obtained

30 Not all diagnosed AIDS cases are reported. This is particularly a problem when a private practice physician is responsible for reporting because the physician may be more responsive to the patient's wishes that his or her disease not be reported (83). Also, some HIV-infected persons, particularly injection drug users, seek care late in the course of an AIDS-defining condition and die before AIDS is diagnosed (175).

on a person who is hospitalized, $CD4^+$ testing is not an indication for hospitalization. Surveillance methods, however, are available to detect and adjust for this reporting bias (15). Surveillance data may help to identify inequities in access to HIV diagnosis and treatment (e.g. , by comparing persons reported because they have a low $CD4^+$ count to those reported because they have an AIDS-indicator illness). Furthermore, under the current AIDS definition or any other surveillance system, only those persons having some interaction with the health care system (either through the emergency room, clinic, or hospital) will be detected (15).

Several States have attempted to estimate the number of AIDS cases that will result from the change in the definition, and the estimates vary among jurisdictions. The variation in estimates may reflect differences in the data upon which the estimates were calculated, differences in the assumptions used in the calculations, or both.

The CDC estimates that there will be a 52 percent increase in the total number of living AIDS cases in the United States if the proposed expanded CDC AIDS case definition is used (218).[31] For its estimate, the CDC relied on data from the Adult/Adolescent Spectrum of HIV Disease Project.[32] The project includes nine centers in the United States: Los Angeles, Denver, Atlanta, New Orleans, Houston, Dallas, Detroit, San Antonio, and Seattle. The project

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31 This estimate is based on the number of persons with $CD4^+$ lymphocyte counts less than 200 $cells/mm^3$ and the number of prevalent AIDS cases in the Adult/Adolescent Spectrum of HIV Disease Project. If the number of incident cases is used (only those AIDS cases diagnosed in a 12-month interval) then the percent increase from the Adult/Adolescent Spectrum of HIV Disease Project would be approximately 75 percent (15).

32 The CDC's Adult/Adolescent Spectrum of HIV Disease Project analyzed data from 10,342 HIV-infected men and women in nine cities across the United States. The purpose of the project is to examine the spectrum of disease associated with HIV infection in men and women (15).

includes HIV-infected patients from public and private hospitals and ambulatory care clinics (16). One observer has noted that New York City and other northeastern cities with large numbers of HIV-infected injection drug users and other HIV-infected persons with poorer access to care are not included in these studies; thus conclusions from these studies may not be generalizable to these parts of the United States (175).

South Carolina is one of two States that currently provides $CD4^+$ tests to all individuals known by the State to be HIV-positive; extrapolating from data that have been collected there, one would anticipate that the number of living AIDS cases in South Carolina will increase by approximately 80 percent after the definition of AIDS is changed (88) . Estimates of the increase in the number of living AIDS cases in San Francisco following the implementation of the new case definition of AIDS range from 92 percent to 135 percent (31,98,150,163). Estimates of the increase in the number of living AIDS cases in New York City range from 36 percent to 100 percent (70,181,182). .The Los Angeles Department of Health Services anticipates an increase in number of living AIDS cases of approximately one-third (94,118).

As discussed earlier, some people have argued that HIV-infected women and injection drug users, many of whom are African American or Hispanic, are less likely than white men who have sex with men to be identified under the CDC's proposed case definition of AIDS. It is interesting to note that among participants in the CDC's Adult/Adolescent Spectrum of HIV Disease Project, people from different sexes, races, and risk groups were all about equally likely to have received $CD4^+$ testing (218). These data have been used by the CDC to suggest that HIV-infected persons of different sexes, races, and risk groups who are aware of their HIV status and are able to receive clinical care are about equally likely to obtain $CD4^+$ lymphocyte counts. These data do not,

however, reveal whether HIV-infected women and injection drug users are as likely to obtain clinical care as are members of other HIV-infected populations. These data do suggest, however, that once HIV-infected women and injection drug users enter clinical care, they receive $CD4^+$ testing as frequently as HIV-infected individuals from other risk groups.

Data from the CDC's Adult/Adolescent Spectrum of HIV Disease Project indicate that women and injection drug users will make up a greater proportion of AIDS cases diagnosed under the proposed AIDS case definition than they do under the 1987 definition (218) . Whereas the total number of persons living with AIDS is expected to increase by 52 percent under the new AIDS case definition, the number of women living with AIDS is expected to increase by 61 percent. Data from the Adult/Adolescent Spectrum of HIV Disease Project also indicate that there will be a 55 percent increase in number of injection drug users living with AIDS under the new definition.

The CDC expects the proposed AIDS case definition to capture many of the profoundly immunosuppressed (with $CD4^+$ counts less than to 200 cells/mm^3) women and injection drug users who are suffering from HIV-associated conditions such as cervical dysplasia, pelvic inflammatory disease, chronic or recurrent vaginal candidiasis, pulmonary tuberculosis, sepsis, endocarditis, and nonopportunistic bacterial pneumonias. These conditions also occur, however, in HIV-infected persons who are relatively immunocompetent. The CDC argues that when these conditions occur in persons with lesser degrees of immunosuppression (i.e., whose $CD4^+$ lymphocyte counts equal or exceed 200 cells/mm^3), they are more likely to be merely coincidental to HIV infection (15). Therefore, the proposed AIDS case definition will capture those HIV-infected women and injection drug users whose symptoms are most likely to be related to HIV-induced immunosuppression.

Although some HIV-positive individuals with $CD4^+$ lymphocyte counts below 200 cells/mm^3 will not have any symptoms, the probability is high they will develop symptoms within 12 months (78). Data from the Multicenter AIDS Cohort Study (MACS) show that one-third of the individuals whose $CD4^+$ lymphocyte counts fell below 200 cells/mm^3 were asymptomatic (129).[33] Under the CDC's proposed AIDS case definition, asymptomatic individuals with $CD4^+$ counts below 200 cells/mm^3 will be diagnosed with AIDS, and some of these individuals may experience adverse psychological and social consequences (47,50). This is in contrast to previous definitions, which only included as cases persons who were diagnosed with AIDS-defining conditions.

The Impact on Federal Funding Allocations

In 1990, Congress passed the Ryan White Comprehensive AIDS Resources Emergency Act (Public Law 101-381) (henceforth referred to as the Ryan White Act). The Ryan White Act authorized payments of up to $1.1 billion over a 2-year period for education about HIV infection and the prevention and treatment of HIV infection. Total Ryan White Act funding for 1991 and 1992 was approximately $500 million, and the President's 1993 budget requests just over $306 million in funding for the act (57).

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33 The **MACS** primarily represents middle-class, white men who have sex with men. For the reasons discussed previously, the proportion of HIV-infected women and injection drug users who are **asymptomatic** with **$CD4^+$** counts less than 200 **cells/mm^3** is likely to be lower. Furthermore, persons in this study were **"asymptomatic"** if they did not have AIDS or one of a limited number of conditions often referred to as AIDS-related complex (which includes fatigue, fever, weight loss, persistent skin rash, oral hairy **leukoplakia**, herpes simplex, and oral thrush) (129). Hence, some persons characterized as **asymptomatic** may indeed be experiencing some HIV-related symptoms.

The Ryan White Act allocates funds under four separate titles, and for three of the titles, the numbers of reported AIDS cases are used in formulas for allocating funds among States and cities.[34] The change in the number of AIDS cases will only affect the allocation of funds under Titles I and II of the Ryan White Act, since Title III, Subpart 1, of the Ryan White Act is not currently funded. Moreover, the change will not affect funding allocations until 1994, because Ryan White funding is based upon the number of AIDS cases reported to the CDC as of March 31 in the year (or two years) prior to the fiscal year for funding.

The AIDS Housing Opportunity Act of 1990 (P.L. 101-625) also distributes funds based in part on the number of cases of CDC-defined AIDS. The act authorizes the U.S. Department of Housing and Urban Development (HUD) to distribute grants to cities and States for housing low-income persons infected with HIV. The grants are to be allocated among cities and States based on the number of AIDS cases; however, no funds have been distributed to date.

Title I Funding Allocations Under the Ryan White Act

Under Title I of the Ryan White Act, the Health Resources and Services Administration (HRSA) provides funds to metropolitan areas for ambulatory medical and support services for low-income individuals with HIV infection. In order *to* be eligible for Title I funding, a metropolitan area must have at least 2,000 cases of AIDS reported to the CDC by March 31 of the year prior to the year in which funding is appropriated, or a per capita cumulative AIDS incidence rate of 25 per 10,000 (0.0025) or greater (42 U.S.C. § 300ff-13).

34 Title IV authorizes funds for research to explore the impact and cost-effectiveness of AIDS care. Funds are to be distributed on a grant basis. However, to date, no funds have been authorized under this title (57).

Half of Title I funds are divided among eligible metropolitan areas based on the ratio of the number of AIDS cases in each metropolitan area to the total number of AIDS cases in all eligible metropolitan areas. The other half of Title I funds are distributed to metropolitan areas that demonstrate to HRSA, among other things, that they have severe need for funds and they are able to use these funds immediately and in a cost-effective manner (42 U.S.C. § 300ff-13).

In 1992, 18 metropolitan areas shared $121.8 million in Title I funds (196). In 1993, HRSA estimates that 24 metropolitan areas will qualify for Title I funds.[35] HRSA has estimated that by 1994 (the first year in which the new AIDS case definition will have an impact on the allocation of Ryan White Act funds), between 32 and 41 metropolitan areas may qualify for Title I funds (20). Because the new AIDS definition will include some people up to 2 years before their first serious opportunistic infection, the increase in the number of new AIDS cases that accompanies the change in the definition may not directly translate into a dramatic increase in health care needs. However, all HIV-infected persons with $CD4^+$ counts of 200 cells/mm^3 or less will need both antiretroviral therapy and pneumocystis prophylaxis. In addition, most of these persons with AIDS will require more comprehensive services within a year or less, which is approximately when the funding will actually be distributed to the cities. Because a larger number of metropolitan areas will be eligible for Title I funds under the proposed definition, the amount of money appropriated to Title I will need to substantially increase by 1994 to maintain the current level of funds that is provided to each metropolitan area.

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35 This estimate is based on the predicted number of AIDS cases that will be reported to the CDC as of March 31, 1992, prior to the proposed change in the CDC AIDS case definition (57).

Fifty percent of the funds under Title I are distributed through a formula grant that provides each metropolitan area with a proportion of funds based on the ratio of the number of AIDS cases in the metropolitan area (and the per capita incidence of AIDS) to the total number of AIDS cases in all eligible metropolitan areas (and total per capita incidence of AIDS). Some cities may be less able than others to identify AIDS cases because, for example, they have a disproportionate number of HIV-infected persons with no access to ambulatory services, or because the local health department may not have adequate funds to carry out a comprehensive AIDS surveillance program (19). These cities may receive proportionately less Ryan White funds than other cities that are better prepared to document the number of AIDS cases.[36]

Title II and Title III Funding Allocations Under the Ryan White Act

Title II of the Ryan White Act provides States and territories with Federal funds for health care and support services for poor HIV-infected individuals and their families (42 U.S.C. §§ 300ff-22 to 300ff-41). Each State and territory receives a proportion of these funds that is equivalent to the proportion of AIDS cases in the United States that were reported from that State or territory in the 2 years prior to the fiscal funding year. For example, if a State reported 10 percent of all AIDS cases in the Nation in those years, it would receive approximately 10 percent of the funds allocated under Title II, subject to adjustments and supplemental grants.

36 Only 50 percent of Title I funds are distributed by a formula that uses the percentage of AIDS cases. The availability of supplemental grants may limit the impact on Title I funding of disproportionate resources among metropolitan areas for AIDS surveillance.

The Ryan White Act authorized $275 million under Title II for 1991 and 1992, but Congress only appropriated $87.8 million for Title II in 1991 and $108 million in 1992 (57). Title II funds are divided over 57 States and territories, and in 1991 the majority of the funds was distributed as follows: New York and California (approximately $13 million each); Florida ($7 million); Puerto Rico ($5 million); Texas and New Jersey (approximately $4 million each); Georgia, Illinois and Pennsylvania (approximately $2 million each); District of Columbia, Louisiana, Maryland, Massachusetts, Michigan, Missouri, North Carolina, Ohio and Washington (approximately $1 million each); and Alabama, Colorado, Connecticut, Indiana, Mississippi, Oregon, South Carolina, and Tennessee (between $500,000 and 800,000 each) (197). The President's proposed budget for 1993 would maintain Title II funding at $108 million (57).

Because the amount of funds distributed under Title II of Ryan White is allocated on the basis of percentage of AIDS cases, a change in the definition of AIDS that increases the absolute numbers of AIDS cases will not affect the allocation of funds unless the change results in disproportionate increases in the numbers of cases identified in certain areas. A disproportionate increase could occur because: 1) some States have HIV name reporting and a few even have records of $CD4^+$ counts on HIV-infected persons, and may be better able to target AIDS surveillance; 2) States with a large number of AIDS cases may not be able to carry out detailed case investigations required for reporting; 3) States may have a disproportionate number of HIV-infected persons who have limited access to ambulatory care and $CD4^+$ testing; and 4) Some States may have a disproportionate number of HIV-infected persons who are profoundly immunosuppressed but who do not have one of the AID-defining conditions

included in the current case definition (19). In sum, States that have difficulty carrying out AIDS surveillance may receive less funds than deserved.

Title III of the Ryan White Act provides money for early intervention services, including HIV antibody testing and counseling, and other clinical and diagnostic services, such as $CD4^+$ testing. Under Subpart I of Title III, CDC is authorized to distribute grants to each State, the District of Columbia, and Puerto Rico using a formula that is similar to the formula used under Title 1l--i.e. , funds are distributed among States in proportion to the number of AIDS cases in each State in relation to the total number of AIDS cases in all States.

No money is currently being distributed under Subpart I of Title III because Title III requires a substantial expansion of CDC's counseling and testing activities and would therefore require a substantial increase in appropriations (63,195). As a result, the CDC's counseling and testing program continues to be carried out under the authority of Public Health Service Act, which does not mandate funding of clinical and diagnostic services (61). The CDC distributes funds for counseling and testing to the States and certain cities on the basis of need, but the CDC does not strictly adhere to a formula that is based on the number of AIDS cases in each State (61,220).

Title III, Subpart II, of the Ryan White Act, which is administered by HRSA, provides specific grants to public and nonprofit entities, such as migrant health centers and family planning centers, to be used for the same type of early intervention services specified for Subpart I. The funds are not distributed by a formula and therefore the change in the CDC definition of AIDS will not affect the allocation of funds under this title.

AIDS Housing Opportunity Act of 1990

The AIDS Housing Opportunity Act of 1990 (P.L. 101-625) is designed to provide housing for low income persons with AIDS. Ninety percent of the funds are designated for: 1) metropolitan areas with populations in excess of 500,000 and which have over 1500 AIDS cases; and 2) States with more than 1,500 cases of AIDS outside of these metropolitan areas (42 U.S.C. § 12903(c)(1)). Metropolitan areas and States can be awarded grants only if they submit a housing strategy that is approved by HUD. Grants will be allocated among eligible metropolitan areas and States in proportion to the number of AIDS cases in each metropolitan area or State. The minimum grant to eligible areas will be $200,000 (42 U.S.C. § 12903(c)(2)).

Currently, approximately 27 metropolitan areas and 12 States are eligible for grants based on the number of AIDS cases reported to the CDC through December 1991 (64,222). Because HUD has not yet promulgated regulations that will govern the grant application process, it is not known how many metropolitan areas and States will apply for grants. HUD recently announced it will publish regulations in June 1992, thereby allowing for disbursement of the $50 million appropriated under this act by late summer of 1992 (5).

PRIVACY CONCERNS AND THE CHANGE IN THE DEFINITION OF AIDS

The proposed change in the CDC's case definition of AIDS has raised concerns about the confidentiality of $CD4^+$ test results and the privacy of persons with AIDS. Because more HIV-infected persons will be diagnosed with AIDS under the proposed definition, an increased number of men and women will be reported by name as AIDS cases to State and local health departments. For persons with AIDS, name reporting raises serious privacy concerns. HIV infection has predominately affected men who have sex with men, injection drug users, and the sexual partners of members of these risk groups. Widespread societal condemnation of these risk behaviors, coupled with irrational fears of transmission (53,84,107), has led to discrimination against, and social ostracization of, persons with AIDS or HIV infection (4,120,193).

The States protect the confidentiality of information gathered through AIDS surveillance activities; however, the States also authorize disclosure of an individual's HIV status to third parties when necessary to stem the spread of the virus (45). Although these exceptions to the confidentiality of HIV-related information are limited, any unauthorized disclosure may be threatening to an HIV-infected individual. There are State and Federal laws that protect HIV-infected persons from discrimination, but these laws are effective only to the extent that they are enforced and they mainly redress wrongful discrimination only after it has occurred.

The incorporation of the $CD4^+$ lymphocyte count into the CDC definition of AIDS will enable States to involve private and public clinical laboratories in AIDS case reporting. In addition, the debate over the change in the AIDS case definition has led to increased attention on the confidentiality of $CD4^+$

lymphocyte test results. Although most State laws afford greater protections to the confidentiality of HIV antibody test results than other medical records, the States are split on whether this heightened confidentiality applies to other HIV-related information, such as the results of $CD4^+$ lymphocyte tests. At issue is whether $CD4^+$ lymphocyte test results should be afforded the same confidentiality protections as HIV antibody test results and whether the requirement for specific informed consent that applies to HIV antibody testing should also apply to $CD4^+$ lymphocyte testing.

Name Reporting of AIDS and Confidentiality

The proposed change in the CDC's case definition of AIDS will increase the number of AIDS cases reported in each State and hence increase the number of names kept on the States' AIDS registries. It is important to note, however, that any expansion of the CDC definition, not just that which has been proposed, would result in more names being reported as AIDS cases to the State and local health departments. In addition, a number of States already require name reporting of all HIV-infected individuals to the State and local health departments (see app. H). In these States, the health departments are already responsible for protecting the confidentiality of all HIV-infected persons' names in their registries.

The CDC and the State and local health departments insist that name reporting of AIDS cases is essential to ensure the accuracy of surveillance. Some advocates for people with AIDS are concerned that States may not be adequately prepared to handle the surge of AIDS cases that will be reported upon implementation of the proposed definition, and they fear that breaches of confidentiality will be more likely to occur. They are also concerned about

the increase in the number of HIV-infected persons that are reported as AIDS cases to the States because they believe that States have become increasingly willing to allow the disclosure of a person's HIV status to third parties in order to stem further spread of infection with HIV. The following sections examine this debate.

AIDS Name Reporting

In all 50 States, the District of Columbia, Puerto Rico, and other territories, information on every confirmed AIDS case, including the name of the person with AIDS, is sent to the State or local health department. This AIDS case information, absent the person's name, is shared with the CDC for purposes of AIDS surveillance using a CDC form called the "Acquired Immunodeficiency Syndrome (AIDS) Adult Confidential Case Report" (see app. C) (34).[37]

The CDC insists that name reporting of AIDS cases is necessary to identify and remove duplicate reports from multiple sites, to collect follow-up data as necessary, and to assess completeness of reporting (15) .[38] Underreporting or overreporting may distort information about the pattern of the AIDS epidemic and bias interpretation of trends in the epidemic (186). For example, epidemiologists may make incorrect inferences about patterns of transmission, the relative contribution of various risk groups to the

37 Names of persons with AIDS are not reported to the CDC; rather each case is identified by a Soundex code.

38 In lieu of names being reported to State health departments, Soundex codes or other systems could be used. Without name repotting, however, duplicate reports cannot be eliminated because more than one person may have the same Soundex code (32).

epidemic, and the effects of treatment. With anonymous reporting, epidemiologists could not go back to the source for additional information,[39] perform survival analysis, or perform special studies on the data (32).

About one-half of the States require that the names of all persons infected with HIV be reported to the State or local health department (see app. H); however, information on the number of HIV-infected persons identified by the States is not yet being used by the CDC for surveillance purposes. Moreover, because most of these States permit persons to be tested anonymously for HIV (119), a substantial percentage of HIV-infected persons is not reported to State health departments. Nonetheless, in those States that require name reporting of persons with HIV infection, confidentiality is a concern to HIV-infected persons regardless of whether they have CDC-defined AIDS.

Confidentiality of HIV-Related Information

The States have a legal duty to protect the confidentiality of medical information that is collected in disease surveillance (238) and every State takes measures to protect the confidentiality of the names of persons in its AIDS case registry (45). In some States, laws governing the confidentiality of reports of sexually transmitted and communicable diseases apply to AIDS case reports.[40] A number of States also has confidentiality laws that specifically apply to AIDS and HIV-related information (45,97). According to

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39 For example, approximately 10 percent of reported AIDS cases in New York do not list risk factors with the AIDS case report (32).

40 See, e.g., WYO. STAT. §§ 35-4-130, 35-4-132 (1991); OR. REV. STAT. § 3701.24(C) (1989)); N.D. CENT. CODE § 23-07-02.2 (Supp. 1991); NEV. REV. STAT. § 441A.220(Supp. 1989); MASS. GEN. LAWS ANN. ch. 111D, § 6 (West 1991, Supp.); DEL. CODE ANN. tit. 16, §§ 3702, 3711 (1991).

one informed commentator, State and local health departments have an excellent record of protecting the confidentiality of reported cases (239). Indeed, OTA has found no reports of inadvertent disclosure of AIDS- or HIV-related information from State or local health departments.

Despite the fact that the States protect the confidentiality of HIV-related information, a number of States also authorize limited disclosure of a person's HIV status to third parties if necessary to protect them from being infected with HIV or to inform them that they may have been exposed to HIV. These disclosure laws are very controversial because they involve serious compromises of HIV-infected persons' privacy rights and yet in a number of instances the disclosure protects against seemingly small risks and the benefits of the disclosure are questionable (45).

Most State HIV and AIDS confidentiality statutes have a general statement that all protected information must be kept confidential and the statutes enumerate specific exceptions to that confidentiality. The types of persons to whom HIV test results and other HIV-related information can be disclosed often include the following: 1) another party pursuant to an authorized release by the person who was subject to an HIV antibody test, or whose medical records contain HIV-related information; 2) the public health department or Federal officials as required by law, or in order to protect public health; 3) the sexual and needle-sharing partners of an HIV-infected individua1[41]; 4) for statistical purposes if the data is disclosed without identifiers; 5) third-party payers, as authorized; 6) facilities that use, process, or distribute human tissues and organs; 7) committees and other parties authorized to conduct oversight and quality reviews of health care

41 This type of disclosure usually requires the cooperation of the HIV-infected individual (183).

facilities; 8) health care workers who may have been exposed to HIV; 9) firefighters, emergency medical workers, and police who may have been exposed; 10) agencies involved in providing foster care services; and 11) schools. HIV-related information can also be disclosed in other situations as required by law (45,65). The laws and regulations that allow such disclosure vary from State to State.[42]

Many State statutes also allow third parties to petition a court for permission to obtain information about whether a person is infected with HIV.[43] Some statutes, however, limit the court's authority to reveal HIV-related information to situations in which there is "clear and convincing evidence" of a "compelling need," or in cases in which the court determines that the public interest outweighs the potential harm due to the breach of the

42 See, e.g., ARIZ. REV. STAT. ANN. § 366-664 (Supp. 1991); COLO. REV. STAT. § 25-4-1404 (1991); CONN. GEN. STAT. ANN. § 19a-503 (1990); FLA. STAT. ANN. § 381.004 (West 1990, Supp.); HAW. REV. STAT. § 325-101 (Supp. 1990); ILL. ANN. STAT. ch. 111 1/2, para. 7309 (Smith-Hurd 1990, Supp.); KAN. STAT. ANN. § 65-6002 (Supp. 1990); ME. REV. STAT. ANN. tit. 6-7, § 19203-D (1991); MICH. COMP. LAWS ANN. § 333.5131 (West 1991, Supp.); N.D. CENT. CODE, §§ 23-07.1-02.1, 23-07.3-02 (Supp. 1991); N.J. STAT. ANN. §§ 26C:5C-6 - 26:5C-14 (West 1991, Supp.); N.Y. PUB. HEALTH LAW § 2782 (McKinney 1992, Supp.); 1989 N.M. Laws Chap. 227, House Bill 490; OHIO REV. CODE ANN. § 3701.243 (Anderson 1990, Supp.); OR. REV. STAT. § 443.045 (1989); R.I. GEN. LAWS, S 23-6-17 (Supp. 1991); VA. CODE ANN. S 32.1-36.1 (Supp. 1991); WASH. REV. CODE ANN. § 70.24.105 (Supp. 1991).

43 See, e.g., CONN. GEN. STAT. § 19a-583 (1990); GA. CODE ANN. § 24-9-47(r) (Supp. 1991); HAW. REV. STAT. § 325-101 (Supp. 1990); ILL. ANN. STAT. ch. 111 1/2, para. 7309 (Smith-Hurd 1990, Supp.); MICH. COMP. LAWS ANN. § 333.5131 (West 1991, Supp.); N.J. STAT. ANN. § 26:5C-9 (West 1991, Supp.); N.Y. PUB. HEALTH LAW § 2785 (McKinney 1992, Supp.); OHIO REV. CODE ANN. § 3701.243 (Anderson 1990, Supp.); PA. STAT. ANN. tit. 35, § 37608 (Purdon 1991, Supp.); VA. CODE ANN. §§ 32.1-36.1 (Supp. 1985).

HIV-infected individual's privacy.[44] However, these standards do not guarantee that courts will make reasonable decisions based on objective evidence of risk (4).

Most State statutes give public health departments the discretion to disclose HIV-related information when necessary to protect public health (45). The U. S. Supreme Court has ruled that States have "broad latitude in experimenting with possible solutions to problems of vital local concern," even when the solution involves disclosure of confidential medical information that could "reflect unfavorably on the character of the patient" (238).[45] Therefore, this exception potentially allows for disclosure in a number of different situations.

While some people may not object to current State laws that permit disclosure, there is the possibility that, in the future, State laws may be changed to allow for broader exceptions to the confidentiality of HIV-related information. In 1991, for example, the Illinois legislature passed a statute that requires the Illinois department of health to inform patients that they may have been exposed to HIV when they have been subject to an invasive

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44 See, e.g., CONN. GEN. STAT. § 19a-583 (1990)(compelling need); GA. CODE ANN. § 24-9-47 (Supp. 1991) (clear and convincing evidence); ME. REV. STAT. ANN. tit. 6-7, § 19203-D (1991)(good cause); MICH. COMP. LAWS ANN. § 333.5131 (West 1991, Supp.)(public need outweighs potential injury); N.J. STAT. ANN. §§ 26C:5C-8, 26:5C-9 (West 1991, Supp.)(good cause); N.Y. PUB. HEALTH LAW § 2785 (McKinney 1992, Supp.)(compelling need; clear and imminent danger); OHIO REV. CODE ANN. § 3701.243 (Anderson 1990, Supp.)(clear and convincing evidence of compelling need) ; PA. STAT. ANN. tit. 35, § 7608 (Purdon 1991, Supp.)(compelling need).

45 In Whalen, the Court upheld a New York State law that required pharmacists to provide the New York Public Health Department with copies of all prescriptions of Schedule II drugs, including cocaine, opium, methadone, amphetamines, and methaqualone. These drugs are often used illegally and the New York legislature hoped to use the name reporting system to prevent the use of stolen or revised prescriptions, over-prescribing by physicians, repeated refills by pharmacists, and to prevent drug users from obtaining multiple prescriptions from different sources.

procedure in which an HIV-infected health care worker participated.[46] Conversely, health care workers who have performed invasive procedures on HIV-infected patients must be told that they may have been exposed to HIV (Ill. Ann. Stat. ch. 111 1/2, para. 7405.5 (Lexis 1991)). The health department is authorized to review medical records to determine who is at risk. The statute provides, however, that all records relating to these investigations shall be confidential. In addition, the health department must inform persons who are notified that they may have been exposed to HIV that the Illinois AIDS Confidentiality Act prohibits them from further disclosing this HIV-related information, and that willful and malicious disclosure is a Class A misdemeanor (Ill. Ann. Stat. ch. 111 1/2, para. 7405.5 (Lexis 1991)).

Despite these protections, and despite the fact that disclosure is only required if there is a risk of transmission, the statute is seen as setting a dangerous precedent by many advocates because it requires disclosure in circumstances where the risk of HIV transmission is considered very small (194). If aggressively implemented, the Illinois law could result in many patients being told that their physician, dentist, podiatrist, or nurse is infected with HIV, or it could result in medical workers being told that they've been put at risk of HIV infection by their patients. Even if the Illinois Department of Health does not reveal the name of the HIV-infected health care worker, the patient may be able to identify the health care worker or make assumptions about who put them at risk, and this will probably damage

46 The act states that it will use the CDC's list of invasive procedures. The CDC planned to develop a list of invasive procedures to be used to prevent HIV transmission from health care workers to patients. Strong opposition to the development of such a list, however, led the CDC to suspend its drafting of this list (3).

these health care workers' reputations and careers. (It is likely to be more difficult for health care workers to determine which of their patients may have exposed them to HIV if HIV-infected patients' names are not revealed.)

Protections Against Discrimination

If there are breaches in confidentiality, there are laws to protect a HIV-infected person from discrimination. The most important Federal law that protects HIV-infected persons from discrimination is the recently enacted Americans With Disabilities Act of 1990 (ADA)(P.L. 101-336), a comprehensive statute that prohibits many types of discrimination against persons with disabilities, including all persons infected with HIV.[47] In short, the ADA prohibits discrimination against the disabled by both public and private employers, discrimination by State and local governments, and discrimination by private entities that operate public accommodations and services. With respect to public accommodations, HIV-infected persons and other disabled persons must be afforded the opportunity for 'full and equal enjoyment of goods, services, facilities, privileges, advantages, or accommodations" in any place of public accommodation- -e.g. , hotels, restaurants, theaters, auditoriums, laundromats, museums, parks, zoos, private schools, day care centers, professional offices of health care providers, and gymnasiums (42 u.s.c. § 12181(7), § 12182(a) (89). The ADA therefore insures that irrational fears will not prevent HIV-infected individuals from using public and private services and accommodations, including health care services (89).

47 The statute itself does not explicitly state that HIV-infected individuals are disabled. In the legislative history of the act, however, Congress stated that persons infected with HIV would be considered disabled and therefore subject to the full protections of the act (125).

In addition to the protections provided by the ADA, virtually every State has laws that protect the disabled from various types of discrimination, and in at least 34 States, legal opinions or pronouncements of State Attorneys General have indicated that infection with HIV is a protected disability (65). Many of these State laws also prohibit housing discrimination, which is of particular concern to persons infected with HIV (66).[48]

Ironically, HIV-infected persons and persons with AIDS are routinely discriminated against in obtaining health insurance. In every State, an insurance company may refuse to provide an individual insurance policy to a person who is HIV positive, and in many States, an insurance company can request an HIV test prior to issuing an individual policy or a small group policy (51,54,149). It is estimated that 20 percent of people with private insurance have individual policies (51).[49] The ADA does not prohibit insurance companies from discriminating among insureds on the basis of risk. (42 U.S.C. § 12201(c))(89).

The importance of the issue of discrimination against HIV-infected persons is demonstrated by the large amount of attention paid to this issue by legislatures and courts. Anti-discrimination laws, however, can provide redress only after the wrong has occurred and the damage is done. Even then, wrongs can be redressed only if persons who have been discriminated against

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48 The Federal Fair Housing Amendments of 1988 also prohibit private owners and landlords from discriminating against persons with disabilities--including HIV-infected persons- -in the sale or rental of housing (Public Law 100-430).

49 Even those persons who obtain insurance through their employer may not be safe from discrimination. Employers who self-insure their employees may be able to place a cap on medical benefits for treatment of AIDS. In a recent case, a record company lowered the maximum payable amount for AIDS-related claims from $1 million to $5000.00 shortly after it found out that one of its employees had AIDS. No limitations were placed on any other catastrophic medical coverage (110)

are willing and able to enforce their rights. Several factors may make HIV-infected persons less likely to sue. Perhaps most obviously, HIV-infected persons who are ill may not be able to endure the stresses of a lawsuit. Many HIV-infected persons who have suffered from discrimination may lack the financial resources to seek legal relief, and some may not even know that there are legal remedies available to them. In addition, HIV-infected persons who have been wrongfully discriminated against may not want to spend their remaining years fighting in court (236). Finally, anti-discrimination laws cannot prevent the more subtle forms of discrimination by colleagues and acquaintances that may have a substantial negative psychological impact on HIV-infected individuals. Therefore, for most persons infected with HIV, the best protection against wrongful discrimination is to limit disclosure of HIV-related information.

The Privacy Implications of Using a $CD4^+$ Lymphocyte Count

The use of the $CD4^+$ lymphocyte count in AIDS surveillance raises new issues about the involvement of public and private laboratories in case reporting. In addition, given the implications of a low $CD4^+$ lymphocyte count, there is a debate over the appropriate counseling that should accompany $CD4^+$ testing and over the confidentiality protections that should apply to $CD4^+$ test results.

Laboratory Reporting of AIDS

With the implementation of the proposed definition of AIDS, many States plan to require that laboratories report the names of all persons who have a $CD4^+$ lymphocyte count below 200 cells/mm^3 to the State or local health

department. The State or local health department can then prompt physicians to report these patients as AIDS cases if they have a positive HIV test result or an AIDS-defining condition. (14,86,88,182). Advocates for HIV-infected persons believe that States, in an effort to ensure completeness of AIDS case reporting, may fail to enact laws and policies that adequately protect the confidentiality of these laboratory data.

These concerns, however, are theoretical, and there are reasons to conclude the laboratories will not be the weak link in the chain of confidentiality. First, laboratories are already responsible for protecting the confidentiality of all laboratory test results, including $CD4^+$ test results, and there is no indication that they do not have adequate procedures in place to protect the results of $CD4^+$ tests from wrongful disclosure. In addition, clinical laboratories are subject to State laws and regulations governing confidentiality of medical records, and these laws and regulations usually permit laboratories to disclose test results only to the State or local departments of health or to the physicians who ordered the test. (38,102,242)(see e.g. ARIZ. REV. STAT.ANN. § 36-470 (Supp. 1990); CAL. [BUS. & PROF.] CODE § 1288 (West Supp. 1991); D.C. CODE ANN. § 32-1511 (Supp. 1991); N.J. STAT. ANN. § 45:9-42-34 (West 1990); OR. REV. STAT. s 438.310 (1989)). If a laboratory employee breaches confidentiality, it is not unusual for him or her to be discharged (28,38). Laboratories are also governed by State HIV confidentiality laws and a number of these laws extend their protections to all information that may indicate that a person is infected with HIV or has

AIDS, including $CD4^+$ lymphocyte counts.[50] In addition, $CD4^+$ test results that are reported to the State or local health departments are subject to State laws regarding the confidentiality of reportable information for communicable or sexually transmitted diseases.[51]

One could argue that, although laws are necessary to protect the confidentiality of HIV-related information, they may not be sufficient; institutional procedures are probably more important in protecting against wrongful disclosures. Most laboratories have policies to protect against breaches of confidentiality (36,184). It may, however, be necessary to reevaluate security measures for $CD4^+$ test results. The Association of State and Territorial Laboratory Directors has recommended that $CD4^+$ test results be treated with the same degree of confidentiality as HIV antibody test results (38).

One way to ensure that the confidentiality of all HIV-related laboratory information is adequately protected is to require laboratories to codify security procedures in writing (184). Some State legislatures have enacted laws that require health care facilities to do this. In Maine, for example, health care providers with patient records that contain information about

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50 GWU, IHPP, "Confidentiality/Laboratories, State Laws Regarding Confidentiality," (December 1991); ARIZ. REV. STAT. ANN. § 36-664 (Supp. 1990); COLO. REV. STAT. § 25-4-1404(3) (1991); CONN. GEN. STAT. ANN. § 19a-583 (West 1990); GA. CODE ANN. § 24-9-47 (Supp. 1991); HAW. REV. STAT. § 325-101 (Supp. 1990); KAN. STAT. ANN. § 56-6002(c) (Supp. 1990); MICH. COMP. LAWS ANN. § 333.5129 (Supp. 1991); N.J. STAT. ANN. § 26:5C-6 (West 1991, Supp.); N.Y. PUB. HEALTH LAW s 2782 (McKinney 1992, Supp.); OHIO REV. CODE ANN. § 3701.243 (Anderson 1990, Supp.); PA. STAT. ANN. tit. 35, ss 7603, 7607 (Purdon 1991, Supp.); WASH. REV. CODE ANN. § 70.24.105 (Supp. 1991)).

51 In order to ensure utmost confidentiality for $CD4^+$ lymphocyte counts, however, the State department of health or Attorney General could issue an opinion that $CD4^+$ test results are covered by the State's AIDS confidentiality statutes or fall within the confidentiality provisions of their communicable disease laws.

patients' HIV status must have a written policy regarding the confidentiality of patient information that is consistent with the Maine HIV confidentiality statute. These written policies must require, at *a minimum,* termination of employment for violations of the confidentiality policy (ME. REV. STAT. ANN. § 19203-D (West 1991)). A similar statute could apply to laboratories that handle HIV-related information.

A final issue that is raised by laboratory-based reporting of $CD4^+$ lymphocyte counts is that some persons who are not infected with HIV will be reported to State health departments as suspected AIDS cases. This is because certain other viral infections, as well as some bacterial infections and hematological malignancies, may lower a person's $CD4^+$ lymphocyte count (123). If laboratories report the names of all persons with $CD4^+$ counts below 200 cells/mm^3 to State health departments as suspected AIDS cases, a number of persons who are not infected with HIV may be reported.[52]

A reporting requirement that would be more specific for HIV-induced immunosuppression would be to report only the names of persons whose $CD4^+$ lymphocyte counts are below 200 cells/mm^3, but whose counts of other T-lymphocyte subset are normal or elevated. HIV infection differs from most other medical conditions that depress T-lymphocyte counts because HIV selectively attacks the $CD4^+$ subset of T-lymphocytes (106).

Increased Use of $CD4^+$ Counts and Confidentiality

In addition to the confidentiality of $CD4^+$ test results held by clinical laboratories, there is also concern about the confidentiality of $CD4^+$ test results generally. Several advocates have argued that the laws that protect

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52 The Maryland legislature is considering reporting all $CD4^+$ lymphocyte counts below 500 cells/mm^3 (22). This could result in a large amount of private medical information being unnecessarily reported to the health department.

the confidentiality of HIV-test results should be extended to protect the confidentiality of $CD4^+$ test results. A number of State HIV confidentiality laws already protect all information that may indicate that a person is infected with HIV or has AIDS, and these laws should therefore apply to $CD4^+$ test results.[53] These States have recognized that there is no distinction between the stigma attached to the disclosure of a positive HIV test and the stigma attached to the disclosure of any other information that may show that a person is infected with HIV. States whose HIV confidentiality statutes apply only to HIV antibody test results may need to consider broadening the scope of these statutes to also include $CD4^+$ lymphocyte test results. It is important to note, however, that even in those States that do not have laws specifically aimed at protecting the confidentiality of $CD4^+$ test results, these results are protected under State laws governing the privacy of medical records generally. Laws governing the confidentiality of medical records, however, may not provide as complete a protection of confidentiality as laws that specifically protect the confidentiality of HIV-related information. (127,245)

53 In Georgia, for example, confidential AIDS information includes all information that discloses that a person: 1) has an AIDS diagnosis; 2) has been treated for AIDS; 3) has been determined to be infected with HIV; 4) has submitted to an HIV test; 5) has had a positive or negative result from an HIV test; 6) has sought or received counseling regarding AIDS; or 7) has been determined to be at risk for HIV infection (GA. CODE ANN. s 31-22-9.1 (Supp. 1991)); see *also* ARIZ. REV. STAT. ANN. §§ 36-661, 36-664 (Supp. 1991); COLO. REV. STAT. § 25-4-1402 (1991); CONN. GEN. STAT. s 19a-581 (1990); HAW. REV. STAT. § 325-101 (Supp. 1990); KAN. STAT. ANN. § 65-6002, (Supp. 1990)(protects information indicating that a person is suffering from AIDS); MICH. COMP. LAWS ANN. § 333.5131 (Supp. 1991)(protects records, reports, data, tests, etc., associated with a diagnosis of AIDS, HIV infection, or HIV-related illnesses) ; N.J. STAT. ANN. s 26C:5C-7 (West 1991, Supp.); N.Y. PUB. HEALTH LAW s 2780 (McKinney 1992, Supp.); N.D. CENT. CODE, § 23-07-02.2 (Supp. 1991) (protects records on HIV status, AIDS, HIV-related illness reported to States); OHIO REV. CODE ANN. § 3701.243 (Anderson 1990, Supp.); PA. CONS. STAT. ANN. § 7603 (Purdon 1991); WASH. REV. CODE ANN. § 70,24,105 (Supp. 1992) (protects any information relating to diagnosis or treatment of HIV infection) .

One argument against extending special confidentiality protections to all diagnostic tests that may be indicative of AIDS or HIV infection is that such protections may unduly complicate the practice of medicine. $CD4^+$ lymphocyte counts are also used to monitor diseases other than HIV infection. The interference of these confidentiality laws with clinical practice should be limited, however, because most of these laws allow for free exchange of information among health care providers and their agents involved in treatment and care of HIV-infected persons.

Many State laws governing HIV testing also require special counseling and informed consent (65), and the question arises whether $CD4^+$ testing should also be subject to these requirements. Counseling and informed consent for HIV antibody tests are required in order to: 1) educate the person about the HIV virus, the HIV antibody test, and risk behaviors that can lead to transmission of the virus; and 2) prepare person psychologically for the results of the HIV test (53).

It is standard medical practice to" perform an HIV antibody test prior to a $CD4^+$ test; thus most persons whose $CD4^+$ lymphocyte counts are measured will have already received counseling about HIV infection. There may, however, be additional psychological implications of being told one has AIDS. Itisnot clear that this psychological impact warrants imposing mandatory pre- and post-test counseling and written consent requirements for $CD4^+$ testing. Such requirements could greatly hinder the provision of medical services, especially in busy inner-city public clinics (182). As for any clinical test, physicians that order $CD4^+$ lymphocyte counts should inform their patients about the purpose and implications of the test. It is not clear, however, whether physicians should have to obtain specific consent for $CD4^+$ testing as they do for HIV testing (194).

Advocates for persons with HIV infection, however, are concerned that $CD4^+$ lymphocyte counts will be used as a proxy for HIV antibody tests in order to avoid the cost and time involved in providing pre- and post-HIV test counseling. The extent to which $CD4^+$ tests are used as a proxy for such HIV antibody tests is not known, although OTA has been told that it does occasionally happen in hospital settings (41). The potential use of $CD4^+$ lymphocyte counts in this manner is present regardless of whether the CDC definition of AIDS is changed. Physicians who are in the position to order such tests are already aware of the connection between a low $CD4^+$ lymphocyte count and HIV infection. Moreover, a low $CD4^+$ lymphocyte count is not a very good proxy for HIV infection because other viral infections as well as certain bacterial infections and hematological malignancies may lower the $CD4^+$ lymphocyte count (123).

Another debate is over whether HIV-infected persons should be able to have a $CD4^+$ test performed anonymously. Unlike other clinical tests, HIV antibody tests are often provided anonymously. Anonymous HIV antibody tests are offered to encourage persons without symptoms to find out about their HIV status. There is an assumption that persons may avoid obtaining HIV tests if they fear that others may learn that they are infected or that they sought testing (53). In addition, as discussed earlier, a person known to be HIV positive may have a difficult time in obtaining individual health insurance. It has been suggested that anonymous $CD4^+$ tests should be made available for similar reasons, especially since, under the proposed AIDS case definition, persons with $CD4^+$ lymphocyte counts below 200 cells/mm^3 may have their names reported to State health departments.

It is not clear, however, whether people who know that they are HIV positive will avoid $CD4^+$ testing and medical treatment because of concerns about confidentiality. While the guarantee of anonymity may induce some

people to find out whether they are infected with HIV, once they know they are HIV positive, they have a greater incentive to seek health care, including $CD4^+$ testing, and this may outweigh their concerns about confidentiality.

Anonymous testing gives HIV-infected persons more control over who has knowledge of their infection, which may be very important because HIV-infected persons have been subject to irrational discrimination. OTA has found one medical clinic, the NO/AIDS Task Force located in New Orleans, which recently started to offer anonymous $CD4^+$ testing.[54] The clinic's medical director claims that many of the clients--which include men who have sex with men, a few African American and Hispanic male injection drug users, and a number of women who were tested for HIV at sexually transmitted disease and family planning clinics--place a high priority on confidentiality (90). The fact that the $CD4^+$ test is free, however, may also have been an important reason that these clients sought testing at the clinic.

Anonymous $CD4^+$ testing also presents several problems, the primary one being that, in the event that medical care is necessary, it is not possible to contact an individual who fails to return for their test results. Anonymous testing may therefore hinder programs designed to bring people into care and it may not be a cost-effective use of the limited resources for care of HIV-infected persons.

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54 The clinic opened in August of 1991. The $CD4^+$ tests are done by a State lab free of charge and by a private laboratory which charges $40 per test (90).

$CD4^+$ Testing as a Surveillance Tool

The proposed incorporation of the $CD4^+$ lymphocyte count in the CDC case definition of AIDS will have several advantages for surveillance. The $CD4^+$ lymphocyte count provides a more objective guide to AIDS diagnosis[55]; HIV-infected persons with $CD4^+$ lymphocyte counts below 200 cells/mm^3 will have AIDS. The $CD4^+$ lymphocyte count also has the advantage of simplicity; HIV-positive patients may be diagnosed with AIDS on the basis of a single laboratory value. AIDS surveillance data will better reflect the extent of severe immune suppression due to HIV infection in the population.

The incorporation of $CD4^+$ lymphocyte counts in the AIDS case definition may also increase the cooperation of physicians in AIDS case reporting, as regular $CD4^+$ lymphocyte testing is already a part of the clinical management of HIV-infected patients. (The $CD4^+$ lymphocyte count has been correlated with the appearance of opportunistic illnesses and is used by physicians to guide initiation of antiretroviral therapy and pneumocystis prophylaxis.) The cooperation of physicians in AIDS case reporting is also likely to be enhanced because use of a single test will simplify AIDS diagnosis and reporting. Finally, it seems likely that AIDS reporting will be facilitated through laboratory-based reporting of cases identified through $CD4^+$ testing; hence, States may expend fewer resources in making sure that AIDS cases are reported.

55 The CDC argues that a diagnosis based on a laboratory value is less prone to subjective interpretation than diagnoses based on the presence of clinical conditions (219). Given the variability inherent in $CD4^+$ lymphocyte testing, however, diagnoses based on the $CD4^+$ lymphocyte count will also involve some degree of subjective interpretation.

Despite its advantages, however, the $CD4^+$ lymphocyte count is not a perfect AIDS surveillance tool. Individuals can only be diagnosed with AIDS through $CD4^+$ lymphocyte counts if they have access to health care and if their physician knows or suspects HIV infection. Because many persons with AIDS under the proposed definition will be without symptoms, the completeness of reporting will be difficult to assess. Furthermore, population groups with less access to $CD4^+$ testing will be underrepresented among identified cases of AIDS, and the interpretation of trends in the epidemic among major risk groups may therefore be subject to substantial bias. Those persons with less access to health care or who receive only discontinuous or emergency health care are unlikely to be diagnosed until they become ill with one of the AIDS-defining conditions. In particular, HIV-infected women and injection drug users, most of whom are African American or Hispanic, are on average poorer than members of other AIDS risk groups; members of these poorer groups may have less access to $CD4^+$ lymphocyte testing and may be underrepresented in AIDS surveillance.[56]

Differences in access to $CD4^+$ lymphocyte counts could lead to a distortion of the trends in AIDS cases reported to the CDC. Once the proposed case definition of AIDS is implemented, the CDC should investigate instances where there appears to be substantial bias in AIDS case reporting that might be attributable to a lack of access to HIV testing and $CD4^+$ testing and adjust for this bias when interpreting trends in the epidemic. The CDC, the National Institute of Allergy and Infectious Diseases, and other Federal agencies should continue to study the spectrum of disease associated with HIV infection, and improve our understanding in the differences in manifestations of HIV infection in injection drug users and women.

56 The poor are more likely *to use* public clinics, however, and a greater proportion of AIDS cases are reported that are identified in public clinics than are identified in private clinics (186).

Once the new case definition of AIDS is implemented, epidemiologists will lose their ability to use AIDS case reports to track trends in specific AIDS-defining conditions. Special epidemiologic studies will be necessary to track these trends. Epidemiologists may also have substantial difficulty linking data collected under the new case definition of AIDS with data collected under the existing case definition.

The CDC argues that many of the concerns about the proposed definition would conceptually apply to alternative approaches to expanding the AIDS case definition, such as adding more diseases to the list of AIDS-defining conditions. In particular, the CDC argues that any expansion of the surveillance definition will complicate the ability to monitor trends in AIDS and in specific AIDS-defining conditions.[57] Lack of access to care will hamper surveillance under any definition, not just one that includes $CD4^+$ testing. The need for $CD4^+$ testing is not changed by the proposed definition, because $CD4^+$ counts are also. used to guide clinical care of HIV-infected patients.

The AIDS Case Definition and Clinical Care

The CDC's proposed case definition of AIDS is not an ideal clinical definition, although the CDC did not intend it to be. There is mounting evidence that there is a broad spectrum of illnesses whose incidence or clinical course is affected by HIV-induced immune suppression. Although the proposed AIDS case definition captures a greater percentage of HIV-infected persons with profound immunosuppression, there are a number of serious HIV-

57 This effect was seen after the 1987 revision, which complicated trend analyses (211).

associated illnesses that are not among the 23 AIDS-defining conditions and which may occur in persons with $CD4^+$ lymphocyte counts that exceed 200 cells/mm^3. The HIV classification system, however, can be used by clinicians and includes a broad range of HIV-associated conditions.

Some experts have argued that we need two definitions of AIDS: a surveillance definition and a clinical definition. For epidemiologic purposes, it is useful to retain a definition that is highly specific for severe manifestations of HIV infection. A clinical definition may be less specific for HIV infection and more sensitive for symptoms that may be related to HIV infection. For example, one may look for manifestations of HIV infection in persons with pneumococcal pneumonia or *Hemophilus influenzae* pneumonia. These pneumonias are not specific for HIV infection, but more people with HIV-induced immune dysfunction will be captured (37). There are other diseases, such as Lyme disease and toxic shock syndrome, where the clinical definition is broader than the CDC, case definition (37). By maintaining these important distinctions between surveillance instruments and clinical classification schemes, the various goals -- i.e. , consistent

epidemiologic monitoring and surveillance, along with appropriate clinical and social service intervention for serious and disabling illnesses -- could be sened.[58]

The new CDC definition of AIDS was developed primarily for surveillance needs. Therefore, clinicians should be made aware of the broad spectrum of HIV infection, including manifestations of HIV infection in women, injection drug users, African Americans, and Hispanics. There is growing evidence that there are a number of HIV-associated conditions in injection drug users and women that are not included in the AIDS case definition. Physicians' awareness of the relationship of HIV infection to some of these conditions, such as pulmonary tuberculosis and cervical dysplasia, is particularly important because early intervention may have an impact on outcome. These HIV-associated conditions are less- useful markers for AIDS surveillance because they are not specific for HIV infection. The CDC's case definition of AIDS was designed for surveillance, and should not be expected to substitute

58 One expert notes that the competing agendas may be satisfied by linking clinical staging and social service disability determinations to the HIV classification system, and not just to the AIDS case definition itself (161). The CDC HIV classification system, which will be revised in parallel with the AIDS case definition, does acknowledge and account for many of the HIV-associated conditions seen in women and injection drug users. (For a description of the current and revised HIV classification systems, see app. F.) Although these HIV-associated conditions seen in women and injection drug users are not deemed AIDS-defining, they nevertheless receive recognition in the HIV-classification system as serious HIV-associated illness. Others argue, however, that we need a single definition of AIDS as a common vocabulary (231). One expert believes that all three goals can be accommodated with one definition. He suggests revising the AIDS case reporting form to place those AIDS-defining conditions which virtually always occur at less than 200 $CD4^+$ cells/mm^3 in a sublist placed after the shorter list of conditions that can occur at greater than or equal to 200 $CD4^+$ cells/mm^3. The majority of patients would be diagnosed with AIDS either on the basis of $CD4^+$ lymphocyte criteria or the short list of conditions that occur at higher counts, and physicians would only rarely have to refer to the longer list of AIDS-defining conditions that virtually always occur in persons with $CD4^+$ lymphocyte counts less than 200 $CD4^+$ cells/mm^3.

for proper physician education as to what screening tests should be done in HIV-infected persons. If the problem is in physician education, the most direct solution may be in physician education.

The $CD4^+$ lymphocyte count is not an ideal clinical marker because it is highly variable and not well standardized. Although the high degree of variability is not important when one is measuring the extent of severe immunosuppression in a population, on an individual basis, an accurate assessment of the $CD4^+$ lymphocyte count is important because it is used to guide therapy. Therefore, a physician should validate the $CD4^+$ lymphocyte count by repeating the test if the initial count appears to be inaccurate, such as when a patient has a sudden large drop in $CD4^+$ lymphocyte count.

On an individual basis, a number of HIV-positive individuals with $CD4^+$ lymphocyte -counts below 200 cells/mm^3 will not have any symptoms, although the probability that they will develop symptoms within a year is high. Data from the Multicenter AIDS Cohort Study (MACS) show that one-third of the individuals whose $CD4^+$ lymphocyte counts fell below 200 cells/mm^3 were asymptomatic (129).[59] Under the CDC's proposed AIDS case definition, asymptomatic HIV-positive individuals with $CD4^+$ counts below 200 cells/mm^3 will be diagnosed with AIDS, and some of these individuals are likely to experience adverse psychological consequences as a result of this diagnosis.

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59 **MACS** participants are primarily middle-class, white men who have sex with men. For the reasons discussed previously, the proportion of HIV-infected women and injection drug users who are **asymptomatic** with **$CD4^+$** lymphocyte counts less than 200 **cells/mm^3** is likely to be lower than that for **HIV-**infected white men who have sex with men. Furthermore, persons in this study were "symptomatic" if they did not have AIDS or one of a limited number of conditions often referred to as AIDS-related complex (which includes fatigue, fever, weight loss, persistent skin rash, oral hairy **leukoplakia**, herpes simplex, and oral thrush). Hence, some persons characterized as **asymptomatic** in this study may have been experiencing some HIV-related symptoms.

The Costs of Implementing the Proposed AIDS Case Definition

Each State will be responsible for implementing the CDC definition of AIDS. State health departments may need additional resources to implement the new definition, including money to establish flow cytometry facilities where necessary, to set up new systems to efficiently identify cases through laboratory-based reporting, and to handle the initial dramatic increase in caseloads. States may also need additional resources to provide adequate access to $CD4^+$ testing. Outreach programs are needed to ensure that persons who in the past have had little access to medical care can enter into a care relationship and receive $CD4^+$ testing.

States may invest in increasing the access of the medically underserved to $CD4^+$ lymphocyte testing. One benefit of increased access to $CD4^+$ testing is that more asymptomatic HIV-infected individuals with low $CD4^+$ lymphocyte counts will be alerted to the need for medical treatment.[60] States may need additional funds to provide access to medical care for the profoundly immunosuppressed individuals who are identified through such surveillance.

Federal Funding Allocations and the New Definition of AIDS

The proposed CDC definition of AIDS may still be appropriate to use in allocating Ryan White funds because AIDS surveillance data, if accurate, will reflect the health care needs in each State. Some States, however, may be

60 This does not necessarily mean that clinicians provide the same type of pre- and post-test counseling to persons obtaining a $CD4^+$ lymphocyte count that is required for persons who are tested for HIV antibody. Clinicians should provide patients with an explanation of diagnostic and therapeutic implications of the $CD4^+$ lymphocyte count.

less able than others to document AIDS cases because they may be unable to offer $CD4^+$ testing to HIV-infected individuals who cannot this test. Physicians may also fail to cooperate with AIDS case reporting, or the State department of health may be overwhelmed by the number of AIDS cases that are reported and may be unable to carry out the detailed case investigations that are necessary.

Under the proposed AIDS case definition, a larger number of metropolitan areas will have the threshold number of cases necessary to qualify for Title I funds under the Ryan White Act. Appropriations for Title I will need to increase if the funding for each metropolitan area is to be maintained at current levels. In theory, the proposed change in the CDC's case definition of AIDS and the expected increase in the total number of AIDS cases should not significantly influence the distribution of funds among States and metropolitan areas under Titles I or II of the Ryan White Act, since they are distributed according to the proportion of AIDS cases, rather than absolute numbers of AIDS cases in each State. In practice, however, the distribution of funds may not be proportional to the' actual needs of each State or metropolitan area if some States and cities are not as capable as others in implementing the new AIDS case definition.

The Office of Technology Assessment (OTA) has not determined whether the current Ryan White Act funding is meeting the States' needs. The President's Commission on AIDS, however, has repeatedly urged the President to recommend that the Ryan White Act be funded up to its full level (73,120). In addition, it is unfortunate that Title III, Subpart I, which authorized money for diagnostic tests for management of HIV infection, such as $CD4^+$ lymphocyte counts, is not currently being funded.

As of April 1992, no money under the AIDS Housing Opportunity Act of 1990 had been distributed. Money will be distributed among eligible areas in proportion to the number of AIDS cases that are reported in each area. Therefore, allocations under this act may also be affected by the ability of the States and cities to document AIDS cases under the new definition.

Privacy Concerns and the New CDC Definition of AIDS

With the proposed expansion of the AIDS case definition, HIV-infected persons will be reported to the State and local health departments earlier in the course of their infections, and there consequently will be a greater number of names held in the AIDS registries of State and local health departments. Thus, there will be a greater number of HIV-infected individuals who will risk having their names disclosed to third parties whom the State decides need to know this information. On the other hand, in States that require name reporting of all HIV-infected persons, those individuals known by the State to be HIV-infected will have their names placed in an HIV registry regardless of whether the CDC definition of AIDS is expanded. In addition, any substantial expansion of the case definition would lead to large increases in case reports.

The States have an incentive to document as many of their AIDS cases as possible in order to obtain a larger share of Federal funds under the Ryan White Act. This goal should not overshadow the privacy concerns of the individuals whose names are being collected. States will have a responsibility to ensure that, in pursuing the goal of conducting comprehensive AIDS surveillance, the privacy rights of persons with AIDS are protected. In making plans to implement the new AIDS case definition, States

should reassess current laws and operational procedures that protect the names of HIV-infected persons. In particular, States should consider whether HIV confidentiality laws should be extended to protect the confidentiality of all information that may indicate that a person is infected with HIV, including the results of $CD4^+$ lymphocyte counts.

State or local health departments may in the future expand the number of situations where the disclosure of the names of persons with AIDS is permitted in. order to protect the public health. Some commentators see a disturbing trend toward expanding the instances where such disclosure is permitted. They believe the privacy rights of HIV-infected individuals are being unduly compromised in order to protect against small risks of transmission. Because more HIV-infected individuals will be reported to State and local health departments under the proposed AIDS case definition, more HIV-infected individuals will be subject to this potential disclosure risk. It is important to note, however, that any expansion of the CDC definition of AIDS, not just that which has been proposed, would result in more names of HIV-infected persons being reported to State and local health departments.

Under the proposed definition, States may enlist flow cytometry laboratories in identifying suspected AIDS cases. The enlistment of clinical laboratories in AIDS case reporting has highlighted concerns about the confidentiality of the results of $CD4^+$ testing. A number of State HIV confidentiality laws also extend to other HIV-related information, including $CD4^+$ lymphocyte counts. In addition, laboratories are subject to State laws governing the confidentiality of medical records generally. Laws protecting the confidentiality of HIV-related information may not be enough; laboratories should consider developing written policies to guard the confidentiality of $CD4^+$ test results. It is important to note, however, that to date, flow

cytometry laboratories have protected the results of $CD4^+$ tests and there is no indication that they will not continue to keep this information confidential.

States should evaluate the privacy implications of having flow cytometry laboratories send the names of all persons with depressed $CD4^+$ lymphocyte counts to State or local health departments, because a number of diseases other than HIV infection can also depress $CD4^+$ lymphocyte counts. In Maryland, the State legislature is considering a bill that requires that laboratories report the names of all persons with $CD4^+$ lymphocyte counts below 500 cells/mm^3 to the State health department. If this bill is enacted, laboratories would send the names of a large number of persons who are not HIV-infected to the Maryland Department of Health for investigation. If a State decides to implement laboratory reporting of $CD4^+$ lymphocyte test results, a preferable alternative would be to have laboratories send to the State only the names of persons who have a depression of the $CD4^+$ subset of T-lymphocytes and normal or elevated levels of other T-lymphocyte subsets. This is because the selective depression of the $CD4^+$ subset of T-lymphocytes is a more specific indicator of HIV-induced immunosuppression.

There are strong arguments for treating $CD4^+$ lymphocyte counts, along with other HIV-related information, with the same degree of confidentiality as HIV test results; however the arguments for requiring special informed consent or permitting anonymous testing are more compelling for HIV testing than they are for $CD4^+$ testing. Persons who know they are HIV positive have additional incentives to obtain medical care and $CD4^+$ tests, and therefore it may not be essential to offer anonymous testing to bring these HIV-infected persons into the health care system.

Chapter III

The Use of the CDC Definition of AIDS in Social Security Disability Determinations

INTRODUCTION

The controversy over the Centers for Disease Control (CDC) definition of acquired immune deficiency syndrome (AIDS) did not primarily arise among epidemiologists and public health professionals concerned about proper tracking of the AIDS epidemical The issue was brought to the public's attention by AIDS activists and lawyers who represent HIV-infected women and injection drug users. These advocates were seeking to obtain access to Federal disability and medical insurance programs because their clients were no longer able to work. In particular, they were seeking financial assistance and medical care under the following Federal programs:

- the Social Security Supplemental Security Income (SSI) program;
- the Social Security Disability Insurance (DI) program; and
- the Medicaid program.

SSI and DI are administered at the Federal level by the Social Security Administration (SSA) in the U.S. Department of Health and Human Services (DHHS) . Medicaid is administered at the Federal level by the Health Care Financing Administration in the DHHS.

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1 The CDC has been exploring ways to simplify its definition of AIDS since 1989; however, this is not what sparked the public debate (16).

The SSI and DI programs are Federal entitlement programs designed to provide income support for persons who are aged, disabled, or blind. Individuals under 65 years of age are eligible for SSI or DI only if they are blind or disabled. In almost all States and the District of Columbia, qualification for SSI benefits, and to a lesser extent qualification for DI benefits, provides an individual with the opportunity to receive health insurance under Medicaid, which is a Federal/State jointly financed health care program for low-income individuals who are aged, blind, or disabled, members of families with dependent children, and certain other pregnant women and children (189).

The SSA began using the CDC definition of AIDS in evaluating disability under its DI and SSI programs in 1983, although it did not issue a ruling acknowledging its use until 1984. The SSA's initial decision to use the CDC definition in disability determinations for HIV-infected individuals was not objectionable. The agency's continued reliance on the CDC definition and its failure to develop specific disability criteria for other HIV-infected persons who were seriously ill but did not have AIDS brought the SSA under considerable criticism from AIDS activists, disability attorneys, and certain members of Congress (113,147).

AIDS activists and legal service attorneys asserted that, while persons with AIDS were almost always awarded disability, the SSA failed to award disability benefits to other seriously ill HIV-infected women and men, many of whom are minorities. They argued that the SSA's instruction that all persons with AIDS are disabled created a perception that symptomatic HIV-infected individuals who did not have AIDS were not disabled. This contradicts the SSA's written instructions to its disability adjudicators and, to some degree, the SSA's own statistics which demonstrate that a number of HIV-infected individuals who did not have AIDS were awarded disability benefits.

This debate is difficult to sort out because there has not been an objective, comprehensive examination of the disposition of disability claims made by symptomatic HIV-infected persons who do not have AIDS. Most of the evidence that deserving claimants with HIV infection are not being awarded disability comes from examples provided by legal services attorneys. Although these examples are quite compelling (see app. I), they may represent only the most egregious cases. Nonetheless, this does not discount the fact that a number of HIV-infected persons who appear to be very ill were unable to get disability benefits.

The SSA, however, has recently revised its criteria for evaluating disability of persons with HIV infection, and this revision changes the nature of the debate. First, it demonstrates that the SSA will not tie its disability determinations to the CDC's new definition of AIDS. HIV-infected individuals who have one of the 1987 AIDS-defining conditions (except Kaposi's sarcoma) will continue to be considered disabled on the basis of their medical conditions alone. HIV-infected persons with $CD4^+$ lymphocyte counts below 200 cells per cubic millimeter ($/mm^3$) , however, will be evaluated in the same manner as HIV-infected individuals with pulmonary tuberculosis, recurrent vaginal candidiasis, endocarditis, and a list of other HIV-associated conditions. The new disability criteria includes a number of HIV-associated conditions that are frequently seen in HIV-infected women and injection drug users. However, as discussed below, the new criteria are not without its critics. Indeed, the SSA has received approximately 3000 comments on their proposed regulations, an unprecedented number (95) .

The following sections present an overview of the SSA's disability programs and the debate over disability determinations for persons with HIV infection. This background enables one to better evaluate the SSA's new disability criteria for HIV infection.

THE SSA DISABILITY PROGRAM--GENERAL PROCEDURES AND STANDARDS

The DI program is a publicly funded disability insurance system. In order to qualify for DI benefits, a person must have worked for a certain number of years, and thus have paid into the Federal Social Security program. The SSI program, on the other hand, is an income-assistance program for financially needy persons who are disabled, blind, or 65 years of age or older. The SSA uses the same definition for disability for both DI and SSI--an *inability to engage in any substantial gainful activity (defined as earning more than* $500 *per month) by reason of any physical or mental impairment which can be expected to result in death or which lasts for a continuous period of not less than 12 months (42* U.S.C. *§* 423(d)(l)(A) (DI); s 1382(a)(3)(A) (SSI)). Applicants with medical conditions that prevent them from performing their previous work or any job that would qualify as substantial gainful activity will be awarded disability benefits, assuming they meet the program's. financial requirements and other criteria (e.g., the citizenship requirements) .

Applying for Disability Benefits

Applications for SSI or DI disability benefits are filed at one of the SSA's approximately 1,300 field offices. Each field office is staffed by trained clerical personnel who help initiate a claim and determine whether an applicant meets the financial, age, and citizenship requirements. In some cases (described below), field office personnel can determine that a claimant is presumptively disabled and award interim benefits. In all cases, however,

the ultimate determination that a claimant is disabled is made by one of the 54 State and territorial Disability Determination Service (DDS) offices (42 U.S.C. § 421(a))(188).[2] The disability determinations are made by a team of disability adjudicators, which includes a physician, a trained disability examiner, and, if needed, one or more vocational experts.

If the State DDS denies an application for disability benefits, the applicant has the right to have the disability determination reconsidered by another DDS adjudicator who was not involved in making the initial decision; this is known as a "reconsideration" (20 C.F.R. §§ 404.907-404.922, 416.1407-416.1413(c)) (see app. H). If the application is denied upon reconsideration, the applicant has the right to a *de novo* hearing before an administrative law judge (20 C.F.R. §§ 404.929-40~.965, 416.1429-1461). If this decision is also adverse to the claimant, he or she can appeal to SSA's Appeals Council, which reviews the decisions of administrative law judges (20 C.F.R. §§ 404.967-404.979, 416.1468-1484). The final stage of review is in the Federal court system (42 U.S.C. §§ 405(g), 1383(c)(3); 20 C.F.R. §§ 404.981, 404.1482).

The SSA's Sequential Disability Process

SSA regulations set forth a five-part sequential procedure that is used by SSA's disability examiners and administrative law judges to determine disability for DI or SSI (see app. G). The disability adjudicator must first determine the following: 1) whether the claimant is working, and 2) whether the claimant has a disabling condition that significantly limits his or her ability to work (20 C.F.R. §§ 416.920(a)(c), 404.1520(b)(c)). If the claimant

2 The State offices only focus on medical disability; the examiners in the State offices do not see the financial information (146).

is not working because of a disabling condition that significantly limits his or her ability to work, the disability adjudicator proceeds to the third step in the disability process.

The third step is to compare the applicant's alleged disability with the SSA's "Listing of Impairments," a list of medical conditions that SSA has designated as being so severe as to "prevent a person from doing any gainful employment" (20 C.F.R. § 416.925). The SSA has designated over 100 medical conditions in its 'Listing of Impairments" in the Code of Federal Regulations (20 C.F.R. Part 404, Subpt P, Appendix 1). (The medical conditions in the "Listing of Impairments" are often referred to by the SSA as a "Listing," a 'listed impairment," or a "listing-level impairment.") The SSA's State disability adjudicators are instructed that if an applicant for SSI or DI presents medical evidence establishing that he or she has one of the listed impairments, that person is disabled and will be awarded disability benefits if he or she meets the financial and other program requirements. In addition, a person will be awarded disability benefits if the evidence demonstrates that his or her medical condition equals, in terms of severity, one of the Listings. Approximately 75 percent of favorable disability decisions are made at this step in the process (189).

If an applicant for disability benefits does not have a medical condition that meets or equals one of the Listings, the SSA disability adjudicator must evaluate the applicant's residual physical and mental capacity to perform in a work environment. In the fourth step of the sequential disability process, the SSA disability adjudicator determines, on the basis of the person's residual capacity, whether the applicant can still perform his or her previous job. If the applicant can perform his or her previous job, the application for disability benefits is denied (20 C.F.R. §§

416.920(e), 404.1520(e)). If the applicant cannot perform his or her previous job, the SSA will determine, taking into account education, age, and prior work experience, whether the applicant can perform any full-time job in the national economy (20 C.F.R. §§ 416.920(f), 404.1520(f)). This is the final step in the disability process.

Presumptive Disability Benefits

Under the SSI program, claimants who have medical impairments that are highly predictive of disability can be awarded presumptive disability benefits during the time their claim is being evaluated under the five-step disability process. Presumptive disability benefits continue for 6 months while the SSA disability adjudicators gather necessary medical evidence to confirm that the person is disabled (42 U.S.C. § 1383(a)(4)(B)) . Presumptive disability benefits can be awarded at any point in the disability process when a disability examiner from one of the 54 State and territorial DDS offices has sufficient medical evidence to conclude that a person is disabled.

The SSA also permits the field offices to award presumptive disability benefits to certain claimants. The medical conditions for which the field offices can award presumptive disability are specified in the SSA's regulations (21 C.F.R. § 416.936), and are usually restricted to conditions that are either easily identified by a trained lay person or can be easily confirmed with a single call to a medical practitioner (e.g., the amputation of two limbs, amputation of a leg at the hip, or allegation of total deafness). By permitting the field office to award presumptive disability benefits, the SSA enables applicants for SSI who are clearly disabled to receive their benefits promptly.

THE LINK BETWEEN SOCIAL SECURITY DISABILITY PROGRAMS AND MEDICAID

An important consideration in the controversy over the SSA's disability decisions for persons with HIV-associated conditions is that SSA's disability programs serve as an entry to federally funded health insurance, primarily Medicaid.[3] Medicaid is a Federal-State funded medical insurance system for low-income individuals who are aged, blind or disabled, and certain other pregnant women and children, or members of families with dependent children. Federal funds account for approximately 57 percent of total funds (192).

The majority of SSI recipients are eligible to receive Medicaid.[4] DI recipients cannot automatically qualify for Medicaid because DI benefits generally exceed State Medicaid income levels. If DI recipients' medical expenses greatly exceed their income, however, they may qualify for Medicaid under State programs for the 'medically needy" (189). As of 1991, 35 States, the District of Columbia, and Puerto Rico had "medically needy" programs (198).

Medicaid is rapidly becoming the primary insurer of persons with AIDS. Researchers have estimated that Medicaid covers approximately 40 percent of individuals with AIDS, private insurance covers 29 percent, Medicare covers 2

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3 Medicare is not available to persons receiving 7DI until 24 months after DI benefits are awarded. (42 U.S.C. § 1395e). In the past, most HIV-infected individuals who qualified for DI did not live long enough to qualify for Medicare (12). This may change, however, as treatment extends the life expectancy of persons with HIV infection.

4 All but 12 States automatically allow SSI recipients to receive Medicaid (198). The other 12 States have more restrictive disability or financial requirements (121). In those States that use more restrictive financial requirements, SSI recipients may become eligible for Medicaid if their medical bills greatly exceed their income (189).

percent, and approximately 29 percent of persons with AIDS are without insurance coverage (120). This trend towards the "Medicaidization" of AIDS (69) demonstrates the demand for publicly funded health care for HIV-infected persons. This demand is likely to continue to grow as there appears to be an increasing number of HIV-infected persons who are poor and who do not have adequate health insurance. Even among those with private insurance, there is some evidence that HIV-infected persons may lose their insurance once they can no longer work (92) .

The costs of providing medical care for HIV-infected individuals without Medicaid or other health insurance will probably be borne by the States (167a). In 1991, the States spent approximately $168 million on medical services for people with AIDS and HIV, excluding State Medicaid funds. The majority of care was provided in outpatient settings (85).

Although many disability claimants may need medical care immediately, they will not be able to get medical care through Medicaid until they are determined to be disabled. The SSA cannot alter the statutory disability definition to make more people eligible for Medicaid; however, if the SSA incorrectly denies a person disability benefits, this decision may also affect the person's ability to obtain federally financed health care.

DISABILITY DETERMINATIONS AND HIV/AIDS

The debate over disability determinations for HIV-infected claimants has focused on the SSA's decision to use the CDC definition of AIDS as a Listing and in presumptive disability determinations. The decision to use the AIDS case definition in disability determinations did not preclude HIV-infected claimants without AIDS from receiving disability benefits; adjudicators had

the discretion to conclude that HIV-infected claimants without AIDS were disabled because their condition was equal in severity to a Listing. Alternatively, HIV-infected claimants could be found disabled at a later stage in the disability process, based upon their residual functional capacity. By 1990, however, the SSA concluded that it needed a Listing that enumerates specific disability criteria for HIV-infected claimants without AIDS. The development of this Listing is discussed below.

Disability Determinations for Persons With AIDS

Since *1983,* the SSA has instructed its disability adjudicators to use the CDC definition of AIDS as a Listing, although it has never published regulations formally incorporating the CDC definition of AIDS into its "Listing of Impairments." The SSA's instruction on AIDS was maintained in an internal policy manual, the Program Operations Manual System (POMS), until 1984, when the SSA outlined this policy in the first of two Social Security Rulings (SSRs) (224a,224b).[5] (These rulings were not published in the Federal Register.) The SSA used the CDC definition of AIDS as a disability definition and incorporated all of the CDC's subsequent revisions of the case

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5 Social Security Rulings are not regulations; instead the rulings draw upon and codify the policies and criteria used at all levels of the administrative adjudication process (e.g., administrative law judge and Appeals Council decisions, decisions by **SSA** disability examiners, opinions of the **SSA's** Office of Disability or Office of the General Counsel, and other policy interpretations by **SSA).** These rulings are binding on all components of the **SSA,** including State DDS examiners, administrative law judges, and the **SSA's** Appeals Council (20 **C.F.R. §** 422.406(b)(l)) . Because they do not have the force and effect of law or **SSA** regulations, however, they are not binding on Federal or State courts (56 FR 65498).

definition into the disability definition. In 1990, however, the SSA added Hodgkin's lymphoma, a condition that is not included in the CDC AIDS definition, to its AIDS disability definition.

In 1985, the SSA published regulations making AIDS one of the conditions for which "presumptive disability" could be awarded at the field office level (50 F.R. 5573). This enabled claimants with AIDS to receive disability benefits quickly[6], and the decision was generally well received. It was also the first time that the appropriateness of using the CDC definition of AIDS in disability determinations was subject to public debate.'

The SSA recognized that a surveillance definition is designed for a different purpose than a definition for determining disability. Nonetheless, the SSA concluded that it was unlikely that any person with AIDS who had stopped working could engage in substantial gainful activity (53 F.R. 3740). The decision to use the CDC definition of AIDS in field office presumptive disability determinations and as a Listing facilitated the processing of disability claims for persons with AIDS, and almost 100 percent of claimants whom the SSA recognized as having AIDS were awarded disability benefits (225) .

Disability Determinations for Persons with HIV Infection

The SSA also recognized that persons with HIV infection could become ill and disabled prior to developing AIDS. In the 1986 Social Security ruling on AIDS and disability, the SSA instructed its adjudicators that persons with HIV

6 Presumptive disability benefits are often awarded within 3 weeks, while an initial determination by the DDS may take 3 months or longer (49,227).

7 The regulations were issued as interim regulations, effective immediately, but public comments were accepted. These comments were addressed in 1988, when SSA renewed the regulations (53 F.R. 3740).

infection might suffer from a number of potentially disabling conditions prior to developing AIDS, including recurrent fevers, lymphadenopathy, prolonged diarrhea, fatigue, weight loss, night sweats, and recurrent infections such as oral candidiasis. The SSA wrote that HIV-infected individuals who suffer from one or more of these conditions may be disabled and their degree of disability should be assessed on a case-by-case basis (224b).

By 1987, the SSA announced that it would soon publish regulations creating a Listing for HIV infection and AIDS (56 F.R. 65704). The SSA failed to publish these regulations, and mounting public and Congressional pressure led the SSA to reconsider its instructions on HIV infection and disability.[8] As a result, in 1988, the SSA decided that it needed more specific criteria for evaluating disability in HIV-infected claimants without AIDS (113).

In February of 1990, the SSA published a new disability definition entitled "Symptomatic HIV Infection Not Indicative of AIDS." This new criteria was published in the POMS, an internal policy manual. The public " does not have input into the development of the POMS, and it is only made available by request to the SSA (5 U.S.C. § 552(2)). Moreover, the POMS does not bind the administrative law judges in their decisions.

The POMS disability definition "Symptomatic HIV Infection Not Indicative of AIDS" (henceforth referred to as POMS "Symptomatic HIV Infection") functioned as a Listing for HIV-infected persons who do not have AIDS. In

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8 In *1988,* Congress mandated that the **SSA** conduct an internal review of disability determinations for persons alleging HIV infection but not AIDS (Public Law 100-647, Sec. 8019). In attempting to complete this report (it has never been completed (115), the **SSA** found that close to half of the State **DDS** offices collected no data separating AIDS 'and other HIV infection claims, and other **DDS** offices often inaccurately classified AIDS and HIV infection claims. Among those States with data, **SSA** found significant variation in allowance and denial rates for HIV infection claims that were not AIDS (147,235).

other words, if an HIV-infected claimant documented that he or she had the combination of medical conditions and symptoms that were included in, or were equal in severity to, the POMS "Symptomatic HIV Infection" criteria, he or she would be awarded disability benefits at step 3 in the disability process.

In order to meet the POMS "Symptomatic HIV Infection" criteria, a claimant needed to document:

1) Evidence of HIV infection (e.g., HIV antibody or viral testing); AND
2) A $CD4^+$ lymphocyte count less than or equal to 200 cells/mm^3 (or a $CD4^+$ percent of lymphocytes less than or equal to 25); **AND**
3) *Two* or more of the following *persisting over a 2-month period:*
    a. anemia (hematocrit value below 30 percent)
    b. granulocytopenia
    c. thrombocytopenia
    d. documented fever
    e. weight loss >/- 10 percent of baseline
    f. oral candidiasis
    g. oral hairy leukoplakia
    h. recurrent herpes zoster
    i. persistent, unresponsive diarrhea;
    AND
4) Marked restriction of activities of daily living (such that individual needs help with most activity including climbing stairs, shopping, cooking, or housework) **or**
    Deficiencies of concentration, persistence, or pace, resulting in frequent failure to complete tasks in a timely manner (in work settings or elsewhere) (POMS).

Advocates for people with HIV infection were generally pleased that the SSA created more specific disability criteria for persons with HIV infection, but they claimed that the POMS 'Symptomatic HIV Infection" criteria did not go far enough. Most of the HIV-associated conditions included in the POMS "Symptomatic HIV Infection" criteria were derived from the same epidemiologic

studies used to develop the CDC definition of AIDS, in which the cohorts largely consisted of white men who have sex with men (168). The conditions identified by these studies--e.g. , fever, weight loss, fatigue, chronic diarrhea, night sweats, lymphadenopathy, oral thrush, and hairy leukoplakia (241a)--do occur in other HIV-infected populations, including women and injection drug users. There are other disabling conditions, however, that are seen particularly in HIV-infected women and injection drug users--e.g. , endocarditis, pneumonia, sepsis, pelvic inflammatory disease, genital herpes, and persistent vaginal candidiasis- -that were not included in the POMS "Symptomatic HIV' Infection" criteria.

CRITICISMS OF THE SSA's DISABILITY PROCESS

By the late 1980s, as more individuals infected with HIV were identified, it became apparent that some of the serious medical conditions that were seen particularly in HIV-infected women and injection drug users were not included in the CDC definition of AIDS. Legal service attorneys and other advocates for HIV-infected persons charged that the SSA routinely denied disability benefits to HIV-infected women and injection drug users whose HIV-associated conditions were not included in the CDC definition of AIDS or, after 1990, in the SSA's POMS "Symptomatic HIV Infection" criteria. This is the main argument made in the lawsuit S.P. v. Sullivan, discussed below.

The SSA, on the other hand, stated that it had no policy that prevented HIV-infected persons who did not have AIDS or meet the POMS "Symptomatic HIV Infection" criteria from obtaining disability. The SSA specifically instructed its disability adjudicators that HIV-infected persons who did not have AIDS or meet the SSA's POMS "Symptomatic HIV Infection" criteria should

be evaluated under the full sequential disability process. In other words, if HIV-infected claimants were not awarded disability on the basis of a Listing, the DDS adjudicator would determine their residual functional capacity to work and evaluate whether they can perform any full-time work in the national economy. If they were unable to work, they were awarded disability.

Legal service attorneys claim that, while this may be the stated policy, in practice their clients with HIV-associated conditions not included in the POMS "Symptomatic HIV Infection" criteria were not able to receive disability at these last steps in the disability process. In addition, attorneys have challenged the legality of the SSA's decision to use the POMS and SSRs to establish that AIDS and the POMS "Symptomatic HIV Infection" equals a Listing.

The SSA Disability Statistics

The SSA's statistics reveal that, in 1990, almost 100 percent of persons with AIDS who applied for either SSI or DI benefits were awarded these benefits. In addition, approximately 50 percent of claimants who alleged HIV infection on their disability claims, but who did not have AIDS, received disability benefits at the initial or reconsideration stage (225). The statistics do not reveal the condition of the other 50 percent of HIV-infected persons who were denied disability, nor do the statistics reveal the race or socioeconomic class of the persons who were awarded disability benefits versus those who were denied benefits.

The SSA states that, when the analysis is limited to claims made by *symptomatic HIV-infected individuals,* approximately 60 percent or more are awarded disability (49,225). The DDS examiners only classify a person as *symptomatic HIV-infected* if he or she has the symptoms described in the POMS

"Symptomatic HIV Infection" criteria (115) . Therefore, HIV-infected disability applicants who claimed they were disabled on the basis of gynecological conditions, endocarditis, bacterial pneumonia, pulmonary tuberculosis, or sepsis, would not be classified as symptomatic *HIV-infected individuals.*

When one only examines claims made by HIV-infected persons who were not classified by the SSA as having AIDS or *symptomatic HIV-infection,* only *23* percent were awarded disability (49,225). The SSA's position is that the 77 percent of claimants who were not awarded disability did not have disabling symptoms of HIV infection. Legal service attorneys argue that many of these HIV-infected claimants are their clients who were incorrectly denied disability.

Legal Challenges to the SSA's Disability Process

Two lawsuits have been filed against the SSA challenging its disability criteria for persons with HIV infection. The first suit alleges, among other things, that the SSA's use of the CDC definition of AIDS and the POMS "Symptomatic HIV Infection" criteria has resulted in discrimination against women, minorities, and other persons who have HIV-related conditions that are not included in these definitions. The second case alleges that the SSA's decision to develop criteria for listing-level impairments through the POMS and SSRs, rather than through notice and comment rule making, violated the Administrative Procedure Act (5 U.S.C. §§ 551 et. seq.). The suit seeks to have adverse disability decisions that were made using these criteria readjudicated with properly promulgated regulations.

The merits of these cases have not been ruled upon by the respective courts. Both suits, however, have survived requests by the Secretary of Health and Human Services[9] to have the cases dismissed for failure to state a legal claim (143,169)

S.P. v. Sullivan

In 1990, legal service attorneys in New York filed a lawsuit against the SSA stating that the SSA's disability process discriminated against HIV-infected women and other HIV-infected persons who have disabling medical conditions that are not included in the CDC definition of AIDS or the POMS "Symptomatic HIV Infection" criteria (165). The 19 named plaintiffs[10] were denied disability benefits by the State DDS, and many had been denied disability benefits upon reconsideration or by an administrative law judge. As of April 1992, almost all of the plaintiffs had received their disability benefits, beginning from the date they originally claimed they were disabled; yet, as a result of being initially denied benefits by the State DDS, they often waited 1 to 3 years, and up to 5 years, for their claims to be properly decided. As their attorney explained, this meant they had to make numerous trips to her office and the SSA's offices to fight for benefits (112). The experiences of these plaintiffs (see app. I) do not necessarily prove a pattern and practice by the SSA; they do, however, signal that the system for determining disability has not worked for a number of HIV-infected persons.

9 The suit is brought against the Secretary of Health and Human Services rather than the SSA. The Secretary is represented by the U.S. Department of Justice.

10 The complaint has been amended three times and additional plaintiffs added (See 165,166,168).

The Secretary of Health and Human Services contends the arguments made in S.P. v. Sullivan are without merit[11], citing language in the POMS and Social Security rulings that contradict the plaintiffs' assertion that the SSA considers disabled only HIV-infected persons who have AIDS or meet the POMS "Symptomatic HIV Infection" criteria. Both of these documents instruct disability adjudicators that HIV-infected individuals who do not meet these medical disability definitions should be evaluated on the basis of whether their residual functional capacity allows them to work; if they cannot work, they should be awarded disability benefits (167).

The Secretary also correctly asserts there is no statutory requirement that a particular impairment or disease be treated as a listed impairment. The Secretary, and hence the SSA, has discretion to "establish [its] own procedures and evidentiary requirements with respect to the evaluation of claims for benefits under the Social Security Act's disability programs" (167). Furthermore, as stated above, a Person with an HIV-associated condition that is not included in the POMS 'Symptomatic HIV-Infection" criteria is not precluded from being awarded disability.

The plaintiffs in S.P. v. Sullivan concede the SSA is not required to create a Listing for every disabling medical condition, but argue that, once the decision is made to create a Listing for a particular disease like HIV disease, the categories must be created by a rational process that brings forth a reasoned and nondiscriminatory classification. Furthermore, although the Secretary correctly asserts that the SSA's written policies do not

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11 The Secretary objected to the suit, in part, because some of the plaintiffs have not exhausted their administrative remedies--i.e., all of the plaintiffs have not had their disability cases adjudicated through to the Appeals Council (see app. H). This procedural issue is not discussed here because it does not relate to the substantive issue.

discriminate against persons with HIV-associated conditions who do not have AIDS or meet the POMS “Symptomatic HIV Infection” criteria, the plaintiffs believe their experiences demonstrate that in practice these policies are not followed.

Rosetti v. Sullivan

In a second lawsuit against the Secretary of Health and Human Services, the plaintiffs argue that the SSA could not make AIDS or the POMS “Symptomatic HIV Infection” equal to a Listing without issuing regulations in accordance with the Administrative Procedure Act (APA) (5 U.S.C. §§ 551 et. seq). The APA requires an executive agency to publish regulations whenever it issues a substantive rule--rules that "grant rights, impose obligations, or produce other significant effects on private interests” (7). The APA regulatory procedures require agencies to publish notice of their intent to develop new regulations and provide interested persons opportunity to participate in developing regulations through submission of data, arguments, and other views (11). An executive agency can only use rulings or internal manuals, such as the POMS, for interpretive rules that “merely clarify or explain existing law or regulations” (132).

Every Listing in the “Listing of Impairments” was promulgated by regulation. AIDS, however, was established as equivalent to a Listing by a SSR, and the POMS ‘Symptomatic HIV Infection” criteria was only published in the SSA’s internal procedures manual. The issuance of both of these documents did not provide for public input (144).

In a preliminary decision,[12] the court in Rosetti v. Sullivan stated that, if the SSA's POMS and SSRs set forth specific disability criteria for AIDS and HIV-associated conditions that function as Listings, these criteria are substantive rules and these policies should have been implemented by notice and comment rulemaking in accordance with the APA (143). The SSA has stated that individuals whose medical conditions meet the CDC definition of AIDS or the POMS "Symptomatic HIV Infection" criteria have met or equaled the "Listing of Impairments" (224b,226a). Therefore, under the test set forth in the court's opinion, the POMS and SSRs concerning HIV infection and disability are substantive rules. The court stated that a failure to follow APA procedures for substantive rules could render these disability criteria void; however, since the SSA recently proposed new regulations governing disability claims by symptomatic HIV-infected persons, it is not clear what relief the court will grant the plaintiffs.

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12 This decision primarily addressed whether the court had the legal jurisdiction to hear the claim and a hearing on the merits was scheduled for May 11, 1992.

The SSA's Assessment of Residual Functional Capacity and Vocational Ability

The SSA has maintained that, if an HIV-infected person is disabled but does not have AIDS or meet the POMS "Symptomatic HIV Infection" criteria, the DDS adjudicator will determine whether he or she has sufficient residual functional capacity to continue to work. If the adjudicator determines that the claimant does not have sufficient residual functional capacity to work, the claimant will be awarded disability. The SSA is statutorily mandated to ignore whether suitable job openings are available or whether the claimant will be able to get a particular job (42 U.S.C. §§ 423(d), 1382c(B)).

Advocates claim that disability examiners interpret the evaluation of residual functional capacity and ability to work so strictly that their HIV-infected clients are virtually never found disabled at this final stage of the disability determination evaluation. Advocates do not believe that any single factor can account for all of these adverse decisions; however, they note that the vocational assessment is biased against younger individuals because the SSA assumes that only persons of advanced age (55 years old and older) are significantly restricted in their ability to 'adapt and adjust to a new work situation and do work in competition with others" (21 C.F.R. s 404.1563(a)) .13

It is difficult to know whether the evaluation of residual functional capacity and ability to work leads to more denials of benefits to younger HIV-infected individuals than is warranted. It may not be possible to craft a Listing with such specificity that every person who meets the Listing would actually be found disabled if his or her residual functional capacity was

13 The SSA also recognizes that persons approaching advanced age--i.e. , 45 years of age to 55 years of age--may have difficulty adjusting to new work situations (20 C.F.R.§ 404.1563(b)(c)).

evaluated. In other words, some people who are not yet disabled might fall within the medical criteria of a Listing.[14] Therefore, the disability process may appear less rigorous for people who obtain disability because they meet a Listing.

On the other hand, it is difficult to believe that a number of the HIV-infected claimants who were denied disability benefits were not in fact disabled. Indeed, a number of the plaintiffs in the case S.P. v. Sullivan eventually were awarded disability on appeal, indicating they were improperly denied disability benefits by the State DDS examiners. Several reports and statistics also lend some support to the advocates' claims.

Procedural Issues and Evaluation of Residual Functional Capacity

When HIV-infected claimants establish that they are disabled on the basis of a medical impairment, they only need to present fairly objective medical evidence. There is no subjective evaluation of the degree to which a claimant's medical condition affects his or her ability to concentrate, carry out certain activities of daily living, or work. It is these subjective evaluations that may be influenced by the SSA's procedures and policies.

First, one report concluded that several procedures used by the SSA in making disability determinations appear to reduce DDS disability examiners' ability to evaluate cases on an individual basis. The report noted that SSA's use of the "Listing of Impairments" and the instructions in its POMS "clericalizes the task of disability assessment, reducing it to a series of yes-no questions," rather than focusing on each individual's unique problems

14 For example, although all persons with AIDS can receive disability, a recent study of over 1000 persons with AIDS found that persons with AIDS exhibit a range of functional abilities depending upon the stage of the disease and other factors (55). This study is discussed in more detail below.

(188). In addition, initial decisions and reconsiderations by the DDS rely extensively on paper evidence that claimants and their physicians submit; there is no face-to-face meeting with claimants.[15] Disability examiners may, however, have difficulty in properly assessing the degree of residual functional capacity by reviewing only the medical records (187).

Second, advocates argue that the extensive DI quality control system imparts excessive rigidity to disability determinations. In 1980, Congress mandated that the SSA review 50 percent of all DI and concurrent DI/SSI allowances prior to awarding benefits (42 U.S.C. § 421(c)). These "pre-effectuation" reviews of DI disability allowances are designed to ensure that the disability adjudicators make decisions that are consistent with SSA's regulations and policies. The review, however, only focuses on allowances, looking for cases in which disability should not be allowed, rather than on incorrect denials (190). Because this quality review focuses on incorrect allowances, it may cause DDS adjudicators to be too conservative in disability decisions.

Differences Between DDS Determinations and Administrative Law Judge Decisions

Evidence that the disability adjudicators might be overly conservative in their determinations also comes from the statistic that initial denials of disability benefits by DDS adjudicators have been reversed by administrative law judges in approximately two out of three cases (42,188). In order to explore the reasons for this disagreement in disability determinations, the

15 The Social Security Reform Act of 1984 requires the SSA to conduct demonstration projects in which claimants would be offered the opportunity to have a personal meeting with the disability determination officer prior to an initial unfavorable decision. The SSA instituted demonstration projects in 10 States between 1986 and 1988 (188).

General Accounting Office reviewed 242 disability cases in which administrative law judges reversed the SSA's initial disability determinations. The General Accounting Office found that in most cases the reversal stemmed from the fact that the DDS examiner overestimated the claimant's residual functional capacity (42). Whereas SSA disability examiners had determined that 54 percent of claimants could do medium or heavy work, the administrative law judges concluded that only 1 percent of these people could do such work. Conversely, administrative law judges determined that 71 percent of the claimants could do only sedentary work, if that, while the SSA disability examiners concluded only 1 percent of the claimants were so limited in functional capacity (187).

Most of the claimants in the sample suffered from back disorders, lung disease, diabetes, and anxiety- -conditions that cause decrements in residual functional capacity that are subjectively measured. Further study is needed to determine whether similar findings would apply specifically to HIV-infected claimants. It is of note that certain common symptoms of HIV-infected patients, such as fatigue, chronic diarrhea, night sweats, gynecological conditions, undefined pain, or early HIV dementia, also cause decrements in residual functional capacity that are subjectively measured (240).

SSA's Implementation of Federal Court of Appeals Decisions

The SSA has also been accused of failing to implement certain decisions of the U.S. Court of Appeals for the Second Circuit (hereinafter Second Circuit), thereby making it more difficult for certain claimants to obtain disability.[16] In Stieberger v. Sullivan (172) the court found the SSA had

16 The deliberate failure by an executive agency to adopt Appeals Court decisions is known as "non-acquiescence" (172).

failed to issue any SSRs implementing Second Circuit decisions regarding disability determinations, and in at least four areas, there was evidence the SSA's inaction led to a "system-wide pattern of mistaken adjudication."[17] For example, in a series of decisions beginning in 1981, the Second Circuit held that a treating physician's opinion on the diagnosis and nature and degree of disability should be binding on the SSA's disability adjudicators unless contradicted by substantial evidence. The courts reasoned that the treating physician is usually most familiar with the claimant's medical condition (172). The SSA did not, however, explicitly adopt this policy until ordered by the court in 1986, and the final version of the instructions were implemented in 1988 (153). The SSA also failed to implement a Second Circuit decision instructing the SSA that a disability decision could not be based on a report that is issued after the claimant's hearing before an administrative law judge, unless the claimant has the opportunity to cross-examine the authors of the report (172). This decision guaranteed the claimant the opportunity to rebut evidence in the report. In addition, the SSA failed to implement Second Circuit decisions that established claimants with good work records were entitled to substantial credibility when they claimed they were unable to work because of a disability (172).

In those cases where the SSA applied different policies than the Federal courts, claimants who could pursue their claims *to* the Federal courts were more likely to receive disability (172). Not only would the outcome of certain claimants' disability determinations depend upon their ability to

17 The SSA did not formally reject Second Circuit decisions, and therefore in order to prove non-acquiescence the plaintiffs needed to offer evidence of individual disability cases that were adversely affected by the SSA's failure to implement a Second Circuit holding (172).

continue to appeal adverse SSA decisions to the Federal courts[18], but the SSA's policy also led to excessive delay in disability determinations as claimants went through lengthy appeals process (see app. H).[19]

During the course of the litigation, the SSA issued several policy statements, and finally regulations in 1990, concerning the proper treatment of Federal Court of Appeals decisions.[20] The SSA, however, never published opinions explaining to its administrative law judges and State disability examiners why the SSA did not need to adopt certain Second Circuit decisions. The SSA decided that publishing such explanations would:

> (2) . .. creat[e] the appearance of "whitewash," i.e. , repeated claim of no real conflict between SSA and the court despite the obvious facts that the conflict was litigated to the circuit court level and produced a decision rejecting the [SSA's] arguments and reversing [SSA's] decision; and
>
> (3) potentially provide evidence for class actions seeking writs *of mandamus*[21] to compel the [SSA] to follow policies she has adopted. Stieberger v. Sullivan (172)

The court in Stieberger v. Sullivan (172) concluded that the SSA's failure to implement the Second Circuit's rulings may have led to inappropriate denials of disability benefits. In a proposed settlement of the case, the SSA has agreed to distribute Second Circuit disability decisions to

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18 By one estimate, only 6 percent of persons who are* initially denied disability appeal to the level of the circuit courts (128).

19 According to the court, a policy of non-acquiescence violated Congressional intent and the Constitution's Equal Protection Clause (172).

20 The court found that these policy statements and regulations left too much "room for non-acquiescence" and further noted that "each significant modification of agency policy came shortly before a major stage of this case" (172).

21 In a *writ* of mandamus, a plaintiff requests a Federal court to compel an executive agency to perform a non-discretionary duty owed to the plaintiff (18).

SSA's administrative law judges and State disability examiners and to instruct the administrative law judges and examiners to apply the decisions (173). In addition, a number of adverse disability decisions may be reviewed (44,93,128). The proposed settlement has yet to be approved by the court, and the impact the decision will have in other judicial circuits is not yet known. The case is instructive because it demonstrates how some of SSA's internal procedures and policies, which are not included in regulations and SSRs, may make it more difficult for claimants to obtain disability.

THE *SSA's* NEW PROPOSED REGULATIONS FOR HIV INFECTION DISABILITY

In December of 1991, the SSA published a ruling and proposed regulations that create a new Listing for HIV infection (56 FR 65498, 65702). The "HIV Infection Listing" contains medical and functional criteria for determining disability for all persons with HIV infection (see app. J) and these criteria will be subject to public comment before being finally incorporated into the SSA's "Listing of Impairments." Because the SSA issued a ruling as well as proposed regulations, the new "HIV Infection Listing" is presently being used and will be amended if the final regulations differ from the proposed "HIV Infection Listing." The SSA also issued a new ruling and proposed regulations that allow the field offices to award presumptive disability to all persons who meet the new "HIV Infection Listing" (56 FR 65682, 65714). This could increase the number of HIV-infected persons awarded presumptive disability benefits by the field offices; however, according to the SSA, the new "HIV Infection Listing" will not increase the overall number of HIV-infected persons that are awarded disability (56 FR 65702)(126).

The new “HIV Infection Listing” combines the 1987 CDC definition of AIDS and the POMS “Symptomatic HIV Infection” criteria and also adds a number of other HIV-associated conditions, including many of the conditions that are more often found in HIV-infected women and injection drug users. The new "HIV Infection Listing” demonstrates that the SSA will no longer assume that every person who meets the CDC definition of AIDS is disabled. HIV-infected individuals with $CD4^{+}$ lymphocyte counts below 200 cells/mm^{3} or Kaposi’s sarcoma will not be granted disability benefits unless they also document that they have marked functional limitations.

The SSA has received a large number of comments on their new "HIV Infection Listing.” A number of commentators are supportive of the SSA’s decision to expand the number of HIV-associated conditions that will be considered in determining whether an HIV-infected claimant meets a Listing. The commentators are dismayed, however, by the complexity of the Listing, and more importantly, by the use of the new functional limitation tests. In particular, they question why the SSA is able to develop strictly medical disability criteria for every non-psychiatric Listing in the “Listing of Impairments” except for the new ‘HIV Infection Listing.” Under the "HIV Infection Listing,” a number of HIV-infected claimants must document both medical impairments and marked functional limitations.

The HIV Infection Listing

Under the SSA's new "HIV-Infection Listing," all adult claimants[22] who have one of the AIDS-defining conditions included in the 1987 CDC definition of AIDS (except Kaposi's sarcoma) will be considered disabled (see app. J). Adult claimants who show evidence of HIV infection and any of the following additional conditions will also be considered disabled:

- Candidiasis, disseminated (beyond the skin, urinary tract, intestinal tract, or oral or vulvovaginal mucous membranes) ;
- Herpes simplex virus infection of the gastrointestinal tract or encephalitis;
- Extraintestinal strongyloidiasis; or
- Nocardiosis;
- Invasive carcinoma of the cervix, International Federation of Gynecology and Obstetrics (FIGO) Stage II and beyond;[23]
- Anal squamous cell carcinoma;
- Hodgkin's disease;
- Cardiomyopathy;
- Nephropathy.[24]

HIV-infected adult claimants with HIV-associated conditions, other than those noted above, can meet the SSA's "HIV Infection Listing" only if they document one of the following medical conditions:

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22 The "HIV Infection Listing" contains separate criteria for children; however, these criteria are not discussed herein.

23 Stage II cervical cancer has progressed beyond the cervix. This is a different Listing, and arguably easier to meet, than the SSA's current medical Listing for cervical cancer, which requires that the cancer be: 1) inoperable and not controlled by existing therapy; 2) recurrent after total hysterectomy; or 3) removed by total pelvic exenteration (20 C.F.R., Part 404, Subpt. P., App. 1, Sec. 13.25).

24 Cardiomyopathy and nephropathy were already included in the SSA's "Listing of Impairments" (20 C.F.R., Part 404, Subpt. P., App. 1, Sees. 4.02, 4.04, 4.05 (cardiomyopathy) and 6,02, and 6.06 (nephropathy), so their inclusion in the SSA's "HIV Infection Listing" is as a cross-reference, not as an addition to the Listings.

- A $CD4^+$ lymphocyte count less than or equal to 200 cells/$m.m^3$; or

- Documentation of one or more of the following persistent and/or resistant to therapy:
  1) Pneumonia;
  2) Pulmonary tuberculosis;
  3) Bacterial or fungal sepsis;
  4) Meningitis;
  5) Septic arthritis;
  6) Endocarditis;
  7) Peripheral neuropathy;
  8) Kaposi's sarcoma; or

a Two or more of the following persisting over a 2-month period:
  1) Anemia (hematocrit value less than 30 percent);
  2) Granulocytopenia;
  3) Thrombocytopenia;
  4) Documented fever;
  5) Weight loss >/= 10 percent of baseline;
  6) Mucosal (including vulvovaginal) candidiasis;
  7) Oral hairy leukoplakia;
  8) Recurrent or chronic herpes *zoster;*
  9) Persistent dermatological conditions such as eczema, or psoriasis;
  10) Persistent, unresponsive diarrhea;
  11) Persistent or recurring documented sinusitis.

In addition, the claimant must document two of the following functional impairments:

1) Marked restriction of activities of daily living;
2) Marked difficulties in maintaining social functioning;
3) Marked difficulties completing tasks in a timely manner due to deficiencies in concentration;
4) Repeated episodes of decompensation, averaging three times a year or once every 4 months, lasting 2 weeks or more per episode, and which cause deterioration in condition.

The SSA also provided its adjudicators with special instructions for evaluating disability in HIV-infected individuals. The SSA wrote that HIV-infected individuals may suffer from anxiety, depression, apathy, and cognitive impairment, and that these mental impairments should be documented with medical evidence and evaluated under the appropriate Listing in the "Listing of Impairments" and/or be evaluated in determining the individual's

residual functional capacity (56 FR 65708). The SSA also noted that, on occasion, therapy for HIV infection may result in long-term or permanent adverse affects.

General Criticisms of the "HIV Infection Listing"

The inclusion of additional HIV-related illnesses in the "Listing of Impairments" comes at the price of more complexity. Critics have stated that the "HIV Infection Listing" has a "Chinese menu" type layout which requires different combinations of criteria depending upon the claimant's symptoms (30,59) (see app. J). It is arguably one of the most complicated Listings in the "Listing of Impairments." The complexity of the definition, critics argue, may delay processing of claims. Quick processing of claims is important because persons with severe manifestations of HIV infection, especially those persons whose health is already compromised by the effects of injection drug use, may already be close to death.

A number of groups are critical of SSA's decision to use a functional limitations test in a Listing because the test requires additional documentation and subjective assessment. The "Listing of Impairments" is designed to facilitate a finding of disability by allowing a disability determination to be made on the basis of fairly objective medical evidence consisting of: 1) symptoms (claimant's own perception of his or her physical or mental impairments) ; 2) signs (anatomical, physiological, or psychological abnormalities that can be demonstrated by medically acceptable clinical techniques); and 3) laboratory findings (226). The new "HIV Infection Listing" relies heavily on documentation of functional limitations,

essentially merging part of the residual functional capacity analysis into a medical listing[25] and thereby diminishing the advantage (to the claimants) of the Listings.

Moreover, the SSA has not explained why certain HIV-related conditions are disabling per se, whereas persons with other HIV-related conditions must also demonstrate functional limitations. An HIV-infected person with *Pneumocystis carinii* pneumonia or another opportunistic infection is considered disabled once he or she documents a single incidence of the disease. HIV-infected persons with serious illnesses, such as bacterial pneumonia, pulmonary tuberculosis, endocarditis, or bacterial sepsis (which often require hospitalization and may be fatal), are only considered disabled if they can also document that their illness is persistent and/or resistant to therapy and that they have marked functional limitations.

The critics contend that the SSA could have developed purely medical criteria to determine when certain HIV-associated conditions are disabling. The American Medical Association has testified that conditions such as endocarditis, pulmonary tuberculosis, Kaposi's sarcoma, and bacterial pneumonia have a high mortality rate in HIV-infected individuals and that HIV-infected persons with these conditions should not also have to prove functional limitations (24). The American Medical Association also argues, that HIV-infected persons with $CD4^+$ lymphocyte counts below 200 cells/mm^3 should be considered disabled because they are likely to succumb to serious opportunistic illnesses within a short period of time.

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25 The residual functional capacity assessment focuses on the activities a person can perform, while the functional limitation assessment examines what activities a person cannot perform. Nonetheless, similar evidence is needed to make each of these assessments.

Advocates and physicians also claim it is possible to develop medical criteria that will be highly predictive of disability, even for HIV-associated conditions that are generally less severe. The National Association of People with AIDS, for example, has proposed that chronic anemia, which is quite prevalent in persons who take AZT, is disabling if an HIV-infected person has any of the following conditions:

- a persistent hemoglobin of less than 10.0 grams per deciliter;
- a hematocrit of less that 30.0 volume percent (regardless of AZT intake);
- the need for blood transfusions due to anemia more often than twice yearly (59) .

HIV-infected persons with chronic anemia who meet these criteria would not have to meet the SSA's functional limitation test.

In sum, the critics argue that HIV-infected individuals could more easily document their disability and obtain benefits if the SSA developed purely medical criteria for most HIV-associated conditions. The alternative the SSA has chosen--i.e. , to require that certain HIV-infected claimants demonstrate medical conditions plus functional limitations--may make it more difficult for certain HIV-infected claimants to document their disabilities.

The need to document functional limitations in two separate areas may be particularly difficult for HIV-infected persons who do not have a regular physician who can attest to their functional limitations on the basis of their treatment history. An official from SSA noted that a physician's opinion about functional limitations under the 'HIV Infection Listing,'"while not definitive, will be given considerable weight (46). Documentation of functional limitations, however, imposes an additional burden on the physician that goes beyond making a medical diagnosis. Many poor claimants receive

their medical care in hospital emergency rooms and busy public clinics and do not have regular physicians who will be able to adequately document their functional limitations (6,91).[26]

The Functional Limitation Test

The functional limitation tests have been the most strongly criticized part of the SSA's new "HIV Infection Listing" (191). The POMS "Symptomatic HIV Infection" criteria contained a functional limitation test,[27] but it was much less stringent than the new SSA functional limitation test, despite the fact that the new "HIV Infection Listing" includes many of the same conditions included in the POMS "Symptomatic HIV Infection" criteria. In other words, the SSA may have made it more difficult for certain individuals with HIV-related conditions to receive disability.[28]

The functional limitation test of the new "HIV Infection Listing" requires that claimants demonstrate marked limitations in <u>two</u> functional areas. The SSA explains that a claimant has marked restrictions in activities

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26 The SSA does provide consultative examinations if a person does not have sufficient medical evidence to document a claim for disability (95) . From this medical evidence the DDS adjudicator might be able to ascertain functional limitations; however, the claimant must wait until the SSA has ascertained that it cannot obtain enough evidence and has scheduled a consultative exam.

27 The functional limitation test under the POMS "Symptomatic HIV Infection Listing" only required that a claimant demonstrate marked restriction in activities of daily living <u>or</u> deficiencies of concentration, persistence, or pace.

28 The new "HIV Infection Listing" has a stricter functional limitation test than the POMS "Symptomatic HIV Infection" criteria. The new "HIV Infection Listing" does not require, however, that an HIV-infected person have both a $CD4^+$ lymphocyte count at or below 200 cells/mm^3 *and* one or more HIV-associated conditions. Nonetheless, HIV-infected persons who would have met the "POMS Symptomatic HIV Infection" criteria must now document more extensive functional limitations.

of daily living if most *of the time* the claimant is unable to perform activities of daily living, such as household chores, grooming and hygiene, taking public transportation, or paying bills. The claimant is markedly restricted in social functioning if *most of the time* the claimant cannot interact appropriately and communicate effectively with others. Marked difficulties in completing tasks in a timely manner due to concentration deficiencies means that, *most of the time,* the claimant is unable to sustain concentration, persistence, or pace to permit timely completion of tasks found in work settings. To meet the final functional limitation test- -repeated episodes of decompensation- -the claimant must document repeated episodes of deterioration or decomposition in work or work-like settings, averaging three times a year, lasting 2 weeks or more per episode, and which cause his or her condition to deteriorate (e.g., repeated hospitalizations) (56 F.R. 65496).

The presence of two or more of these functional limitations establishes that the person cannot perform any substantial gainful activity (46). The functional limitation test is therefore used to establish the claimant's disability status and his or her medical condition is needed to establish that there is an underlying organic cause for the dysfunction (46). This distinguishes the "HIV Infection Listing" from most other medical listings for disability which do not require that claimants extensively document their ability to engage in personal hygiene, interact, or perform in the workplace.[29]

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29 To the extent a Listing contains functional tests, these are usually quite general (e.g., documentation of interference with daily activities caused by neurological impairments or by restrictions in mobility caused by musculoskeletal impairments (20 C.F.R. Part 404, Subpt. P, App. 1, Sec. 11.01, 1.01)).

The functional limitation test included in the SSA's "HIV Infection Listing" is derived from the functional limitation test included in the Mental Disorders section of the "Listing of Impairments" (20 C.F.R. Subpt. P, App. 1, Sec. 12.00). A functional limitation test is appropriate for evaluating psychiatric illness because it is often difficult to judge the severity or disabling impact of these conditions using typical medical diagnostic techniques. The functional limitation test used for evaluating the severity of disability due to mental impairments may, however, be ill-suited for evaluating the severity of disability due to physical impairments.

For example, one of the functional limitation tests in the "HIV-Infection Listing" requires that the claimant demonstrate repeated episodes of decompensation or deterioration in work or work-like settings. Decompensation is a psychological term which means "progressive loss of normal functioning in favor of psychotic behavior" or "disorganization of the personality under stress" (31a). For the "Mental Disorders Listing," a person can establish decompensation by documenting repeated failure to adapt to stressful circumstances that cause the person to withdraw from the situation, coupled with a difficulty in maintaining activities of daily living or maintaining concentration, persistence, or pace (20 C.F.R. Part 404, Subpt. P, App. 1, Sec. 1200(C)). It is unclear how a person with a physical impairment would demonstrate decompensation.

The SSA has responded to this problem by establishing different criteria for decompensation for the "HIV Infection Listing." Repeated episodes of decompensation can be demonstrated by at least three hospitalizations or absences from work per year lasting at least 14 days each. The decompensation test used in the "HIV Infection Listing" is, therefore, much less flexible than the decompensation test used in the 'Mental Disorders Listing."

In the 'Mental Disorders Listing," impairment of social functioning is demonstrated by a history of altercations, fear of strangers, avoidance of interpersonal relationships, social isolation, and a lack of awareness of others' feelings (20 C.F.R. Subpt. P., App. 1 Sec. 1200 (C)). For the "HIV Infection Listing," impairment of social functioning is indicated by an inability to communicate and interact with people. This may not be a very sensitive test for determining disability in HIV-infected individuals. As noted by attorneys for HIV-infected clients, many very ill people with HIV infection are able to maintain close contacts with family and friends; indeed, social interaction may be an 'important and life-sustaining activity" (170).

Advocates for persons with HIV infection argue that having different definitions for the same functional limitation test may cause confusion. They are also critical of the fact that a person must document functional limitations in two separate areas. They argue that many HIV-infected people will be unable to work if they show a marked functional limitation in just one area. For example, to demonstrate marked restrictions in activities of daily living, one must show that most of the time he or she can't groom or perform personal hygiene, pay bills, or perform other household chores. State DDS disability examiners in New York interpret 'marked" to mean that the person is unable to perform the activity approximately 80 percent of the time (111) . This level of disability has been characterized by advocates and physicians' groups as being close to a nursing home level of functioning (111). A person is likely to lose his or her job prior to reaching this level of restriction in activities of daily living (6).

Similarly, to demonstrate marked difficulties in completing tasks, one must document that most of the time he or she cannot complete work tasks. One would not expect a person who is unable to complete work tasks more than 50

percent of the time to be able to perform in the workplace, and it therefore seems unnecessary to require that person to document another functional limitation (170). One must remember that these claimants will already have documented that they are HIV-infected and that they are either severely immunocompromised (i.e., they have a $CD4^+$ lymphocyte count at or below 200 cells/mm^3) or suffer from one or more HIV-associated conditions that are persistent and/or resistant to therapy.

One study has indicated that the ability to perform activities of daily living may not be the best predictor of disability in persons with AIDS and, presumably, in other persons with symptomatic HIV-infection. A recent assessment of disability in 1024 persons with AIDS from various areas--Atlanta; New Jersey; Seattle; Miami; Ft. Lauderdale; New Orleans; Dallas; and Nassau County, New York[30]--found that, despite the fact that approximately 50 percent of the sample could not work and a quarter needed some assistance, only 2.6 percent had a very difficult time bathing or dressing, and that close to 60 percent could do heavy housework and walk up 10 steps. Even among respondents who had been hospitalized within 3 months of the interview, only 4.5 percent said they could not bathe or dress themselves and 40 percent could do heavy housework and walk up 10 steps (55).[31]

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30 The authors caution that the sample was not randomly selected and that participants tended to be those persons who were more connected to the medical service delivery system and may have included a disproportionate number of persons who were less physically or mentally impaired. In addition, the study consisted of a majority of "white" males, a significant number identifying themselves as homosexuals (55).

31 The overwhelming majority of AIDS patients who had significant difficulty in bathing, washing, and doing heavy household chores, however, died within 11 months (55).

The authors' analysis of the data led them to conclude that the ability to engage in activities of daily living is not necessarily the best measure of the degree of impairment, which they defined as limitations in functioning of bodily organs or systems. The authors concluded that the ability to do strenuous activities may be a better measure of the degree of physical impairment and that the degree of physical impairment was strongly related to ability to work. In addition, they found that when one controlled for physical impairment, HIV-related symptoms and depression "had consistent effects on disability,"[32] and in particular, persistent symptoms such as diarrhea or losing sleep due to night sweats may limit one's ability to carry out daily activity roles, such as employment (55). In other words, the authors imply that disability determinations for HIV-infected persons should focus primarily on the nature of conditions and symptoms related to HIV infection and the impact these conditions and symptoms have on a person's ability to consistently perform daily life roles, such as occupational roles.

The Impact of the SSA's New "HIV Infection Listing" on Women

The SSA added cervical cancer to the "HIV Infection Listing" so that HIV-infected women with Stage II cervical cancer- -cancer that has progressed beyond the cervix- -need not document functional limitations in order to receive disability. Gynecologists and other groups contend that a woman may be disabled before her cancer progresses to Stage II, and recommend that disability not be limited to Stage II (6,170).

32 Disability was defined as limitations in performing important social roles, such as occupational roles (55).

The SSA also added vulvovaginal candidiasis and genital herpes to the "HIV Infection Listing"; however, to meet the Listing an HIV-infected woman must document that these conditions persist *continuously* over a 2-month period and that she has marked functional limitations.

Pelvic inflammatory disease (PID) is not included in the "HIV Infection Listing," nor are two other serious gynecological diseases that the American Medical Association claims may occur more frequently in HIV-infected women: chronic genital ulcers and recurrent herpes (24). With respect to PID, the SSA did instruct its adjudicators that this condition, in combination with other HIV-associated conditions, may be disabling and that the adjudicators should determine whether the conditions of a claimant with pelvic inflammatory disease *equals* the "HIV Infection Listing," even though the condition is not included in the Listing.[33]

Advocates argue that HIV-infected women who document recurrent episodes of these gynecological conditions should be awarded "disability without having to also document marked functional limitations. They argue that an HIV-infected woman is disabled if she has had three or more episodes of PID, or one episode of PID that is resistant to therapy and requires hospitalization and/or surgery (59). Similarly, they contend that recurrent herpes lesions are disabling if the lesions recur more often than once every 8 weeks and if the lesions are incompletely suppressed despite continuous therapy (112). Finally, they question why SSA excluded PID and genital ulcers from the "HIV Infection Listing," since HIV-infected women with these conditions would also need to document functional limitations in order to meet the Listing.

33 These instructions are similar to the instructions given in the March 1991 program circular that the SSA issued on evaluating disability in women (228).

The SSA would likely respond that the DDS adjudicators have the discretion to award a woman disability if her gynecological conditions are equally severe to the conditions contained in the 'HIV Infection Listing." Moreover, if a disabled woman does not meet the "HIV Infection Listing," she can still receive disability at a later step in the disability determination process. At the heart of the controversy over SSA's disability evaluations, however, is the question of whether the DDS examiners exercise this discretion or whether they primarily rely on stated disability criteria. With respect to SSA's second point, advocates argue that because HIV infection is ultimately fatal, the disability process should be simplified so that benefits are awarded at the earliest stage possible.

Presumptive Disability and HIV Infection

On December 18, 1991, the SSA also issued a notice of proposed rulemaking and a final rule to revise its regulations governing presumptive disability under SSI (56 F.R. 65682, 65714). Under the final rule, field offices will no longer be limited to awarding presumptive disability to persons with CDC-defined AIDS (56 F.R. 65682). Instead, the field offices will be able to award presumptive disability benefits to all HIV-infected claimants who meet the SSA's new "HIV Infection Listing." The personnel in the field offices are not trained to evaluate medical evidence, so they will send checklists to the treating physicians of SSI claimants who allege HIV infection. The checklist itemizes the HIV-associated conditions and functional limitations that meet the SSA's new "HIV Infection Listing" (see app. K). If the claimant's physician verifies that the claimant meets the "HIV Infection Listing," the field office will award the claimant presumptive

disability benefits (56 F.R. 65714). In the event that the field office does not award presumptive disability benefits, the DDS offices may award presumptive disability benefits when they find sufficient evidence to conclude that the person is likely to be disabled (56 F.R. 65714).

When the CDC definition of AIDS was used for presumptive disability determinations, the field office could confirm the case with a phone call to a physician or other health care provider because the medical community also uses the CDC definition of AIDS. In contrast, health care providers may not be familiar with the "HIV Infection Listing" because it will not be used in clinical care. The SSA has responded to this problem by devising a checklist that will be sent to physicians who will verify that their patients meet the "HIV Infection Listing." This procedure should enable the field offices to continue to award presumptive disability to a larger group of HIV-infected individuals. In addition, by using a standard form for all HIV-infected claimants, the SSA hopes to simplify presumptive disability determinations.

However, there is some concern that the confusion caused by the new procedure will outweigh its benefits. The physician is expected to fill out the presumptive disability form and mail it back to the field office; yet, many State DDS offices also send forms to physicians in order to gather information on specific impairments, such as AIDS.[34] If a physician first receives the field office presumptive disability form and then several days later receives a more detailed medical form from the State DDS, the physician may only fill out one form because he or she believes this is sufficient, or because of time constraints (182a). It may be unreasonable to expect

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34 Although the SSA did not know how many State DDS offices have such a system, an official said this system is not unusual, especially in States with major metropolitan areas (46).

physicians who are treating a large number of HIV-infected patients to fill out two similar forms on the same patient, possibly requiring the physician to review the patient's record twice (29).

If the treating physician only fills out the field office form, believing this to be sufficient, then the State DDS either will be left with little information or will have to go back to the physician to remind him or her to fill out the DDS form. One State DDS has suggested that the physician should only be expected to fill out the State DDS form. The DDS can then award presumptive disability benefits if warranted and proceed with the final disability determination (182a). This alternative would ensure that the one document received from the physician would provide all the information that is needed.

SUMMARY

The debate over the CDC definition of AIDS arose in large part because the case definition was being used in Social Security disability determinations. Advocates for HIV-infected women and injection drug users have presented numerous examples of their very ill clients who were denied disability by SSA. Some of these clients were often awarded disability on appeal, providing support for the advocates' position that the clients were wrongly denied disability. The advocates claim that the use of the CDC definition of AIDS in disability determinations biased the DDS adjudicators against HIV-infected individuals who did not have an AIDS-defining illness, a claim the SSA strongly denied. One court has indicated, however, that SSA's failure to issue regulations making AIDS and the POMS "Symptomatic HIV Infection" criteria equal to a Listing may have violated the Administrative Procedure Act.

It is difficult to sort out why seemingly deserving HIV-infected claimants were being denied disability. They may have been the most egregious cases, or they may be indicative of a larger problem warranting further investigation. One cannot discern the way in which claims were decided from SSA statistics on allowances and denials. However, the statistics do indicate that persons who had AIDS or who met the POMS "Symptomatic HIV Infection" criteria were significantly more likely to receive disability benefits. Moreover, several reports about the SSA's procedures for determining residual functional capacity, including concern about the quality control system and the differing assessments of residual functional capacity among DDS examiners and administrative law judges, may warrant further investigation. Finally, it is of note that the Second Circuit court opinions that the SSA failed to incorporate into its disability process were decisions that appeared to facilitate a finding of disability for certain claimants.

With the new "HIV Infection Listing," the SSA has clearly demonstrated that changes in the CDC definition of AIDS will not necessarily be incorporated into the disability process and that all persons who meet the proposed CDC definition of AIDS will not automatically receive disability. Nonetheless, people with the AIDS-defining conditions included in the 1987 case definition (except Kaposi's sarcoma) will continue to be judged disabled on the basis of their medical condition alone, whereas HIV-infected individuals with other serious diseases, including conditions that may result in hospitalization and death, will also need to prove that they have functional limitations in two of the following areas: activities of daily living, social functioning, difficulties in completing tasks, and repeated episodes of deterioration or decompensation in work or work-like settings.

The new debate over SSA's disability determinations now centers on whether the functional limitation test included in the new "HIV Infection Listing" is reasonable. Critics contend that the SSA should have developed strictly medical criteria for determining disability for persons with any one of the HIV-associated conditions included in the Listing. A number of medical experts and persons who are knowledgeable about HIV infection insist that the functional limitation test is too stringent, especially the requirement that an HIV-infected claimant must document two out of four possible functional limitations. HIV-infected persons may be unfairly barred from obtaining disability because they are unable to document functional limitations to this degree. It may be especially difficult for poor and uninsured HIV-infected claimants to document marked functional limitations in two separate areas because they do not have a continuing relationship with a single physician. The functional limitation tests appear to demand detailed documentation involving physician input.

The debate over the SSA's disability determinations for people with HIV infection is probably not over, as the overwhelming number of public comments on the SSA's new "HIV Infection Listing" demonstrate. The impact that the new "HIV Infection Listing" will have on HIV-infected women and injection drug users is not yet known. The SSA claims, however, that the new "HIV Infection Listing" will not increase the overall number of HIV-infected individuals who obtain disability.

The new "HIV Infection Listing" does separate the debate on the SSA's disability determinations for persons with HIV from the debate about the appropriate surveillance case definition of AIDS. The CDC's definition of AIDS cannot be expected to adequately serve both the purposes of surveillance and disability.

Appendix A--Glossary of Acronyms and Terms

Abbreviations

ADA	--Americans With Disabilities Act of 1990 (Public Law 101-336)
AHCPR	--Agency for Health Care Policy and Research (Public Health Service)
AIDS	--acquired immunodeficiency syndrome
APA	--Administrative Procedure Act
ARC	--AIDS-related complex
AZT	--azidothymidine (now zidovudine)
CAP	--College of American Pathologists
CDC	--Centers for Disease Control (PHS)
CFR	--Code of Federal Regulations
CNS	--central nervous system
CRS	--Congressional Research Service (U.S. Congress)
CSTE .	--Conference of State and Territorial Epidemiologists
DDS	--State Disability Determination Service (SSA)
DHHS	--U.S. Department of Health and Human Services
DI	--Social Security Disability Insurance
ELISA	--enzyme-linked immunosorbant assay
FR	--Federal Register
FY	--fiscal year
GAO	--General Accounting Office (U.S. Congress)
HIV	--human immunodeficiency virus
HPV	--human papilloma virus
HRSA	--Health Resources and Services Administration (DHHS)
HTLV - III	--human T-cell lymphotropic virus, type 111 (now referred to as HIV)
HUD	--U.S. Department of Housing and Urban Development

LAV	--lymphadenopathy-associated virus (now referred to as HIV)
MACs	--Multicenter AIDS Cohort Study
NIAID	--National Institute of Allergy and Infectious Diseases (NIH)
NIH	--National Institutes of Health (PHS)
OR	--Office of Research (Health Care Financing Administration)
OTA	--Office of Technology Assessment (U.S. Congress)
PCP	--pentachlorophenal
PHS	--Public Health Service (DHHS)
PID	--pelvic inflammatory disease
POMS	--Program Operations Manual System (SSA)
SSA	--Social Security Administration (DHHS)
SSI	--Supplemental Security Income
SSR	--Social Security Ruling
U.S. C.	--United States Code

Terms

NOTE: # - AIDS-defining condition

Access: Potential and actual entry of a population into the health care delivery system.

Activities of daily living: Activities related to personal care, including bathing, dressing, getting in and out of bed or a chair, using the toilet, and eating.

Acquired immunodeficiency syndrome (AIDS): See AIDS.

Administrative law judge: One who presides at an administrative hearing, with power to administer oaths, take testimony, rule on questions of evidence, and make agency determinations of fact.

African Americans: Americans having origin in any of the black racial groups in Africa.

AIDS (acquired immunodeficiency syndrome): A condition, caused by infection with the retrovirus human immunodeficiency virus (HIV), in which the primary defect is an acquired, persistent, and profound functional depression in cell-mediated immunity; this depression often leads to infections caused by micro-organisms that usually do not produce infections in individuals with normal immunity (e.g. , Pneumocystis *carinii* pneumonia) or to the development of rare cancers (Kaposi's sarcoma, B-cell non-Hodgkin's lymphoma) that occur more frequently in immunocompromised individuals than in persons with normal immunity. HIV infection can be transmitted from one infected individual to another by means that include the sharing of a contaminated intravenous needle and engaging in unprotected sexual intercourse (i.e., intercourse without the use of a condom) with an infected person. See also CDC's case definition of AIDS.

AIDS-defining condition: In the Centers for Disease Control's (CDC) 1987 surveillance case definition of AIDS, a person who has any of the following 23 indicator conditions--and who meets other condition-specific criteria specified in the definition (e.g., an age requirement, a requirement for a positive HIV test)--is considered to have AIDS:

1) candidiasis of bronchi, trachea, or lungs;
2) candidiasis, esophageal;
3) coccidiodomycosis (disseminated or extrapulmonary) ;
4) cryptococcosis (extrapulmonary) ;
5) cryptosporidiosis (chronic intestinal, with diarrhea of more than l-month's duration);
6) cytomegalovirus disease of an organ other than the liver, spleen, or nodes;
7) cytomegalovirus retinitis (with loss of vision)
8) HIV encephalopathy;
9) herpes simplex virus infection causing chronic ulcers or bronchitis, pneumonitis, or esophagitis;
10) histoplasmosis (disseminated or extrapulmonary) ;
11) isosporiasis (chronic intestinal of more than l-month's duration);

12) Kaposi's sarcoma;
13) lymphoma, noncleaved small cell (Burkitt's or non-Burkitt's);
14) lymphoma, immunoblastic or large cell;
15) lymphoma, primarily in brain;
16) *Mycobacterium avium complex* or *M. kansasii* (disseminated or extrapulmonary) ;
17) *Mycobacterium tuberculosis* (disseminated or extrapulmonary) ;
18) *Mycobacterium,* other species or unidentified species (disseminated or extrapulmonary);
19) Pneumocystis *carinii* pneumonia;
20) progressive multifocal leukoencephalopathy;
21) *Salmonella* septicemia, recurrent;
22) toxoplasmosis of the brain;
23) HIV wasting syndrome.

These 23 conditions are strongly associated with severe immunodeficiency, occur frequently in HIV-infected individuals, and cause serious morbidity or mortality. Some of these conditions, when diagnosed definitively or presumptively (i.e., on the basis of clinical signs and symptoms), are considered indicators of AIDS only if a patient has a positive test for HIV, but some of these conditions (e.g., *Pneumocystis carinii* pneumonia when diagnosed definitively) are considered indicators of AIDS even if a patient has a negative test for HIV.

In children (under 13 years old), additional AIDS-defining conditions apply that do not apply in adults or adolescents:
1) bacterial infections, serious and multiple or recurrent;
2) lymphoid interstitial pneumonia or pulmonary lymphoid hyperplasia.

AIDS dementia: A form of dementia that is due to brain infection by HIV. AIDS dementia is an AIDS-defining condition (HIV encephalopathy) if severe (e.g. , interfering with occupation or activities of daily living). See dementia.

AIDS-related complex (ARC): A complex of signs and symptoms representing a less severe form of HIV infection than classic AIDS, characterized by chronic generalized lymphadenopathy, recurrent fevers, weight loss, minor alterations in the immune system, and minor infections. The term was used for a period of time by the medical community for persons infected with HIV and experiencing HIV-associated conditions and symptoms that were not included in the CDC definition of AIDS. Recently, however, the term has fallen out of use.

AIDS surveillance: Monitoring trends in the number and distribution of AIDS cases and in the scope of severe morbidity due to infection with HIV. The responsibility and authority for AIDS surveillance rests with individual State and local health departments; these departments share their data with the Centers for Disease Control (CDC) in the U.S. Public Health Service.

Ambulatory medical care: Medical goods and services rendered outside of a hospital or other inpatient health care facility, including such items as physician office visits, outpatient laboratory diagnostic services, and outpatient prescription drugs.

Anal squamous cell carcinoma: A cancer of the anus with scaly or platelike cells. See also cancer.

Anemia: A condition that exists when the level of hemoglobin in a person's blood drops to an abnormally low level (e.g., below 11 grams per deciliter of whole blood).

Antibody: A blood protein (immunoglobulin) produced by white blood cells in mammals in response to the introduction of a specific antigen (usually a protein). Once produced, the antibody has the ability to combine with the specific antigen that stimulated antibody production. This reaction to foreign substances is part of the immune response.

Antigen: A specific type of substance, usually a protein or carbohydrate, that when introduced into the body of a human or other mammal is capable, under appropriate conditions, of inducing a specific immune response (including antibody production) and of reacting with the products of that response (i.e., specific antibody or specifically sensitized T-lymphocytes or both) .

Antiretroviral therapy: Therapy to combat retroviruses such as HIV. Antiretroviral therapy consisting of zidovudine to treat HIV-infected persons is recommended for all persons with a $CD4^{+}$ lymphocyte count below 500 cells per cubic millimeter ($/mm^{3}$).

Aspergillosis: A fungal infection caused by species of *Aspergillus* and marked by inflammatory granulomatous lesions in the skin, ear, orbit, nasal sinuses, lungs, and sometimes in the bones and meninges.

Asymptomatic: Showing or causing no symptoms.

AZT: See zidovudine.

Bacteremia: The presence of bacteria in the circulating bloodstream, an indication of severe bacterial infection.

Bacterial pneumonia: Pneumonia caused by bacteria (e.g., *Streptococcus pneumoniae).* Compare *Pneumocystis carinii pneumonia.*

Bacterium (pi., bacteria): Any of a group of one-celled micro-organisms having round, rodlike, spiral, or filamentous bodies that are enclosed by a cell wall or membrane and lack fully differentiated nuclei. Bacteria may exist as free-living organisms in soil, water, organic matter, or in the bodies of plants and animals. Some, but not all, bacteria can cause disease.

Bronchoscopy: Examination of the bronchi (any of the larger air passages of the lungs) through a bronchoscope (an instrument for inspecting the interior of the tracheobronchial tree).

#Burkitt's lymphoma: A type of noncleaved small cell lymphoma, manifested most often as an osteolytic lesion in the jaw or as an abdominal mass. The Epstein-Barr virus, a herpes virus, has been implicated as a causative agent. In the CDC's 1987 case definition of AIDS, Burkitt's lymphoma is considered an AIDS-defining condition.

Cancer: A tumor with the potential for invading neighboring tissue and/or metastasizing to distant sites, or one that has already done so. Cancers are categorized into major classes by their cell types. Thus, for example, a carcinoma is a cancer of the epithelia, including the external epithelia (e.g., skin and linings of the gastrointestinal tract, lungs, and cervix) and the internal epithelia that line various glands (e.g., breast, pancreas, thyroid). A sarcoma is a cancer made up of cells resembling embryonic connective tissue, which normally develops into tissues such as muscle, fat, bone, and blood vessels; sarcomas are often highly malignant. A lymphoma is a cancer of cells of the immune system (i.e. , the various types of lymphocytes).

Candida: A genus of yeastlike fungi of the family *Cryptococcaceae,* order *Monillales,* characterized by producing yeast cells, mycelia, pseudomycelia, and blastospores. It is commonly part of the normal flora of the skin, mouth, intestinal tract, and vagina, but can cause a variety of infections, including candidiasis. *Candida albicans* is the usual pathogen.

#Candidiasis: Infection with a fungus of the genus *Candida.* It is usually a superficial infection of the moist cutaneous areas of the body and is generally caused by *Candida albicans.* In the CDC's 1987 case definition of AIDS, candidiasis of the esophagus, trachea, bronchi, or lungs is considered an AIDS-defining condition.

Carcinoma: A cancer of the epithelia, including the external epithelia (e.g., skin and linings of the gastrointestinal tract, lungs, and cervix) and the internal epithelia that line various glands (e.g., breast, pancreas, thyroid).

Cardiomyopathy: A general diagnostic term designating primary myocardial disease, often of obscure or unknown etiology.

Case control study: Studies that compare a group of people with a disease (or other outcome event)--the cases- -to another group without the disease--the controls- -and then determine whether they differ in their previous exposure to a presumed causal agent. These studies are retrospective in nature, the exposure having occurred prior to the identification of the cases and controls.

Case report form: See AIDS case report form.

CDC's case definition of AIDS: The definition of AIDS, set forth by the Centers for Disease Control (CDC) in the Public Health Service of the DHHS, that is used in AIDS surveillance. In 1982, before HIV was identified as the agent that causes AIDS, the CDC defined AIDS as a disease, at least moderately indicative of an underlying defect in cell-mediated immunity, occurring in a person with no known cause for diminished resistance to the disease. With the identification of HIV as the causative agent for AIDS and the availability of laboratory tests to detect HIV antibody, the case definition was revised in 1985 and again in 1987 to reflect an increased understanding of HIV infection. The 1987 case definition lists 23 AIDS-defining conditions; these are severe

life-threatening opportunistic diseases highly specific for HIV infection in persons who are not immunosuppressed for other reasons. Under the CDC's proposed case definition, to be implemented in the summer of 1992, individuals with $CD4^+$ lymphocyte counts below 200 cells/mm^3 would be considered to have AIDS in addition to individuals who meet the criteria of the 1987 definition.

CDC's classification system for HIV infection: A classification system developed by the Centers for Disease Control (CDC) to categorize the spectrum of manifestations of HIV infection for epidemiologic and clinical purposes. The classification system currently in use divides HIV infection into four broad categories (and numerous subcategories) based on patients' clinical disease states. In November 1991, the CDC proposed a new classification system for HIV infection that would divide HIV infection into nine mutually exclusive categories based on combinations of three broad categories of clinical conditions associated with HIV infection and three categories that reflect different ranges of patients' $CD4^+$ lymphocyte counts.

CDC's Adult/Adolescent Spectrum of HIV Disease Project: A project, including nine centers throughout the United States, that was designed to examine the spectrum of disease associated with HIV infection. Participants are not a statistical sample of HIV patients. However, the project includes both public and private hospitals and clinics, including hospitals and clinics with a large number of indigent patients.

$CD4^+$ lymphocytes: T-helper lymphocytes. $CD4^+$ lymphocytes are the primary target cell for HIV infection because of HIV's affinity for the $CD4^+$ lymphocyte cell surface marker. $CD4^+$ lymphocytes coordinate a number of important immunologic functions, and a loss of these functions results in a progressive impairment of the immune response.

$CD4^+$ lymphocyte count: The absolute number of $CD4^+$ lymphocytes per cubic millimeter of blood. This figure is number calculated as the product of the total white blood cell count (white blood cells/mm^3) multiplied by the percentage of lymphocytes (number of lymphocytes/number of leukocytes * 100) and the percentage of $CD4^+$ lymphocytes (number of $CD4^+$ lymphocytes/number of gated lymphocytes * 100). Calculating the $CD4^+$ lymphocyte count requires a hematologic measurement (the total lymphocyte count) and a flow cytometry measure (the $CD4^+$ percent of total lymphocytes). The $CD4^+$ lymphocyte count has been found to be a marker of the progression of HIV-related immunosuppression (i.e. , a decrease in the number of $CD4^+$ lymphocytes correlates with an increase in the risk and severity of HIV-related opportunistic infections, cancers, and other manifestations of HIV-induced immunodeficiency) . Under the CDC's proposed case definition of AIDS, to be implemented in the summer of 1992, any person with a $CD4^+$ lymphocyte count of less than 200 cells/mm^3 of blood is considered to have AIDS.

$CD4^+$ percent of lymphocytes: $CD4^+$ lymphocytes as a percentage of total lymphocytes. This figure is calculated as the number of $CD4^+$ lymphocytes divided by the number of gated lymphocytes (flow cytometry) multiplied by 100. The $CD4^+$ lymphocyte percent has been proposed as an alternative to the $CD4^+$ lymphocyte count because there is less

variability inherent in the measurement of $CD4^+$ lymphocyte percent. The $CD4^+$ percent of lymphocytes is also technically easier to obtain, because it involves only a flow cytometry measurement.

$CD4^+$ lymphocyte testing: The use of flow cytometry and hematologic measurements to determine a person's $CD4^+$ lymphocyte count or $CD4^+$ percent of lymphocytes. In the United States, there are 600 to 1,000 labs with capabilities to perform $CD4^+$ lymphocyte testing. The $CD4^+$ lymphocyte test costs most labs about $50 plus personnel (an additional $50) to perform. Charges range from $50 to $600, but the majority of labs charge between $100 and $150.

Cell: The smallest membrane-bound protoplasmic body (consisting of a nucleus and its surrounding cytoplasm) capable of independent reproduction.

Cell-mediated immunity: Immunity resulting from increase of activity by living cells in the blood and other tissues (e.g., T-lymphocytes, natural killer cells) that directly and nonspecifically destroy foreign material. See also immunity.

Cervical cancer: Cancer of the uterine cervix (neck). See also cancer,

Cervical dysplasia: Abnormalities in the cells of the epitheliums of the uterine cervix (neck). Cervical dysplasia is thought to be a precursor to cervical cancer.

Cervix: The neck of the uterus.

Class action suit: Litigation in which a small number of plaintiffs. represents a class of plaintiffs which is similarly situated in terms of the legal claims and/or factual occurrences.

#Coccidioidomycosis: A fungal infection caused by infection with *Coccidioides immitis.* In the CDC's 1987 case definition of AIDS, disseminated or extrapulmonary coccidioidomycosis is considered an AIDS-defining condition.

Cofactor: Factors or agents that are necessary for or that increase the probability of the development of disease in the presence of the basic etiologic agent of that disease.

#Cryptosporidiosis: Infection with protozoa of the genus *Cryptosporidium.* In humans, such infection occurs both in immunocompetent persons (especially those who work with cattle), in which it causes self-limited diarrhea, and in immunocompromised persons, in whom it is much more serious, being manifested clinically as prolonged debilitating diarrhea, weight loss, fever, and abdominal pain. In the CDC's 1987 case definition of AIDS, intestinal cryptosporidiosis of more than l-month's duration is considered an AIDS-defining condition.

Cytomegalovirus: One of a group of highly host-specific herpes viruses that infects humans, monkeys, or rodents. Depending on the age and immune status of the host, cytomegalovirus can cause a variety of clinical syndromes, known collectively as cytomegalic inclusion disease, although the majority of infections is very mild or subclinical.

#Cytomegalovirus disease: Symptomatic conditions caused by infection with cytomegalovirus. In the CDC's 1987 case definition of AIDS, cytomegalovirus disease other than in the liver, spleen, or nodes is considered an AIDS-defining condition.

#Cytomegalovirus retinitis: Inflammation of the retina of the eye due to infection with cytomegalovirus. In the CDC's 1987 case definition of AIDS, this is considered an AIDS-defining condition.

cytology: The study of cells.

Cytometry: The counting of blood cells.

Cytotoxic: Poisonous to cells.

Decompensation: In psychiatry, it refers to failure of defense mechanisms, resulting in progressive personality disintegration.

Definitive diagnosis: A diagnosis of a disease that is certainly known because it is based on conclusive indicators (e.g. , histology, biopsy, culture, antigen detection, or stool microscopy, as appropriate). For public health reporting purposes, AIDS-defining conditions are considered "definitively diagnosed" if they are diagnosed by methods specified in Appendix II of CDC's 1987 revision of the AIDS surveillance definition. Diagnosis by any other methods is considered somewhat less reliable, is called "presumptive." Compare presumptive diagnosis.

Dementia: Organic loss of mental function, which may include deterioration of intellectual function, memory loss, and personality changes, without altered consciousness. Many types of dementia are thought to involve structural and biochemical abnormalities in the nervous system.

Disability: For purposes of the Supplemental Security Income (SSI) and the Social Security Disability Insurance (DI) programs, disability is defined as an inability to engage in any substantial gainful activity by reason of any physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.

Disability determination service (DDS): Any of the 54 State and territorial offices that, under regulatory authority with the Social Security Administration (SSA) within the U.S. Department of Health and Human Services, make disability determinations on individual applications for Social Security disability benefits (e.g., under the Supplemental Security Income (SSI) program).

Eczema: A pruritic papulovesicular dermatitis (inflammation or irritation of the skin) occurring as a reaction to many endogenous and exogenous agents. Also called "eczematous dermatitis."

Encephalitis: Inflammation of the brain.

Endocarditis: Inflammatory alterations of the endocardium (the endothelial lining of the cavities of the heart and the connective tissue bed on which it lies). Endocarditis may occur as a primary disorder or as a complication of or in association with another disease.

Entitlement programs: Government programs that provide a right to benefits or income which may not be abridged without due process.

Enzyme-linked immunosorbant assay (ELISA) or enzyme immunoassay (EIA): A method of testing for an antibody. The ELISA test for the HIV antibody has become the most commonly used screening test for HIV.

Epidemic: A sudden increase in the incidence rate of a human illness, affecting large numbers of people, in a defined geographic area.

Epidemiology: The scientific study of the distribution and occurrence of human diseases and health conditions, and their determinants.

Epidemiologic studies: Studies concerned with the relationships of various factors determining the frequency and distribution of specific diseases in a human community.

#Esophageal candidiasis: Candidiasis of the esophagus (the musculomembranous passage from the pharynx to the stomach). In the CDC's 1987 case definition of AIDS, this is considered an AIDS-defining condition. See candidiasis.

Extraintestinal strongyloidiasis: Infection outside the intestine with S. *stercoralis,* a species of Strongyloides. See strongyloidiasis.

Federal regulations: A statement by a Federal executive branch agency that implements, interprets, or prescribes law or policy or describes the organization, procedure, or practices of an agency. Federal agencies are given the authority to issue regulations to implement specific statutes, and the regulations have the same force of law as the statute. Congress requires, however, that executive branch agencies promulgate regulations in accordance with the procedures outlined in the Administrative Procedures Act.

Fluorescence microscopy: A technique of microscopy that involves staining cells with a fluorescent dye and then examining them under a microscope.

Flow cytometer: An instrument that will analyze thousands of particles (blood cells, in this case) individually for light scatter and fluorescence patterns. For $CD4^+$ lymphocyte determinations, it is used to determine what proportion, or percent, of the lymphocytes (identified by scatter patterns) are positive for $CD4^+$ lymphocytes (identified by fluorescence) . This percentage is then used with a white blood cell count and leukocyte differential to calculate the absolute number of $CD4^+$ lymphocytes. Each clinical flow cytometer costs approximately $80,000 - $100,000 purchased new.

Flow cytometry: A technique for counting blood cells that involves the use of a flow cytometer.

Functional limitations: Restrictions in the ability *to* perform activities of daily living and work-related activities.

Functional limitation test: A measure of degree to which an individual's functional activities are hindered by a physical or mental impairment. The SSA has developed a functional limitation test for evaluating the degree of impairment caused by HIV infection. The SSA will examine a person's ability to engage in activities of daily living (e.g. , ability to do household chores, groom, perform personal hygiene); and social activity (e.g. , ability to interact appropriately and communicate effectively with others); and his or her ability to perform work-related tasks in a timely and precise manner. The SSA will also take into account whether the person has repeated episodes of illness or other symptoms that limit his or her ability to adapt to work or work-like settings.

Fungicide: An agent that kills fungi.

Fungus (pi., fungi): A general term used to denote a group of eukaryotic protists, including mushrooms, yeasts, rusts, molds, smuts, etc. , which are characterized by the absence of chlorophyll and by the presence of a rigid cell wall composed of chitin, mannans, and sometimes cellulose.

Genital herpes: See herpes simplex virus infections.

Genital warts: See human papilloma virus infection.

Granulocytopenia: A symptom complex characterized by a marked decrease in the number of granulocytes (cells containing granules, especially leukocytes containing neutrophyl, basophil, or eosinophil) and by lesions of the throat and other mucous membranes, of the gastrointestinal tract, and of the skin.

Herpes genitalis (genital herpes): A sexually transmitted disease caused by HSV-2. Symptoms include blister-like sores in the genital region, but diagnosis is by an HSV viral cell culture or antigen detection technique. Potential complications include aseptic meningitis, recurrent infections, and possible maternal-to-infant transmission.

#Herpes simplex virus infections: Infections caused by herpes simplex virus (HSV) type 1 or type 2 and usually characterized by the development of one or more small fluid-filled vesicles with a raised erythematous base on the skin or mucous membranes and occurring as a primary infection or recurring because of reactivation of latent infection. Type 1 infections usually involve nongenital regions of the body (e.g. , herpes labialis), whereas type 2 infections more commonly causes lesions on the genital and surrounding areas (e.g., herpes genitalis). In the CDC's 1987 case definition of AIDS, HSV infection leading to chronic ulcers or bronchitis, pneumonitis, or esophagitis is considered an AIDS-defining condition.

Herpes zoster: Also called shingles, this is an acute infectious, usually self-limited, disease believed to represent activation of latent varicella-zoster virus in those who have been rendered partially immune

after a previous attack of chicken pox. It involves the sensory ganglia and their areas of innervation, characterized by severe neuralgic pain along the distribution of the affected nerve.

Hispanics: Persons who identify themselves as of Hispanic origin, or, less typically, individuals with Hispanic surnames identified by others (e.g., health care providers identifying patients in surveys) as of Hispanic origin. Hispanics can be those whose families have emigrated directly from Spain, or from Cuba, Central America, or South America. Persons of Hispanic origin can be of any race (e.g., white, black, American Indian); most have been found to be white.

Histology: The area of anatomy that deals with the minute structure, composition, and function of the tissues; also called microscopical anatomy.

#Histoplasmosis: Infection resulting from inhalation, or infrequently, the ingestion of spores *of Histoplasmosis capsulatum. The* infection is asymptomatic in most cases, but in 1 to 5 percent of cases, it causes acute pneumonia or disseminated reticuloendothelial hyperplasia with hepatosplenomegaly and anemia. In the CDC's 1987 case definition of AIDS, disseminated or extrapulmonary histoplasmosis is considered an AIDS-defining condition.

HIV(humanimmunodeficiency virus): The virus that causes acquired immunodeficiency syndrome (AIDS). Two distinct subtypes of HIV have been identified: HIV-1 was first isolated in 1983 and has a worldwide distribution. HIV-2 was first isolated in 1986 and is found mainly in West Africa.

HIV antibody test: A test to detect the presence of antibodies to the human immunodeficiency virus (HIV) in the blood. The presence of the antibody indicates infection with the virus. See also Enzyme-linked immuno-sorbant assay and Western blot.

HIV-associated conditions: A general term that includes medical conditions' associated with HIV infection. This term is broader than the term AIDS-defining conditions, which refers only to conditions listed in the case definition of AIDS set forth by the Centers for Disease Control.

#HIV encephalopathy: Degenerative disease of the brain that is due to infection with HIV. In the CDC's 1987 case definition of AIDS, this is considered an AIDS-defining condition.

HIV infection: Infection with HIV (human immunodeficiency virus). Some HIV-infected people are asymptomatic. Some people manifest conditions that are attributed to HIV infection and/or are indicative of a defect in cell-mediated immunity; or conditions that are considered by physicians to have a clinical course or management that is complicated by HIV infection (e.g., candidiasis, vulvovaginal or oropharyngeal) . Finally, some people with severe HIV-related immunodeficiency manifest conditions that are strongly associated with severe immunodeficiency, and cause serious morbidity or mortality; these include the 23 AIDS-defining conditions listed in the CDC's 1987 case definition of AIDS (e.g. , *Pneumocystis carinii* pneumonia).

HIV negative: Not showing any antibodies to HIV.

HIV positive: Showing antibodies to HIV (indicating infection with HIV).

HIV-related immunosuppression: Decrease in cell-medicated immunity caused by infection with the human immunodeficiency virus (HIV). See also cell-medicated immunity.

#HIV wasting syndrome: A syndrome in HIV-infected persons characterized by progressive involuntary weight loss and either chronic diarrhea or chronic fever and weakness. In the CDC's 1987 case definition of AIDS, this is considered an AIDS-defining condition.

Hodgkin's disease (or Hodgkin's lymphoma): A form of malignant lymphoma characterized by painless, progressive enlargement of the lymph nodes, spleen, and general lymphoid tissue; other symptoms may include anorexia, lassitude, weight loss, fever, pruritis, night sweats, and anemia.

HTLV-III: Human T-cell lymphotropic virus, type III--now referred to as HIV.

Human immunodeficiency virus: See HIV.

Human papilloma virus infection: A papilloma virus that selectively infects the skin or mucous membranes. These infections may be asymptomatic, produce warts, or be associated with a variety at both benign and malignant neoplasms.

Immune: Protected against disease by innate or acquired (active or passive) immunity.

Immune deficiencies: Any of a number of conditions (e.g., adenosine deaminase deficiency, purine nucleoside phosphorylase deficiency, or AIDS) resulting from a failure or malfunction of the bodily defense mechanisms, or immune system.

Immunity: The condition of being immune (i.e. , protected against infectious disease conferred either by the immune response generated by immunization or previous infection or by other nonimmunologic factors (i.e., innate immunity). See also cell-mediated immunity.

Immunoblastic lymphoma or sarcoma: A malignant lymphoma composed of a diffuse, relatively uniform proliferation of cells with rough or convoluted nuclei and scanty cytoplasm. In the CDC's 1987 case definition of AIDS, immunoblastic lymphoma is considered an AIDS-defining condition.

Immumcompetent: Having a normal or adequate immune response.

Immunocompromised: Having the immune response attenuated by administration of immunosuppressive drugs, by irradiation, by malnutrition, or by some disease processes (e.g., cancer, AIDS).

Immunodeficiency: A deficiency of immune response or a disorder characterized by deficiency of immune response; classified as antibody (B cell), cellular (T cell), combined deficiency, or phagocytic dysfunction disorders. Cellular immunodeficiencies are marked by recurrent infections with low-grade or opportunistic pathogens, by graft-versus-host reactions following blood transfusions, and by severe disease following immunization with live vaccines.

Immunophenotyping: The methodology by which cells are identified using monoclinal antibodies directed at cell surface antigens. For HIV-infected specimens, this methodology commonly involves incubating anticoagulated blood with fluorochrome-labelled monoclinal antibodies, then lysing (killing) the red blood cells, so that only leukocytes (white blood cells) remain. The cells are then analyzed by flow cytometry for light scatter patterns (which identify various leukocyte populations) and fluorescence intensity (identifying various subpopulations of cells based on the presence or absence of antigens labelled by the monoclinal antibodies).

Immunosuppressed: Having the immune response prevented or attenuated. Also called immunodepressed.

Incidence: The frequency of new occurrences of disease within a defined time internal. The incidence rate is the number of new cases of specified disease divided by the number of people in a population over a specified period of time, usually 1 year. Compare prevalence.

Incident cases: New cases of a disease within a defined time interval.

Informed consent: A person's agreement to allow something to happen (e.g., a medical procedure) that is based on a full disclosure of the facts needed to make the decision intelligently. Informed consent is also the name for a general principle of law that a physician has a duty to disclose information about the risks of a proposed treatment to a patient so that the patient may intelligently exercise his or her " judgment about whether to undergo that treatment.

Injection drug user: A person who uses a hypodermic needle to inject illicit drugs (e.g., heroin, amphetamines).

Inpatient care: Care that includes an overnight stay in a hospital or other medical facility.

#Isosporiasis: Infection with coccidia from the genes *Isospora.* In the CDC's 1987 case definition of AIDS, chronic intestinal isosporiasis with diarrhea of more than l-month's duration is considered an AIDS-defining condition.

#Kaposi's sarcoma: A multifocal, spreading cancer of connective tissue, principally involving the skin; it usually begins on the toes or the feet as reddish blue or brownish soft nodules and tumors. Previously seen in older men of Jewish or Mediterranean descent, Kaposi's sarcoma is now one of the opportunistic diseases occurring in AIDS patients.

#Leukoencephalopathy: Any of a group of diseases affecting the white matter of the brain, especially of the cerebral hemispheres, and occurring as a rule in infants and children. Progressive multifocal leukoencephalopathy is a generally fatal disease probably of viral origin. Progressive multifocal leukoencephalopathy is an AIDS-defining condition.

Listing: Any one of the more than 100 medical conditions that are included in the Social Security Administration's "Listing of Impairments". Also called "listed impairments."

"Listing of Impairments": See Social Security Administration's "Listing of Impairments."

Lymphadenopathy: Lymph node enlargement in a region or regions of the body.

Lymphocytes: Specialized white blood cells involved in the body's immune response. B-lymphocytes originate in the bone marrow and when stimulated by an antigen produce circulating antibodies (humoral immunity). T-lymphocytes are produced in the bone marrow and mature in the thymus gland and engage in a type of defense that does not depend directly on antibody attack (cell-mediated immunity). Approximately 10-15 percent of the body's lymphocytes are natural killer cells.

#Lymphoma: Cancer of cells of the immune system (i.e. , the various types of lymphocytes). In the CDC's 1987 case definition of AIDS, Burkitt's lymphoma, immunoblastic lymphoma, and lymphoma of the brain are " considered AIDS-defining conditions. See also cancer.

Medicaid: A federally-aided, State-administered program, authorized under Title XIX of the Social Security Act; that provides medical assistance to low-income elderly and disabled individuals; low-income pregnant women and children; and families with dependent children who meet specific income and family structure requirements. Medicaid regulations are established by each State within Federal guidelines, and the eligibility requirements and services covered vary significantly among the States. In general, Medicaid covers medical, nursing home, and home health care for individuals who meet the eligibility requirements for those services. In some States, Medicaid also pays for adult day care and in-home services such as personal care and homemaker services. Financial eligibility for Medicaid is determined by a means test, in which a ceiling is placed on the maximum income and assets an individual may have in order to qualify for assistance. The income and assets levels are quite low in all States.

"Medically needy" persons (under Medicaid): Persons who meet the nonfinancial qualifications for Medicaid (e.g., the disability requirement) but whose income or resources exceed eligibility levels. Not all States allow Medicaid eligibility for "medically needy" people. The States with programs for the medically needy provide a spend-down option so that persons whose medical expenses greatly exceed eligibility income or resource levels can obtain Medicaid.

Meningitis: Inflammation of the meninges (the three membranes that envelope the brain and spinal cord).

Mortality: Death.

Microscopy: Examination under or observation by means of the microscope.

#Mycobacterium: A genus of bacteria of the family *Mycobacteriaceae,* order *Actinomycetales,* occurring as gram-positive, aerobic, mostly slow-growing, slightly curved or straight rods, sometimes branching and filamentous. It contains many species, including the highly pathogenic organisms that cause tuberculosis (M. *tuberculosis)* and leprosy (M. *leprae).* In the CDC's 1987 case definition of AIDS, *Mycobacterium avium* complex or M. *Kansasii* (disseminated or extrapulmonary) , M. *tuberculosis* (disseminated or extrapulmonary), and disseminated or extrapulmonary infection with other species of Mycobacterium are considered AIDS-defining conditions.

Name reporting of AIDS and HIV: The reporting of the names of persons known to have AIDS or HIV infection to State or local health departments.

Nephropathy: Disease of the kidneys.

Nocardiosis: An acute or chronic suppurative infection, usually of the lungs but with a marked tendency to spread to any organ of the body, especially to the brain; abscess formation occurs in any organ, most commonly in the lungs, brain, skin, or subcutaneous tissue. Lung abscesses tend to cavitate with time. The causative agent in most instances in *Nocardia asteroids,* but N. *"brasiliensis* and N. *caviae* occasional cause cases.

Non-Hodgkin's lymphoma: A heterogeneous group of malignant lymphomas, the only common feature being an absence of the giant Reed-Sternberg cells characteristic of Hodgkin's disease. See lymphoma.

Notice of proposed rulemaking (NPRM): A notice of a Federal agency's intent to issue new regulations.

Opportunistic illness: The term includes infections caused by a micro-organism that does not ordinarily cause disease but which, under certain conditions (e.g. , impaired immune responses), becomes pathologic. The term also includes cancers associated with immune suppression. Kaposi's sarcoma (a cancer) and *Pneumocystis carinii* pneumonia (an infectious disease) in AIDS patients are examples of opportunistic illnesses. In this paper, the term is often used synonymously with AIDS-defining condition.

Oral candidiasis: See candidiasis.

Outpatient care: Care that is provided in a hospital and that does not include an overnight stay.

Pap test: Papanicolaou's test. A cell-staining procedure used for the detection and diagnosis of various conditions, particularly malignant and premalignant conditions of the female genital tract (cancer of the vagina, cervix, and endometrium) .

Pelvic inflammatory disease: A disease among females commonly associated with sexually transmitted pathogens, the symptoms of which include abdominal pain, fever, chills, vomiting, foul-smelling discharge, and postcoital bleeding. Potential complications include sterility, chronic pain, chronic infections, and even death. Methods of prevention include limiting the number of sexual partners, using condoms, and avoiding the use of intrauterine contraceptive devices. Treatment is with antibiotics.

#Pneumocystis carinii pneumonia: A type of pneumonia caused by the protozoan *Pneumocystis carinii,* which usually occurs in infants or debilitated persons (e.g., persons receiving cytotoxic drugs, immunosuppressive drugs) but is now one of the opportunistic diseases commonly found in AIDS patients. In the CDC's 1987 case definition of AIDS, *P. carinii* pneumonia is considered an AIDS-defining condition. Diagnosed definitively, it is considered indicative of AIDS even if a patient tests negative for HIV if the patient has no other causes of underlying immunodeficiency.

Pneumocystis pneumonia: See *Pneumocystis carinii* pneumonia.

Pneumocystis prophylaxis: The prevention of *Pneumocystis carinii* pneumonia through the use of agents such as trimethoprim sulfamethoxazole or aerosolized pentamadine. Prophylaxis against *Pneumocystis carinii* pneumonia is recommended for all HIV-infected persons with $CD4^+$ lymphocyte counts below 200 cells/mm^3 of blood.

Pneumonia: A disease of the lungs characterized by inflammation and consolidation, which is usually caused by infection or irritation. See also *Pneumocystis carinii* pneumonia, bacterial pneumonia.

Presumptive diagnosis: A diagnosis of a disease that is presumed to be correct but is not certainly known because it is not based on conclusive indicators (e.g. , histology, biopsy, culture, antigen detection, or stool microscopy, as appropriate). Compare definitive diagnosis.

Presumptive disability under the Supplemental Security Income (SSI) program: The Social Security Administration (SSA) is mandated by Congress to provide claimants who are "presumptively disabled or blind" with SSI disability benefits during the time that their application is being reviewed. Presumptive disability can be awarded by the field offices or by the State Disability Determination Services (DDS). Field office determinations of presumptive disability are usually restricted to impairment categories that can be easily identified by a trained lay person or can be easily confirmed with a single call to a physician or other health care provider (e.g. , the amputation of two limbs, allegation of total blindness) ; in 1985, AIDS became part of the presumptive disability process at the field office level. Determinations of presumptive disability that require more medical knowledge are made by the State DDS, which has medically trained personnel.

Prevalence: In epidemiology, the number of cases of disease, infected persons, or persons with disabilities or some other condition, present at a particular time and in relation to the size of the population. Also called "prevalence rate." Compare incidence.

Prevalent cases: Total number of cases of a disease present in a defined population at a particular time.

Privacy rights: According to Black's Law Dictionary, the term "right of privacy" is a generic term encompassing various rights recognized to be inherent in ordered liberty and such rights prevent governmental interference in intimate personal relationships or activities, freedom of the individual to make fundamental choices involving himself, his family, and his relationship with others. It is said to exist only so far as its assertion is consistent with law or public policy. Various Federal and State statutes prohibit an invasion of a person's right to be left alone and also restrict access to personal information (e.g., income tax returns) and overhearing of private communications.

Program Operations Manual System: An internal Social Security Administration (SSA) manual that instructs all SSA employees and the State Disability Determination Service (DDS) employees on the SSA's operating procedures.

#Progressive multifocal leukoencephalopathy: Leukoencephalopathy is of a group of diseases affecting the white matter of the brain, especially of the cerebral hemispheres, thought to be caused by a papovavirus. Progressive multifocal leukoencephalopathy is a generally fatal disease probably of viral origin. In the CDC's 1987 case definition of AIDS, this is considered an AIDS-defining condition.

Prophylaxis: The prevention of disease; preventive treatment.

Psoriasis: A common chronic squamous dermatosis, marked by exacerbations and remissions and having a polygenic inheritance pattern. It is characterized clinically by the presence of rounded, circumscribed, erythematous, dry, scaling patches of various sizes, covered by grayish white or silvery white, umbilicated, and lamellar scales, which have a predilection for the extensor surfaces, nails, scalp, genitalia, and lumbosacral region.

Pulmonary tuberculosis: See tuberculosis.

Regulations: See Federal regulations.

Residual functional capacity: The physical and mental tasks that a person can still perform despite the physical and mental impairments caused by a disease or other medical condition. When a SSA disability examiner determines the applicant's residual physical and mental capacity, he or she focuses on the person's ability to perform in a work environment. The physical evaluation takes into account his or her ability to lift, carry, push, pull, and perform other purely physical functions. The mental evaluation concentrates on the ability to understand, carry out, and remember instructions, and to respond appropriately to supervision, coworkers, and work pressures. The assessment of residual functional

capacity is used to determine whether a disability claimant can still perform his or her previous job, or can perform any meaningful job in the national economy.

Retrovirus: Any of a large group of viruses that contain RNA, not DNA, and that produce a DNA analog of their RNA through the production of an enzyme known as 'reverse transcriptase." (The resulting DNA is incorporated into the genetic structure of the cell invaded by the retrovirus.) HIV is a type of retrovirus.

Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (Public Law 101-381): An act that authorizes Federal funds for treatment, prevention, and other services related to HIV. Funds are administered by the Health Resources and Services Administration and the Centers for Disease Control in the U.S. Department of Health and Human Services.

#Salmonella septicemia: The presence and persistence of bacteria of the genus *Salmonella* in the blood. In the CDC's 1987 case definition of AIDS, recurrent Salmonella septicemia is considered an AIDS-defining condition.

Sarcoma: A cancer made up of cells resembling embryonic connective tissue which normally develops into tissues such as muscle, fat, bone, and blood vessels; sarcomas are often highly malignant.

Sensitivity (of a test): One measure of the validity (or accuracy) of a diagnostic or screening test: the percentage of all those who actually have the condition being tested for who are correctly identified as positive by the test. Operationally, it is the number of true positive test results divided by the number of patients that actually have the disease (true positives divided by the sum of true positives plus false negatives) . Compare specificity.

Sepsis (bacterial or fungal): The presence in the blood or other tissues of pathogenic micro-organisms or their toxins.

Septic arthritis: Inflammation of the joints caused by microbial infection.

Septicemia: Systemic disease associated with the presence and persistence of pathogenic micro-organisms or their toxins in the blood.

Serology: The study of in vitro reactions of immune sera; or the use of such reactions to measure serum antibody titers to infectious disease.

Sinusitis: Inflammation of a sinus. The condition may be purulent or nonpurulent, acute or chronic.

Social Security Administration's 'HIV Infection Listing" for disability determinations: A proposed addition to the "Listing of Impairments, " published for review and comment in 1991, that sets forth criteria for determining disability in persons with HIV infection.

Social Security Administration's 'Listing of Impairments": A list of over 100 physical and mental impairments which the Social Security Administration (SSA) considers to be so severe as to make a person disabled (i.e.,

unable to engage in any substantial gainful activity). The "Listing of Impairments" is used in making disability determinations under SSA disability programs. Any claimant who has a "listed impairment," or an impairment that is equal in severity to a listed impairment, is to be considered disabled. The "Listing of Impairments" is published in the Code of Federal Regulations (20 C.F.R., Part 404, Subpt P, Appendix 1).

Social Security Disability Insurance (DI): A Federal disability social insurance program, administered at the Federal level by the Social Security Administration within the U.S. Department of Health and Human Services, for workers who have contributed to the Social Security retirement program and have become disabled before retirement age. Beneficiaries receive monthly cash payments.

Social Security Rulings: Statements by the Social Security Administration (SSA) that draw upon and codify the policies and criteria used at all levels of the administrative adjudication process (in administrative law judge and Appeals Council decisions, in decisions by SSA disability examiners, etc.). The rulings are binding on all components of the SSA, including State disability examiners, administrative law judges, and the SSA Appeals Council. Unlike SSA regulations, however, they are not binding on Federal or State courts.

Soundex codes: Alpha-numeric codes used by the State or local health department as a substitute for individuals' names on AIDS case reporting forms sent to the Centers for Disease Control (CDC) in the U.S. Public Health Service. The CDC does not receive the names of persons with AIDS; names are retained by the State or local health department.

Specificity (of a test): One measure of the validity (or accuracy) of a diagnostic or screening test: the percentage of all those who do not " have the condition being tested and who are correctly identified as negative by the test. Operationally, it is the number of true test negatives (all those with a negative test result who actually do not have the condition being tested for) divided by the sum of true negatives plus false positives (i.e., all those who do not have the condition). Compare sensitivity.

Strongyloidiasis: Infection with S. *stercoralis,* a species of *Strongyloides. S. stercoralis (S. intestinalis)* is a roundworm occurring widely in tropical and subtropical countries. The female worm and her larvae inhabit the mucosa and submucosa of the small intestine, where they cause diarrhea and ulceration. The larvae expelled from an infected person with his or her feces develop in the soil and penetrate the human skin on contact. They eventually are carried in the bloodstream to the lungs, where they cause hemorrhage (pulmonary strongyloidiasis) ; from the lungs, they reach the intestine via the trachea and esophagus. Massive infections may be seen in patients with depressed immune systems.

Strongyloides: A genus of plasmids belonging to the superfamily *Rhabditoidea,* widely distributed as intestinal parasites of mammals.

Supplemental Security Income (SSI): A Federal income support program for low-income disabled, aged, and blind persons. Eligibility for the monthly cash payments is based on the individual's current status without regard to previous work or contributions to a trust fund. Some States supplement the Federal benefit.

Surveillance: See AIDS surveillance.

"Symptomatic HIV Infection Not Indicative of AIDS": A category of disability adopted by the Social Security Administration for use in disability determinations under the DI and SSI programs that was equivalent to a Listing.

Syndrome: The aggregate of symptoms considered to constitute the characteristics of a morbid entity; used especially when the cause of the condition is unknown.

T-cells (or T-lymphocytes): Specialized lymphocytes (white blood cells involved in the body's, immune response) that are produced in the bone marrow and mature in the thymus gland and engage in a type of defense that does not depend directly on antibody attack (cell-mediated immunity). T-helper lymphocytes are known as $CD4^+$ lymphocytes. T-suppressor/cytotoxic lymphocytes are known as $CD8^+$ cells. Normally, about 2/3 of the T-cells are $CD4^+$ lymphocytes, and about 1/3 are $CD8^+$ lymphocytes.

Third-party payment: Payment by a private insurer or government program to a medical provider for care given to a patient.

Thrombocytopenia: Decrease in the number of blood platelets.

#Toxoplasmosis: An acute or chronic widespread disease of animals and humans caused by the protozoan *Toxoplasma gondii,* transmitted by oocysts containing the pathogen in the feces of cats, usually by contaminated soil or direct exposure to infected feces. Most human infections are asymptomatic, but when symptoms occur, they may range from a mild, self-limited disease clinically resembling mononucleosis to a fulminating, disseminated disease that may cause extensive damage to the brain, eyes, skeletal and cardiac muscles, liver, and lungs. Severe manifestations are seen principally in immunocompromised patients. In the CDC's 1987 case definition of AIDS, toxoplasmosis of the brain is considered an AIDS-defining condition.

Tuberculosis: A chronic infectious disease of humans and animals caused by any of several species of mycobacteria. Tuberculosis usually begins with lesions in the lung but can metastasize (spread) to other parts of the body. Tuberculosis in the lung is known as pulmonary tuberculosis.

Vaginal candidiasis: See candidiasis.

Virology: The branch of microbiology that specializes in viruses.

virus : Any of a large group of submicroscopic agents infecting plants, animals, and bacteria and characterized by a total dependence on living cells for reproduction and by a lack of independent metabolism. A fully formed virus consists of nucleic acid (DNA or RNA) surrounded by a protein or protein and lipid coat.

Wasting syndrome due to HIV: See HIV wasting syndrome.

Western blot: A method of separating proteins, such as antibodies, by electrophoresis. The Western blot for HIV has become the most commonly used confirmatory test for HIV.

Zidovudine (Retrovir): A drug used to reduce symptoms prolonging the lives of persons infected with human immunodeficiency virus (HIV). This drug was formerly called azidothymidine (AZT).

Appendix B- -Evolution of the CDC's Case Definition of AIDS

In 1981, the Centers for Disease Control (CDC) in the U.S. Department of Health and Human Services (DHHS) began surveillance for a newly recognized constellation of diseases, now termed acquired immunodeficiency syndrome (AIDS). As described below, CDC developed a surveillance case definition for this syndrome in 1982 and received case reports directly from health care providers and State and local health departments. Bear in mind that the CDC's case definition of AIDS was developed for surveillance purposes. According to the CDC, the goals of AIDS surveillance are to monitor trends in the number of AIDS cases and monitor the scope of severe morbidity due to infection with human immunodeficiency virus (HIV)(219). Since 1982, the CDC's case definition has been revised twice, once in 1985 and once in 1987. In November of 1991, the CDC proposed changing its definition once again.

The CDC's 1982 Case Definition of AIDS

From 1980 to 1981, the CDC received its first reports of five cases involving homosexual males diagnosed with *Pneumocystis carinii* pneumonia due to severe immunodeficiency.[1] From 1979 to 1981, CDC also received reports of 26 homosexual males diagnosed with Kaposi's sarcoma. Of these 26 men, 6 also had *Pneumocystis carinii* pneumonia (25 were white and 1 was African American) (200).

1 *Pneumocystis carinii* pneumonia virtually always occurs in limited to severely immunocompromised patients (199).

The CDC published its first case definition of what is now called acquired immunodeficiency syndrome (AIDS) in September 1982 (201). The case definition was "a disease, at least moderately predictive of a defect in cell-mediated immunity, occurring in a person with no known cause for diminished resistance to that disease" (see table B-l).

The CDC received reports of 593 cases of what is now called AIDS between June 1, 1981 and September 15, 1982. Fifty-one percent of these 593 cases had Pneumocystis *carinii* pneumonia without Kaposi's sarcoma (with or without other opportunistic infections), 30 percent had Kaposi's sarcoma without Pneumocystis carinii pneumonia (with or without other opportunistic infections), 7 percent had both *Pneumocystis carinii* pneumonia and Kaposi's sarcoma (with or without opportunistic infections), and 12 percent had opportunistic infections with neither *Pneumocystis carinii* pneumonia nor Kaposi's sarcoma. Men who have sex with men made up 75 percent of 593 cases reported, while injection drug users made up 25.5 percent (201).

As of December 19, 1983, 3,000 cases that met the case definition of AIDS had been reported to the CDC (202).[2] The pattern of opportunistic illnesses remained fairly constant with 51 percent of cases reporting *Pneumocystis carinii* pneumonia without Kaposi's sarcoma, 26 percent reporting both Kaposi's sarcoma without *Pneumocystis carinii* pneumonia, 7 percent both *Pneumocystis carinii* pneumonia and Kaposi's sarcoma, and 16 percent reporting opportunistic infections without either Kaposi's sarcoma or *Pneumocystis carinii* pneumonia. Fifty-nine percent of the 3,000 AIDS cases reported occurred among whites, 26 percent among African Americans, and 14 percent

2 This figure does not include 42 children under age 5 who met the surveillance definition for pediatric AIDS.

among Hispanics. Women accounted for only 7 percent of the cases reported at this time. The groups at highest risk for contracting AIDS were men who have sex with men (71 percent) and injection drug users (17 percent) (202).

Men who have sex with men and injection drug users with immunodeficiency represented the at-risk group for acquiring AIDS in 1982 when the syndrome was initially defined. The indicators of AIDS were limited to Kaposi's sarcoma and opportunistic infections diagnosed without known causes of immunodeficiency (87). Opportunistic illnesses that were most problematic for the high-risk groups, and therefore met the criteria for the CDC's 1982 definition of AIDS, are presented in table B-1. The CDC grouped symptoms into five etiologic categories: protozoal and helminthic, fungal, bacterial, viral, and neoplastic.

The CDC's 1985 Case Definition of AIDS

After the CDC's first case definition of what is now called AIDS was published in 1982, researchers identified human immunodeficiency virus (HIV) as the cause of AIDS.[3] Furthermore, laboratory tests were developed to identify the presence of the HIV antibody. The HIV laboratory test could be used as a diagnostic indicator for severe manifestations of HIV disease that were not included in the 1982 case definition. Consequently, the CDC changed its AIDS surveillance definition in 1985 (see table B-2). Among other things, the 1985 definition specified that in patients with a positive HIV test, cases of disseminated histoplasmosis, isosporiasis causing chronic diarrhea,

3 At the time the virus was identified, HIV was termed human T-cell lymphotropic virus, type III (HTLV-III)/lymphadenopathy-associated virus (LAV).

bronchial or pulmonary candidiasis, non-Hodgkin's lymphoma, and Kaposi's sarcoma in persons 60 years of age or over were considered cases of AIDS (203).

From June 1981 to September 8, 1986, health departments and physicians in the United States reported 24,576 cases of AIDS to the CDC. Of the reported cases, 25 percent (6,192) occurred among African Americans and 14 percent (3,488) occurred among Hispanics, although African Americans and Hispanics only make up 12 percent and 6 percent respectively of the U.S. population. African American and Hispanic women accounted for 51 percent and 21 percent respectively of women with AIDS, while African American and Hispanic men accounted for 23 percent and 14 percent respectively of men with AIDS (205). The CDC estimated that approximately 750,000 people in the United States were infected with the AIDS virus at the beginning of 1986 (215).

The CDC's 1987 Case Definition of AIDS

In August of 1987, the CDC's case definition of AIDS was once again modified to reflect increases in the understanding of HIV infection, and the 1987 case definition is the definition currently in use (see table B-3). The CDC's goals in making the 1987 revision were: 1) to simplify AIDS reporting; 2) to make the definition consistent with standards of medical care for HIV-infected persons; and 3) to more accurately record the number of persons with severe HIV-related immunosuppression (208).

The CDC expanded the case definition of AIDS to include 23 AIDS-defining conditions, including bronchial, tracheal, or pulmonary candidiasis; esophageal candidiasis; HIV encephalopathy; HIV wasting syndrome; and a broader range of malignancies (208).

The 1987 case definition of AIDS is arranged in three sections according to laboratory evidence of HIV infection: unknown or inconclusive HIV test, positive HIV test, and negative HIV test (see table B-3). With laboratory evidence of HIV infection, the 1987 definition allows some opportunistic illnesses to be presumptively (rather than definitively) diagnosed. In other words, these conditions (e.g. , Pneumocystis *carinii* pneumonia and Kaposi's sarcoma) in HIV-positive persons can be diagnosed on the basis of clinical signs and symptoms, without confirmation by a laboratory test.

Twenty-nine percent of the 40,836 AIDS cases reported between September 1987 and December 1988 met the criteria of the CDC's 1987 case definition only and would not have been reported as AIDS cases under earlier definitions. The use of the 1987 case definition of AIDS increased the proportions of AIDS cases in women, injection drug users, and minorities. Of the cases meeting only the criteria of the 1987 definition, 15 percent were women, as compared with 9 percent of cases meeting the pre-1987 definition. Thirty-five percent of the cases meeting only the 1987 definition were heterosexual injection drug users, as compared with 18 percent meeting the pre-1987 definition. Of cases meeting the 1987 definition only, 34 percent were African Americans, as compared with 26 percent meeting the pre-1987 definition; and 21 percent were Hispanic, as compared with 14 percent meeting the pre-1987 definition (211).

The CDC's Proposed 1992 Case Definition of AIDS

In November of 1991, the CDC has proposed changing its case definition of AIDS (219). The proposed case definition would count as AIDS cases persons with the clinical conditions listed in the 1987 case definition (see table B-3). In addition, the proposed case definition would include as AIDS cases all HIV-infected adolescents and adults who have laboratory evidence of severe

HIV-related immunosuppression--defined as a $CD4^+$ lymphocyte count of below 200 cells per cubic millimeter (\mm^3) of blood (or a $CD4^+$ percent of total lymphocytes below 14 if the absolute count is not available). The proposed expanded AIDS case definition also includes persons with clinical conditions listed in the 1987 case definition (table B-3). The case definition of AIDS is expected to become effective in the summer of 1992 (219).

Table B-1--CDC's 1982 Case Definition of AIDS

In 1982, the Centers for Disease Control's (CDC) case definition of what is now referred to as acquired immunodeficiency syndrome (AIDS) was "a disease at least moderately predictive of a defect in cell-mediated immunity, occurring in a person with no known cause for diminished resistance to that disease" (U.S. DHHS, PHS, CDC, MMWR, September 1982). Examples of opportunistic illnesses associated with the syndrome are listed below.

A. Protozoal and helminthic infections
   1. Cryptosporidiosis, intestinal, causing diarrhea for over one month (on histology or stool microscopy).
   2. Pneumocystis *carinii* pneumonia (on histology or on microscopy of a "touch" preparation or bronchial washings).
   3. Strongyloidosis, causing pneumonia, central nervous system (CNS) infection, or disseminated infection (on histology) .
   4. Toxoplasmosis, causing pneumonia or CNS infection (on histology or microscopy of a "touch" preparation).

B. Fungal infections
   1. Candidiasis, causing esophagitis (on histology, microscopy of a "wet" preparation from the esophagus, or endoscopic findings of white plaques on an erythematous mucosal base).
   2. Cryptococcosis, causing pulmonary, CNS, or disseminated infection (on culture, antigen detection, histology, or India ink preparation of CSF) .

C. Bacterial infection
   1. "Atypical" mycobacteriosis (species other than tuberculosis or lepra), causing disseminated infection (on culture).

D. Viral infections
   1. Cytomegalovirus, causing pulmonary, gastrointestinal tract, or CNS infection (on histology).
   2. Herpes simplex virus, causing chronic mucocutaneous infection with ulcers persisting more than 1 month or pulmonary, gastrointestinal tract, or disseminated infection (on culture, histology, or cytology).
   3. Progressive multifocal leukoencephalopathy (presumed to be caused by papovavirus) (on histology).

E. Cancer
   1. Kaposi's sarcoma in persons less than 60 years of age (on histologic study).
   2. Lymphoma, limited to the brain.

SOURCE: Selik, R.M., Haverkos, H.W., Curran, J.W., "Acquired Immune Deficiency Syndrome (AIDS) Trends in the United States, 1978-1982, " American Journal of Medicine 76(3):493-500, 1984.

Table B-2--The CDC's 1985 Case Definition of AIDS

[The Centers for Disease Control agreed] that the following refinements be adopted in the case definition of AIDS used for national reporting:

A. In the absence of the opportunistic diseases required by the current [1982] case definition, any of the following diseases will be considered indicative of AIDS if the patient has a positive serologic or virologic test for HTLV-III/LAV [human T-cell lymphotropic virus, type III/lymphadenopathy-associated virus, presently termed human immunodeficiency virus (HIV)]:

1. Disseminated histoplasmosis (not confined to lungs or lymph nodes), diagnosed by culture, histology, or antigen detection;

2. Isosporiasis, causing chronic diarrhea (over 1 month), diagnosed by histology or stool microscopy;

3. Bronchial or pulmonary candidiasis, diagnosed by microscopy or by presence of characteristic white plaques grossly on the bronchial mucosa (not by culture alone);

4. Non-Hodgkin's lymphoma of high-grade pathologic type (diffuse, undifferentiated) and of B-cell or unknown immunologic phenotype, diagnosed by biopsy;

5. Histologically confirmed Kaposi's sarcoma in patients who are 60 years old or older when diagnosed. .

B. In the absence of the opportunistic diseases required by the current case definition, a histologically confirmed diagnosis of chronic lymphoid interstitial pneumonitis in a child (under 13 years of age) will be considered indicative of AIDS unless test(s) for HTLV-III/LAV are negative.

C. Patients who have a lymphoreticular malignancy diagnosed more than 3 months after the diagnosis of an opportunistic disease used as a marker for AIDS will no longer be excluded as AIDS cases.

D. To increase the specificity of the case definition, patients will be excluded as AIDS cases if they have a negative result on testing for serum antibody to HTLV-III/LAV, have no other type of HTLV-III/LAV test with a positive result, and do not have a low number of T-helper lymphocytes or a low ratio of T-helper to T-suppressor lymphocytes. In the absence of test results, patients satisfying all other criteria in the definition will continue to be included.

SOURCE: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Morbidity and Mortality Weekly Report, "Revision of the Case Definition of Acquired Immunodeficiency Syndrome for National Reporting--United States," 34(25):373-374, 1985.

Table B-3--The CDC's 1987 Case Definition of AIDS

I. Without Laboratory Evidence Regarding HIV Infection

If laboratory tests for HIV were not performed or gave inconclusive results . . . and the patient had no other cause of immunodeficiency listed in Section I.A below, then any disease listed in Section I.B indicates AIDS if it was diagnosed by a definitive method:

A. Causes of immunodeficiency that disqualify diseases as indicators of AIDS in the absence of laboratory evidence for HIV infection.
1. High-dose or long-term systemic corticosteriod therapy or other immunosuppressive/cytotoxic therapy < 3 months before the onset of the indicator disease.
2. Any of the following diseases diagnosed < 3 months after diagnosis of the indicator disease: Hodgkin's disease, non-Hodgkin's lymphoma (other than primary brain lymphoma), lymphocytic leukemia, multiple myeloma, any other cancer of lymphoreticular or histiocytic tissue, or angiommunoblastic lymphadenopathy.
3. A genetic (congenital) immunodeficiency syndrome or an acquired immunodeficiency syndrome atypical of HIV infection, such as one involving hypogammaglobulinemia.

B. Indicator diseases diagnosed definitively:
1. Candidiasis of the esophagus, trachea, bronchi, or lungs.
2. Cryptococcosis, extrapulmonary.
3. Cryptosporidosis with diarrhea persisting > 1 month.
4. Cytomegalovirus disease of an organ other than liver, spleen, or lymph nodes in a patient"> 1 month of age.
5. Herpes simplex virus infection causing a mucocutaneous ulcer that persists longer than 1 month; or bronchitis, pneumonitis, or esophagitis for any duration affecting a patient > 1 month of age.
6. Kaposi's sarcoma affecting a patient < 60 years of age.
7. Lymphoma of the brain (primary) affecting a patient < 60 years of age.
8. Lymphoid interstitial pneumonia and/or pulmonary lymphoid hyperplasia (LIP/PHL complex) affecting a child < 13 years of age.
9. Mycobacterium avium complex or M. *kansasii* disease, disseminated (at a site other than or in addition to lungs, skin, or cervical or hilar lymph nodes).
10. *Pneumocystis carinii* pneumonia.
11. Progressive multifocal leukoencephalopathy.
12. Toxoplasmosis of the brain affecting a patient > 1 month of age.

II. With Laboratory Evidence of HIV Infection

Regardless of the presence of other causes of immunodeficiency (I.A.), in the presence of laboratory evidence for HIV infection . . . any disease listed above (1.B) or below (II.A or II.B) indicates a diagnosis of AIDS.

A. Indicator diseases diagnosed definitively:
1. Bacterial infections, multiple or recurrent (any combination of at least two within a 2-year period), or the following types affecting a child < 13 years of age:

septicemia, pneumonia, meningitis, bone or joint infection, or abscess of an internal organ or body cavity (excluding otitis media or superficial skin or mucosal abscesses), caused by *Haemophilus, Streptococcus* (including pneumococcus), or other pyogenic bacteria;

2. Coccidiodomycosis, disseminated (at a site other than or in addition to lungs or cervical or hilar lymph nodes);
3. HIV encephalopathy (also called "HIV dementia," "AIDS dementia," or 'subacute encephalitis due to HIV") ...;
4. Histoplasmosis, disseminated (at a site other than or in addition to lungs or cervical or hilar lymph nodes);
5. Isosporiasis with diarrhea persisting > 1 month;
6. Kaposi's sarcoma at any age;
7. Lymphoma of the brain (primary) at any age.
8. Other non-Hodgkin's lymphoma of B-cell or unknown immunologic phenotype and the following histologic types:
   a. small noncleaved lymphoma (either Burkitt or non-Burkitt type);
   b. immunoblastic sarcoma (equivalent to any of the following, although not necessarily all in combination: immunoblastic lymphoma, large-cell lymphoma, diffuse histiocytic lymphoma, diffuse undifferentiated lymphoma, or high-grade lymphoma)
   Note: Lymphomas are not included here if they are of T-cell immunologic phenotype or their histologic type is not described or is described as "lymphocytic," "lymphoblastic," "small cleaved," or "plasmacytoid lymphocytic";
9. Any mycobacterial disease caused by mycobacteria other than M. *tuberculosis,* disseminated (at a site other than or in addition to lungs, skin, or cervical or hilar lymph nodes),
10. Disease caused by M. *tuberculosis,* extrapulmonary (involving at least one site outside the lungs, regardless of whether there is concurrent pulmonary involvement) ;
11. *Salmonella* (nontyphoid) septicemia, recurrent;
12. HIV wasting syndrome (emaciation, "slim disease").

B. Indicator diseases diagnosed presumptively:

Note: Given the seriousness of diseases indicative of AIDS, it is generally important to diagnose them definitively, especially when therapy that would be used may have serious side effects or when definitive diagnosis is needed for eligibility for antiretroviral therapy. Nonetheless, in some situations, a Patient's condition will not permit the performance of definitive tests. In other situations, accepted clinical practice may be to presumptively based on the presence of characteristic clinical and laboratory abnormalities.

1. Candidiasis of the esophagus;
2. Cytomegalovirus retinitis with loss of vision;
3. Kaposi's sarcoma;
4. Lymphoid interstitial pneumonia and/or pulmonary lymphoid hyperplasia (LIP/PHL complex) affecting a child < 13 years of age;
5. Mycobacterial disease (acid-fast bacilli with species not identified by culture), disseminated (involving at least one site other than or in addition to lungs, skin, or cervical or hilar lymph nodes);
6. Pneumocystis *carinii* pneumonia;
7. Toxoplasmosis of the brain affecting a patient > 1 month of age.

III. With Laboratory Evidence Against HIV Infection

With laboratory test results negative for HIV Infection . . . a diagnosis of AIDS for surveillance purposes is ruled out unless:

A. all the other causes of immunodeficiency listed above in Section I.A are excluded; AND

B. the patient has had either;

1. *Pneuznocystis carinii* pneumonia diagnosed by a definitive method ...; or

2. a. any of the other diseases indicative of AIDS listed above in Section I.B diagnosed by a definitive method ...; and
   b. a T-helper/inducer ($CD4^+$) lymphocyte count $<400/mm^3$.

SOURCE: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "1987 Revision of Case Definition for AIDS for Surveillance Purposes," Morbidity and Mortality Weekly Report 36(1S):4s-14s, 1987.

APPENDIX C--THE CDC's AIDS CASE REPORTING FORM (FIGURE)

Patient's Name: _____ Phone No.: ( ) _____
(Last, First, M.I.)

Address: _____ City: _____ County: _____

– DETACH HERE – – Patient identifier information is not transmitted to CD

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)
ADULT CONFIDENTIAL CASE REPORT
(Patients ≥ 13 years of age at time of diagnosis)

Form Approv
OMB No. 092
Exp. 11/30/92

Public burden for this collection of information is estimated to average 10 minutes per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to PHS Reports Clearance Officer; ATTN: PRA; Hubert H. Humphrey Bldg, Rm 721-B; 200 Independence Ave., SW; Washington, DC 20201, and to the Office of Management and Budget; Paperwork Reduction Project (0920-0009); Washington, DC 20503.

This report is authorized by law (Sections 304 and 306 of the Public Health Service Act, 42 USC 242b 242k). Response in this case is voluntary for federal government purposes, but may be mandatory under s and local statutes. Your cooperation is necessary for the understanding and control of AIDS. Information ir surveillance system that would permit identification of any individual on whom a record is maintained collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in assurance on file at your local health department, and will not otherwise be disclosed or released without consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m)

HEALTH DEPARTMENT USE ONLY

DATE FORM COMPLETED: Mo. Day Yr. ☐☐ ☐☐ ☐☐

SOUNDEX CODE: ☐☐☐☐

REPORT STATUS: [1] New Report [2] Update

REPORTING HEALTH DEPARTMENT: State: _____ City/ County: _____

State Patient No.: ☐☐☐☐☐☐☐☐☐☐

City/County Patient No.: ☐☐☐☐☐☐☐☐☐☐

I. BASIC PATIENT INFORMATION

CDC PATIENT NUMBER: ☐☐☐☐☐☐☐

DATE OF BIRTH: Mo. Day Yr. ☐☐ ☐☐ ☐☐

AGE AT DIAGNOSIS OF AIDS: ☐☐ Years

CURRENT STATUS: Alive [1] Dead [2] Unk. [9]

DATE OF DEATH: Mo. Day Yr. ☐☐ ☐☐ ☐☐

STATE OF DEATH: ☐☐

SEX: [1] Ma [2] Fe

RACE/ETHNICITY:
[1] White (not Hispanic) [2] Black (not Hispanic) [3] Hispanic
[4] Asian/Pacific Islander [5] American Indian/ Alaskan Native [9] Not Specified

COUNTR ' OF BIRTH:
[1] U.S. [2] U.S. Dependencies and Possessions (including Puerto Rico)
(specify): _____
[8] Other (specify): _____ [9] Unknown

RESIDENCE AT DIAGNOSIS OF AIDS:
City: _____ County: _____ State/ Country: _____ Zip Code: ☐☐☐☐☐☐☐☐☐

II. FACILITY OF DIAGNOSIS

FACILITY NAME: _____

City _____

State/ Country: _____

[1] Outpatient (Clinic, Private Physician, HMO)
[2] Hospital, Inpatient
[8] Other (specify): _____

III. SOURCE OF REPORT

SOURCE:
[1] Healthcare provider/on-site review
[2] Death certificate review
[3] HIV report follow-up
[4] Alternate database
(specify): _____
[8] Other (specify): _____

IV. PATIENT HISTORY

AFTER 1977 AND PRECEDING THE DIAGNOSIS OF HIV INFECTION OR AIDS THIS PATIENT HAD:
(Respond to ALL Categories)

	Yes	No
• Sex with male	[1]	[0]
• Sex with female	[1]	[0]
• Injected nonprescription drugs	[1]	[0]
• Received clotting factor for coagulation disorder	[1]	[0]
• Specify disorder: [1] Factor VIII (Hemophilia A) [2] Factor IX (Hemophilia B) [8] Other (specify): _____		
• Heterosexual relations with:		
• Intravenous/injection drug user	[1]	[0]
• Bisexual male	[1]	[0]
• Person with hemophilia/coagulation disorder	[1]	[0]
• Transfusion recipient with HIV infection	[1]	[0]
• Person with HIV/AIDS infection, risk not specified	[1]	[0]
• Person born in a country where heterosexual transmission predominates	[1]	[0]
(specify country): _____		
• Received transfusion of blood/blood components (other than clotting factor)	[1]	[0]
First Mo. ☐☐ Yr. ☐☐ Last Mo. ☐☐ Yr. ☐☐		
• Received transplant of tissue/organs or artificial insemination	[1]	[0]
• Worked in a health-care or clinical laboratory setting	[1]	[0]
(specify occupation): _____		

Physician"s Name: _____ Phone No.: ( ) _____

Hospital/Facility: _____ Med Rec. No.: _____

Person completing form: _____ Phone No.: ( ) _____

ETACH HERE – – Patient identifier information is not transmitted to CDC –

V. SELECTED DISEASES *(check all that apply)*

AIDS INDICATOR DISEASE	Initial Diagnosis Def.	Initial Diagnosis Pres.	Initial Date Mo.	Initial Date Yr.
Candidiasis, bronchi, trachea, or lungs	1	NA		
Candidiasis, esophageal	1	2		
Coccidioidomycosis, disseminated or extrapulmonary	1	NA		
Cryptococcosis, extrapulmonary	1	NA		
Cryptosporidiosis, chronic intestinal (>1 mo. duration)	1	NA		
Cytomegalovirus disease (other than in liver, spleen, or nodes)	1	NA		
Cytomegalovirus retinitis (with loss of vision)	1	2		
HIV encephalopathy	1	NA		
Herpes simplex: chronic ulcer(s) (>1 mo. duration); or bronchitis, pneumonitis or esophagitis	1	NA		
Histoplasmosis, disseminated or extrapulmonary	1	NA		
Isosporiasis, chronic intestinal (>1 mo. duration)	1	NA		
Kaposi's sarcoma	1	2		
Lymphoma, Burkitt's (or equivalent term)	1	NA		
Lymphoma, immunoblastic (or equivalent term)	1	NA		
Lymphoma, primary in brain	1	NA		
Mycobacterium avium complex or *M.kansasii*, disseminated or extrapulmonary	1	2		
M. tuberculosis, disseminated or extrapulmonary	1	2		
Mycobacterium, of other species or unidentified species, disseminated or extrapulmonary	1	2		
Pneumocystis carinii pneumonia	1	2		
Progressive multifocal leukoencephalopathy	1	NA		
Salmonella septicemia, recurrent	1	NA		
Toxoplasmosis of brain	1	2		
Wasting syndrome due to HIV	1	NA		

Def. = definitive diagnosis Pres. = presumptive diagnosis

Has patient been diagnosed with pulmonary tuberculosis? ..... 1 Yes 2 No 9 Unk. DATE: Mo. Yr.

VI. LABORATORY DATA

I. HIV TESTS (If more than one positive test, indicate date of *first* positive test.)

	Reactive	Non-reactive	Inconclusive	Not Done	TEST DATE Mo.	TEST DATE Yr.
▸ HIV-1 SERUM ANTIBODY TESTS:						
• EIA	1	0	–	9		
• Western blot/immunofluorescence assay	1	0	8	9		
▸ OTHER HIV- 1 TEST:	1	0	8	9		
(specify): _____						
▸ HIV-2 SERUM ANTIBODY TESTS:						
• EIA	1	0	–	9		

J. If HIV tests were not positive or were not done, does this patient have an immunodeficiency that would disqualify him/her from the AIDS case definition? ..... Yes 1 No 2 Unk. 9

II. IMMUNOLOGIC LAB TESTS (If more than one test, indicate lowest available test.)

	TEST DATE Mo.	TEST DATE Yr.
▸ T HELPER (CD4+) LYMPHOCYTE COUNT:		
• Absolute number/mm^3	,___ cells/mm^3	
• Percent	%	

VII. COMMENTS

_____

_____

_____

Appendix D--Epidemiology of AIDS in Women, Injection Drug Users, African Americans, and Hispanics

The epidemic of acquired immunodeficiency syndrome (AIDS) in the United States has now entered its second decade, and the fastest growing populations of people in the United States with AIDS are women, injection drug users, African Americans, and Hispanics. Although the rate of increase in the number of AIDS cases among homosexual and bisexual men (excluding those who are also injection drug users) began declining by 1987 (215), the rate of increase in the number of AIDS cases associated with injection drug use and heterosexual transmission has continued to rise (212).

Through February 1992, 29 percent of all AIDS cases reported to the Centers for Disease Control (CDC) in the U.S. Department of Health and Human Services (DHHS) were among injection drug users (including male injection drug users who reported having had sex with men)(223), as compared with 25.5 percent in 1982. The increased incidence of AIDS among injection drug users in this country is associated with an increased incidence of AIDS among minorities and women. A disproportionate number of HIV-infected injection drug users are African American or Hispanic. As of February 1992, African American men and women accounted for 50 percent of U.S. AIDS cases reported among heterosexual injection drug users, and Hispanic men and women accounted for 29 percent of AIDS cases among heterosexual injection drug users (223).

Similarly, a large number of AIDS cases among women in the United States are associated with injection drug use. Approximately 50 percent of women who were reported as AIDS cases to the CDC through February 1992 had used injection drugs. An additional 21 percent of female AIDS cases occurred among women who reported sexual contact with an injection drug user (223) .

The Epidemiology of AIDS in U.S. Women

By the end of February 1992, there were more than 22,000 reported cases of AIDS among women in the United States (223). The incidence of AIDS among U.S. women is climbing faster than the AIDS incidence among U.S. men. From 1988 to 1989, the annual number of AIDS diagnoses increased by 29 percent in women and 18 percent in men (35). Between 1985 and 1990, the percentage of adult AIDS cases occurring in women increased from 6.6 percent to 11.5 percent (48).

In 1988, AIDS/HIV accounted for 3 percent of all deaths among U.S. women of reproductive age (35).[1] The number of deaths per year due to HIV/AIDS in women of reproductive age increased from 18 in 1980 (35) to 5,730 in 1991 (222).

AIDS is now the eighth leading cause of death in U.S. women of reproductive age. In New York and New Jersey, it is the leading cause of death in women of reproductive age. If current mortality trends continue, AIDS will become one of the five leading causes of death for U.S. women of reproductive age (35).

African American and Hispanic women represent 72 percent of all U.S. women diagnosed with AIDS as of 1989 (213). African American women, who constituted 13.3 percent of U.S. women in 1988, represented 57.6 percent of all women of reproductive age with AIDS between 1981 and 1989. Hispanic women, who constituted 7.9 percent of U.S. women in 1988, accounted for 16.8 percent of all AIDS cases reported in women of reproductive age between 1981

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1 Reproductive age for women is defined as 15 to 44 years of age. Approximately 85 percent of women with AIDS are of reproductive age at the time of their diagnosis (221).

and 1989. Non-Hispanic white women, who constituted 75.1 percent of the U.S. women in 1988, accounted for 24.9 percent of the AIDS cases in women between 1981 and 1989 (216).

Death rates associated with HIV infection/AIDS are much higher for African American women than for white women. In 1988, the death rate from HIV infection was nine times higher for African American women of reproductive age than for white women (213). For African American women, the age-adjusted death rate for HIV/AIDS increased from 4.4 deaths per 100,000 population in 1986 to 10.3 deaths per 100,000 in 1988. For white women, the age-adjusted death rate for HIV/AIDS increased from 0.6 deaths per 100,000 in 1985 to 1.2 deaths per 100,000 in 1988 (35).

The median survival time from AIDS diagnosis to death for women does not differ significantly from that for heterosexual men. A recent study by Ellerbrock and colleagues found that the median survival time from AIDS diagnosis to death to be 9.8 months for U.S. women and 9.3 months for heterosexual U.S. men (48). This study-found the 3-year survival rate after a diagnosis of AIDS to be 20 percent for women and 19 percent for heterosexual men. These findings differ from the findings of a previous study by Rothenberg and colleagues, which found that the median survival time from AIDS diagnosis to death to be shorter for women (263 days) than for men (357 days) (145). One reason for the differences in the two studies' findings may be that the earlier study by Rothenberg and colleagues compared women with all men, including men who have sex with men; survival time in men who have sex with men is higher than in other risk groups (in part because a higher percentage of men who have sex with men have Kaposi's sarcoma, which is associated with a longer survival time than other opportunistic diseases)

(48). Heterosexual men with AIDS may be a more appropriate comparison group for women with AIDS because they are more similar demographically and have risk factors similar to those of women with AIDS.

The Epidemiology of AIDS in U.S. Injection Drug Users

From the beginning of the AIDS epidemic through December 1991, there have been 58,888 cumulative AIDS cases among injection drug users in the United States (including male injection drug users who had sex with men)(222). These cases represent 29 percent of all adult and adolescent AIDS cases reported to the CDC in that period. In 78 percent (45,753) of the reported AIDS cases among injection drug users, the only risk factor for HIV infection reported was injection drug use (222). The high incidence of AIDS among injection drug users is associated with an increased incidence of AIDS among sexual partners of injection drug users and an increased incidence of AIDS among children whose mothers are injection drug users or are sex partners of injection drug users.

Higher HIV antibody seroprevalence rates are observed among African American and Hispanic injection drug users than among non-Hispanic white injection drug users. A review of 92 studies of the prevalence of HIV infection among injection drug users by Hahn and colleagues found that the risk of HIV infection was associated not only with male homosexual contact and particular injection drug use practices, but also with African American or Hispanic ethnicity (71). This racial/ethnic disparity may be explained, in part, by differences in drug use behavior. In particular, the practice of sharing needles or syringes among strangers and acquaintances appears to be more common among African American and Hispanic injection drug users than among non-Hispanic white injection drug users (154).

Of the 45,753 AIDS cases reported among heterosexual injection drug users through December 1991, 50 percent occurred among African American men and women and 29 percent occurred among Hispanic men and women (222). Of the AIDS cases reported among heterosexual sex partners of injection drug users, 52 percent were African American men and women and 26 percent were Hispanic men and women (222) . Of the AIDS cases reported among female injection drug users in the same time period, 58 percent were among African Americans and 20 percent were among Hispanics (222).

Regional variations in the distribution of AIDS cases in the United States are evident. The injection-drug-using population most severely affected by the AIDS virus is concentrated in northeastern cities, primarily New York City and surrounding metropolitan areas (241), and in Puerto Rico (71).

The Epidemiology of AIDS in African Americans and Hispanics

In 1991, the annual rate per 100,000 population of AIDS cases was 95.3 (11,059) among African American men and 69.9 (6,850) among Hispanic men. The annual rate per 100,000 population among non-Hispanic white men was 27.8 (20,716)(222). Cases of AIDS in African Americans and Hispanics represented 28 percent and 17 percent, respectively, of the 39,093 male AIDS cases, and 52 percent and 22 percent, respectively, of the 4,890 female AIDS cases reported in 1991 (222). HIV transmission among African American and Hispanic persons with AIDS occurred predominantly through injection drug use (222).

As measured in terms of cumulative incidence rate, the relative risk of AIDS in African Americans and Hispanics was approximately three times the risk in non-Hispanic whites. The risks of AIDS in African American and Hispanic men were 2.8 and 2.7 times, respectively, that of non-Hispanic white men (157).

Racial disparities in the distribution of AIDS cases are even more striking among women than among men. Between 1985 and 1990, 52 percent of the women with AIDS were African American and 21 percent were Hispanic (221).[2] During this period, African American women had a cumulative incidence rate 13 times that of non-Hispanic whites, and Hispanic women had a cumulative incidence rate that was 8 times that of non-Hispanic whites (48).

In 1991, a total of 45,506 new AIDS cases were reported to the CDC. The annual rate of new AIDS cases for the U.S, population as a whole was 17.8 cases per 100,000 population for 1991. Annual rates for African Americans and Hispanics were much higher- -49.2 cases per 100,000 in the case of African Americans and 31.4 cases per 100,000 for Hispanics (222).

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2 Thirteen percent of all U.S. women are African American and 8 percent are Hispanic.

Appendix E--The CDC's Current and Proposed Classification System for HIV Infection

The Centers for Disease Control (CDC) has developed a classification system for human immunodeficiency virus (HIV) infection in adolescents and adults that categorizes the clinical conditions associated with the broad spectrum of HIV infection--from no symptoms of HIV infection to severe manifestations of HIV infection. This classification system was created for epidemiologic and clinical purposes. Unlike the CDC's case definition of AIDS, this classification system is not used for reporting purposes.

The CDC's current HIV classification system, published in 1986, uses clinical disease states to divide HIV infection into four broad clinical categories. This system is described further in box E-1.

In November 1991, the CDC proposed revising its classification system for HIV infection. The proposed system would sub-categorize the clinical conditions associated with HIV infection on the basis of patients' $CD4^+$ lymphocyte counts.

As shown in box E-2, the proposed classification system includes three laboratory categories (i.e., ranges of $CD4^+$ lymphocyte counts) and three clinical categories, resulting in a matrix of nine mutually exclusive categories. In incorporating $CD4^+$ lymphocyte counts along with various clinical conditions, the CDC's proposed classification system for HIV infection is similar to the CDC's proposed case definition of AIDS (see app. B). The clinical categories in the proposed HIV classification system, however, differ from those in the CDC's proposed case definition. As shown in box E-2, the clinical categories are as follows:

- **Clinical category A** includes asymptomatic HIV infection, persistent generalized lymphadenopathy, and acute primary HIV infection;

- Clinical category B includes a variety of symptomatic conditions which are not included in the CDC's 1987 surveillance case definition of AIDS, but which may be attributed to HIV infection or whose clinical course or management is complicated by HIV infection; and
- Clinical category C includes any condition listed in the CDC's 1987 surveillance case definition of AIDS.

Clinical category B of the proposed classification system for HIV infection includes some conditions which a physician judges to be HIV-related or the management of which is affected by HIV status. This category includes many of the conditions (e.g., bacterial endocarditis, pneumonia, sepsis, and pulmonary tuberculosis) that are noted to occur more commonly among HIV-infected injection drug users. Clinical category B also includes female-specific symptoms that are not included in the CDC's 1987 case definition of AIDS. Cervical dysplasia or carcinoma and vulvovaginal candidiasis are included in category B.

The 23 AIDS-defining conditions in the CDC's 1987 case definition of " AIDS, included in clinical category C, have a much stronger relation to impairment of immune function caused by HIV-infection than do the conditions included in category B.

Box E-l--The CDC's Current Classification System for HIV Infection (HTLV-III/LAV)

The CDC's current classification system for HIV infection was published in 1986. At the time, HIV was known as human T-cell lymphotropic virus type III/lymphadenopathy-associated virus.

The current classification system classifies HTLV-III/LAV infection into four mutually exclusive groups, designated by Roman numerals I though IV and described further below. Classification in a particular group is not explicitly intended to have prognostic significance, nor to designate severity of illness. However, classification in the four principal groups, I to IV, is hierarchical, in that persons classified in a particular group should not be reclassified in a preceding group if clinical findings resolve, since clinical improvement may not accurately reflect changes in the severity of the underlying disease.

Group I (Acute HTLV-III/LAV Infection) includes patients with transient signs and symptoms that appear at the time of, or shortly after, initial infection with HTLV-III/LAV as identified by laboratory studies. All patients in Group I will be reclassified in another group following resolution of this acute syndrome.

Group I is defined as a mononucleosis-like syndrome, with or without aseptic meningitis, associated with seroconversion for HTLV-III/LAV antibody (15-16). Antibody seroconversion is required as evidence of initial infection; current viral isolation procedures are not adequately sensitive to be relied on for demonstrating the onset of infections.

Group II (Symptomatic HTLV-III/LAV Infection) includes patients who have had no signs or symptoms of HTLV-III/LAV infection. Patients in Group II may be subclassified based on whether hematologic and/or immunologic laboratory studies have been performed and whether test results are consistent with defects associated with HTLV-III/LAV infection.

Group II is defined as the absence of signs or symptoms of HTLV-III/LAV infection. To be classified in Group II, patients must have had no previous signs or symptoms that would have led to classification in Groups III or IV. Patients whose clinical findings caused them to be classified in Groups III or IV.should not be reclassified in Group II if those clinical findings resolve.

Patients in this group may be subclassified on the basis of a laboratory evaluation. Laboratory studies commonly indicated for patients with HTLV-III/LAV infection include, but are not limited to, a complete blood count (including differential with blood cell count) and a platelet count. Immunologic tests, especially T-lymphocyte helper ($CD4^+$) and suppressor ($CD8^+$) cell counts, are also an important part of the overall evaluation. Patients whose test results are within normal limits, as well as those for whom a laboratory-evaluation has not yet been completed, should be differentiated from patients whose test results are consistent with defects associated with HTLV-III/LAV infection (e.g., lymphopenia, thrombocytopenia, decreased number of helper ($CD4^+$) T-lymphocytes).

Group III (Persistent Generalized Lymphadenopathy) includes patients with persistent generalized lymphadenopathy, but without findings that would lead to classification in Group IV. Patients in this category may be subclassified based on the results of laboratory studies in the same manner as patients in Group II.

Group III is defined as palpable lymphadenopathy (lymph node enlargement of 1 centimeter or greater) at two or more extra-inguinal sites persisting for more than 3 months in the absence of a concurrent illness or condition other than HTLV-III/LAV infection to explain the findings. Patients in this group may also be subclassified on the basis of a laboratory evaluation, as is done for asymptomatic patients in Group II (see above). Patients with persistent generalized lymphadenopathy whose clinical findings caused them to be classified in Group IV should not be reclassified in Group III if those other clinical findings resolve.

Group IV (other HTLV-III/LAV) includes patients with clinical symptoms and signs of HTLV-III/LAV infection other than or in addition to lymphadenopathy. Patients in this group are assigned to one *or more* subgroups based on clinical findings: A) constitutional disease; B) necrologic disease; C) secondary infectious diseases; D) secondary cancers; and E) other conditions resulting from HTLV-III/LAV infection. There is no a *priori* hierarchy of severity among subgroups A through E, and these subgroups are not mutually exclusive.

The clinical manifestations of patients in this group may be designated by assignment to one or more subgroups (A-E) listed below. Within Group IV, subgroup classification is independent of the presence or absence of lymphadenopathy. Each subgroup may include patients who are minimally symptomatic, as well as patients who are severely ill. Increased specificity for manifestations of HTLV-III/LAV infection, if needed for clinical purposes or research or for disability determinations, may be achieved by creating additional divisions within each subgroup.

- Subgroup A (Constitutional disease)--Defined as one or more of the following: fever persisting more than 1 month, involuntary weight loss of greater than 10 percent of baseline, or diarrhea persisting more than 1 month; and the absence of a concurrent illness or condition other than HTLV-III/LAV infection to explain the findings.

Subgroup B (Necrologic disease)--Defined as one or more of the following: dementia, myelopathy, or peripheral neuropathy; and the absence of a concurrent illness or condition other than HTLV-III/LAV infection to explain the findings.

- Subgroup C (Secondary infectious diseases)--Defined as the diagnosis of an infectious disease associated with HTLV-III/LAV infection and/or at least moderately indicative of a defect in cell-mediated immunity. Patients in this subgroup are divided further into two categories.

  --*Category C-l*--Includes patients with symptomatic or invasive disease due to one of 12 specified secondary infectious diseases listed in the surveillance definition of AIDS: *Pneumocystis carinii* pneumonia, chronic cyptosporidiosis, toxoplasmosis, extraintestinal strongyloidiasis, isosporiasis, candidiasis (esophageal, bronchial, or pulmonary), cryptococcosis, histoplasmosis, mycobacterial infection with *Mycobacterium avium* complex or M. *kansasii,* cytomegalovirus, chronic mucocutaneous or disseminated herpes simplex virus infection, and progressive multifocal leukoencephalopathy.

--*Category* C-2--Includes patients with symptomatic or invasive disease due to one of six other specified secondary infectious diseases: oral hairy leukoplakia, multidermatomal herpes zoster, recurrent *Salmonella* bacteremia, nocardiosis, tuberculosis, or oral candidiasis (thrush).

- Subgroup D (Secondary cancers) --Defined as the diagnosis of one or more kinds of cancer known to be associated with HTLV-III/LAV infection as listed in the surveillance definition of AIDS and at least moderately indicative of a defect in cell-mediated immunity: Kaposi's sarcoma, non-Hodgkin's lymphoma (small, noncleaved lymphoma or immunoblastic sarcoma) , or primary lymphoma of the brain.
- Subgroup E (Other conditions in HTLV-IIILAV infection) --Defined as the presence of other clinical findings or diseases, not classifiable above, that may be attributed to HTLV-III/LAV infection and/or may be indicative of a defect in cell-mediated immunity. Included are patients with chronic lymphoid interstitial pneumonitis. Also included are those patients whose signs or symptoms could be attributed either to HTLV-III/LAV infection or to another coexisting disease not classified elsewhere, and patients with other clinical illnesses, the course or management of which may be complicated or altered by HTLV-III/LAV infection. Examples include patients with constitutional symptoms not meeting the criteria for subgroup IV-A; patients with infectious diseases not listed in subgroup IV-C; and patients with neoplasms not listed in subgroup IV-D.

SOURCE: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, 'Classification System for Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus Infections," Morbidity and Mortality Weekly Report 35(20): 334-339, 1986.

Box E-2--The CDC's Proposed Classification System for HIV Infection

The CDC's proposed classification system for HIV infection divides HIV-infected patients into three laboratory categories and three clinical categories.

Laboratory Categories

[The three designated laboratory categories correspond to $CD4^+$ lymphocyte counts per cubic millimeter ($/mm^3$) of blood that guide clinical and/or therapeutic actions in the management of HIV-infected adolescents and adults. The laboratory categories are as follows]:

- Category 1--A $CD4^+$ lymphocyte count of more than 500 cells/mm^3
- Category 2--A $CD4^+$ lymphocyte count from 200 through 499 cells/mm^3
- Category 3--A $CD4^+$ lymphocyte count below 200 cells/mm^3.

Clinical Categories

The clinical categories are defined as follows:

- Category A--One or more of the conditions listed below occurring in an adolescent or adult with documented HIV infection. Conditions listed in categories B and C (below) must not have occurred.
  - Asymptomatic HIV infection;
  - Persistent generalized lymphadenopathy;
  - Acute (primary) HIV infection with accompanying illness or history of acute HIV infection.

- Category B--Symptomatic conditions occurring in an HIV-infected adolescent or adult which are not included among conditions listed in clinical category C and which meet at least one of the following criteria: (a) the conditions are attributed to HIV infection and/or are indicative of a defect in cell-mediated immunity; or (b) the conditions are considered by physicians to have a clinical course or management that is complicated by HIV infection. Examples of conditions in clinical category B include, *but are not limited to:*
  - Bacterial endocarditis, meningitis, pneumonia, or sepsis;
  - Candidiasis, vulvovaginal; persistent (> 1 month duration), or poorly responsive to therapy;
  - Candidiasis, oropharyngeal (thrush);
  - Cervical dysplasia, severe; or carcinoma;
  - Constitutional symptoms, such as fever (> 38.5°C) or diarrhea lasting > 1 month;
  - Hairy leukoplakia, oral;
  - Herpes zoster (shingles), involving at least two distinct episodes or more than one dermatome;
  - Idiopathic thrombocytopenic purpura;
  - *Mycobacterium tuberculosis,* pulmonary;
  - Nocardiosis;
  - Pelvic inflammatory disease;
  - Peripheral neuropathy;

- **Category C-** -Any condition listed in the CDC's 1987 surveillance case definition of AIDS and affecting an adolescent or adult . . . . The conditions in clinical category C are strongly associated with severe immunodeficiency, occur frequently in HIV-infected individuals, and cause serious morbidity or mortality. HIV-infected persons should be classified based on both the lowest accurate (but not necessarily the more recent) $CD4^+$ lymphocyte determination and the most severe clinical condition diagnosed, regardless of the patient's current clinical condition (e.g., someone previously treated for oral or persistent vaginal candidiasis but who is now asymptomatic should be classified in clinical category B). The classification system is based on the absolute number of $CD4^+$ cells but allows for the use of $CD4^+$ percent when the counts cannot be obtained or are outdated in view of the patient's current clinical condition . . . .

SOURCE: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "1992 Revised Classification System for HIV Infection and Expanded AIDS Surveillance Case Definition for Adolescents and Adults," Draft, Nov. 15, 1991.

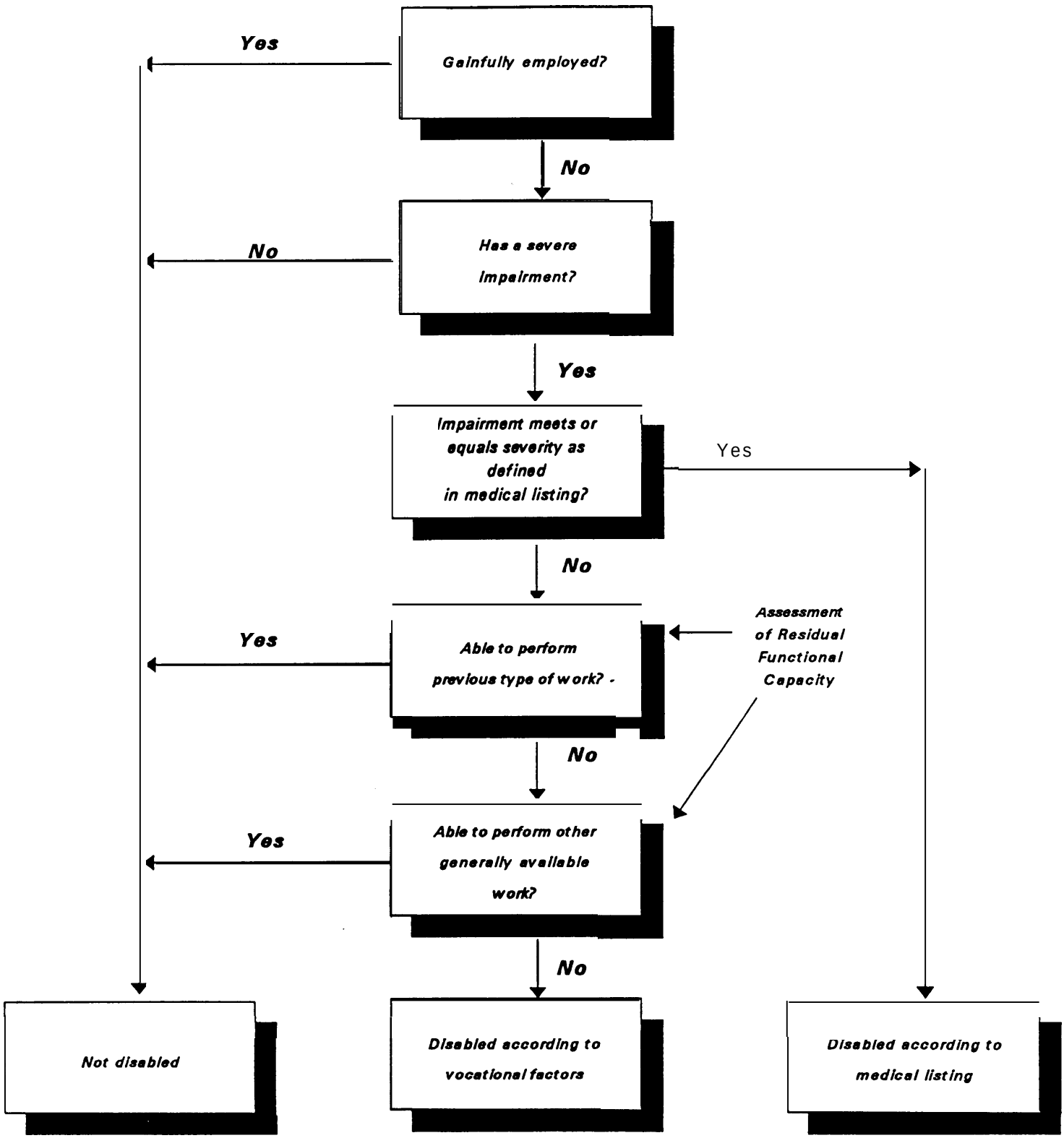
Appendix F-HIV Testing and Reporting Requirements in the States and the District of Columbia

Names only	*Names* with opportunities for anonymous testing	Anonymous with names reported in specific situations	strictly anonymous (demographics only)	No requirements
Alabama	Arizona	California	Florida	Alaska
Idaho	Arkansas	Delaware	Georgia	District of Columbia
Minnesota	Colorado	Oregon	Hawaii	Louisiana
North Dakota	Connecticut?	Tennessee	Illinois	Massachusetts
South Dakota	Indiana		Iowa	Nebraska
South Carolina	Kentucky		Kansas	New Mexico
	Michigan		Maine	Pennsylvania
	Mississippi		Maryland	Vermont
	Missouri		Montana	
	New Jersey		Nevada	
	North Carolina		New Hampshire	
	Oklahoma		New York	
	Ohio		Rhode Island	
	Utah		Texas	
	Virginia		Washington	
	West Virginia			
	Wisconsin			
	Wyoming			
TOTAL = 6	TOTAL = 18	TOTAL = 4	TOTAL = 15.	TOTAL = 8

[a]Requires combined reporting of HIV and tuberculosis.
bFor example, donation to blood banks.

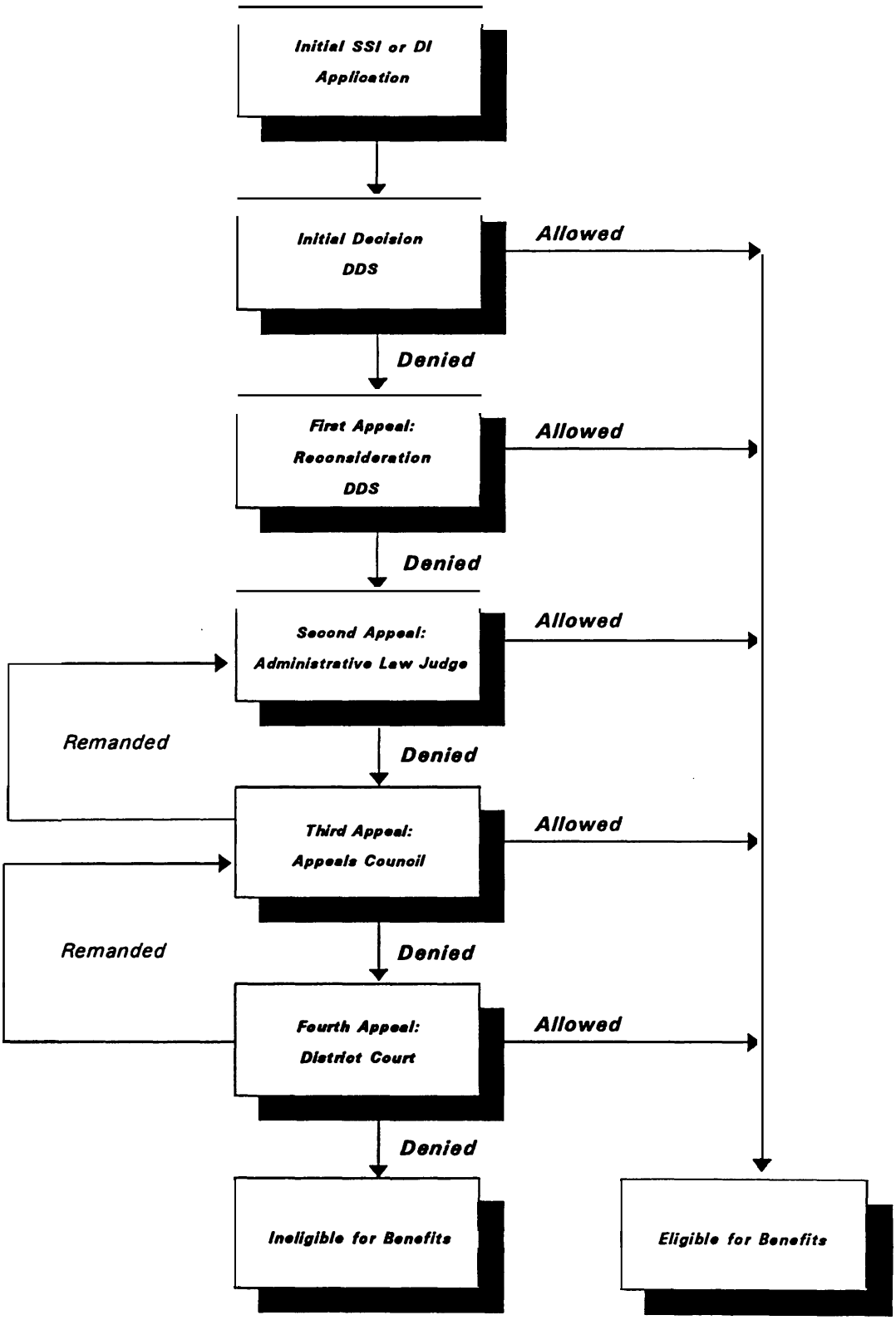
SOURCE: George Washington University, Intergovernmental Health Policy Project, AIDS Policy Center, Washington, DC, January 1992.

Appendix G: Social Security Administration's Sequential Disability Determination Process



SOURCE : U.S. Congress, General Accounting Office, Social Security: Selective Face to Face Interviews With Disability Claimants Could Reduce Appeals, GAO/HRD-89-22 (Washington, DC: U.S. Government Printing Office, April 1989).

Appendix H: Social Security Administration's Disability Appeals Process



SOURCE : U.S. Congress, General Accounting Office, Social Security: Selective Face to Face Interviews With Disability Claimants Could Reduce Appeals, GAO/HR.D-89-22 (Washington, DC: U.S. Government Printing Office, April 1989).

Presented below are summaries of case histories of several of the plaintiffs as described in the Third Amended Class Action Complaint in S.P. v. Sullivan (168). OTA presents the facts as reported in the Complaint to provide context for the debate over the Social Security Administration's (SSA) disability determinations for HIV-infected persons.

Case History I

- Mr. R.G. --is a 26-year-old Latino who resides in Manhattan, New York. He learned that he was infected with HIV in January of 1989. He had been suffering from ulcers, diarrhea, seborrheic dermatitis, oral thrush, anal fissures, bronchial asthma, enlargement of the liver, and a severe borderline personality disorder. In June of 1989, he broke his leg in a car accident. As of December 1991, his leg had not healed and he uses crutches to walk.

- He applied for Supplemental Security Income (SSI) benefits on July 21, 1989. On November 27, 1989, he was notified that his claim was denied, and he requested reconsideration on December 13, 1989. He was notified on February 1, 1990, that his reconsideration was denied, and he requested a hearing before an administrative law judge on March 8, 1990.

- On May 8, 1990, Mr. R.G. had a hearing before an administrative law judge at which the following evidence was presented:

  (a) A treating physician report, dated September 1988, indicating Mr. R.G. had diarrhea, asthma, ulcers, migraine headaches, and "fatigue " [which] limits his ability to function for any more than several hours at a time."

  (b) A treating psychiatrist report, dated September 1989, documenting that Mr. R.G. was depressed, that his social functioning was "very poor," and that his ability to work was severely compromised due to his "totally disabling" personality disorder.

  (c) A June 1989 blood test indicating that his $CD4^+$ lymphocyte count was 553 and his $CD4^+/CD8^+$ ratio was 0.34, which was indicative of a compromised immune system. A blood test taken in June 1990 showed that his $CD4^+$ lymphocyte count had dropped to 425 cells per cubic millimeter ($/mm^3$).

  (d) A November 1989 report of a consultative physician retained by the SSA diagnosing Mr. R.G. with HIV Group III and possible chronic liver disease, in addition to a leg fracture which had not healed. The report documented a history of personality disorder and his complaints of anxiety, diarrhea, recurrent fevers, and sweats, and noted that Mr. R.G. receives assistance with shopping and household chores. The consultative physician noted Mr. R.G.'s complaints of asthma but did not order a pulmonary function test because Mr. R.G. "tested positive for HIV."

(e) Two reports from Mr. R.G.'s treating physician, both dating from April 1990, documenting that Mr. R.G. had suffered from AIDS-related complex (ARC) since 1989. In particular, Mr. R.G. suffered from asthma, thrush, dermatitis, upper respiratory infection, anxiety, and short-term memory impairment. In addition, the reports note that Mr. R.G. was unable to walk due to a fractured leg which had not healed; that he had to lie down during the day due to fatigue; that he was only able to stand for a single hour or walk for half an hour in an 8-hour work day, and that he was unable to climb or reach and was severely limited in his ability to lift and carry. The doctor certified Mr. R.G. 's need for assistance with many activities of daily living and recommended that Medicaid provide him with a home attendant.

- At the hearing, Mr. R.G. testified about his medical impairments, including his need for a home attendant, and provided evidence of prescription medication for the treatment of asthma, herpes, migraine headaches, allergies, and dermatitis. He also testified that he had been prescribed AT for his HIV infection.

- On July 27, 1990, the administrative law judge issued a decision denying Mr. R.G.'s claim. The judge found that Mr. R.G.'s subjective complaints were not credible to the extent alleged and found that he did not have a disabling condition, noting that 'until we have a full-blown case of AIDS on our hands. . . this is not a disabling impairment."

m On August 5, 1990, Mr. R.G. requested that the Appeals Council review the administrative law judge's decision. On March 20, 1991, the Appeals Council remanded Mr. R.G.'s application for a second hearing before a different administrative law judge. On July 9, 1991, the second administrative law judge found that R.G. had been disabled since July21, 1989, almost 2 years earlier, as Mr. R.G. had initially claimed.

Case History II

= Mr. G.S. --is a 31-year-old veteran who resides in Brooklyn, New York. Since leaving the military service in 1981, Mr. G.S. worked as a machinist, carpenter, and maintenance mechanic. Mr. G.S. tested HIV positive in 1988.

- On April 4, 1990, Mr. G.S. applied for Social Security Disability Insurance (DU) benefits because he was unable to maintain employment. Mr. G.S. presented medical evidence of the following symptoms and illnesses: recurrent bouts of bacterial pneumonia, chronic chest pain, an episode of endocarditis, weakness due to thrombocytopenia, recurrent oral thrush, hepatomegaly, an enlarged spleen and liver, hepatitis, depression, weight loss, fevers, chills, chronic fatigue, shortness of breath, and a $CD4^{+}$ lymphocyte count of 210 cells/mm^3.

- In a report dated May 24, 1990, a disability analyst employed by the Office of Disability Determination Services (DDS) wrote, "claimant has advanced ARC. Last T4 was 210. Please give RFC [residual functional capacity]." On the portion of the form entitled "Advice," the non-examining physician from

the DDS wrote in response, 'no opportunistic disease .. .T4($CD4^+$21010 above the indicated criteria of 200. Does not equal [POMS Symptomatic HIV Infection Listing] -RFC light." The Disability Determination Transmittal Forms on initial and reconsideration review classified Mr. G.S.'s primary diagnosis as HIV positive, and indicated no secondary diagnosis.

- Mr. G.S. was notified that his claims were denied on June 6, 1990. On August 2, 1990, he filed for reconsideration, and on August 30, 1990, he was notified that his reconsideration was denied. On September 19, 1990, Mr. G.S. filed a request for a hearing before an administrative law judge.

- On April 26, 1991, a year after his initial application, the administrative law judge found Mr. R.G. disabled as of November 14, 1989, and awarded him disability benefits.

Case History III

- Ms. D.C. --is a 31-year-old woman who resides in Brooklyn, New York. She tested positive for HIV in April of 1987.

- On October 12, 1990, she applied for SSI after she was unable to work due to chronic bronchitis, cervical carcinoma, chronic fatigue, headaches, and vaginal candidiasis. She also documented a $CD4^+$ lymphocyte count of approximately 300 cells/mm^3.

- In a notice dated January 20, 1991, the SSA denied Ms. D.C.'S application, noting that although Ms. D.C. has suffered from 'repeated infections)" "[t]he reports did not show any conditions of a nature that would prevent [her] from working."

- Ms. D.C. requested that the SSA reconsider its initial determination on March 14, 1991, and upon reconsideration, her claim was again denied.

- On October 3, 1991, Ms. D.C. attended a hearing before an administrative law judge and testified that she was unable to work because of recurrent headaches, constant abdominal pain, depression, chronic bronchitis, recurrent yeast infections and urinary tract infections, vaginal discharge, night sweats, and a precancerous condition of the cervix. During the hearing, she requested that she be given an opportunity to submit to a psychiatric examination to document her HIV-related depression. This request was denied.

- By notice dated October 30, 1991, the administrative law judge denied Ms. D.C.'s claim finding that Ms. D.C.'s allegations of multiple symptoms were not substantiated by the record and were not credible.

- Ms. D.C. requested that the Appeals Council review her claim and the request was pending as of December 1991.

Case History IV

- Ms. P.S. --is a 39-year-old African-American woman who resides in the Bronx, New York, with her three minor children. She learned that she was HIV positive in February of 1988.

- Ms. P.S. applied for DI and SSIbenefits in April of 1989 because she was unable to work. Ms. P.S. suffers from recurrent urinary tract infections, recurrent vaginal candidiasis, irregular menses, chronic fatigue, shortness of breath, depression, anxiety, and pain. Ms. P.S. requires the assistance of a home health care worker 5 days a week, 8 hours a day, to do cleaning, lifting, and shopping, and to assist in meal preparation and dressing and caring for her children, including a three-year-old who is herself infected with HIV.

- Her applications for disability were denied at the initial and reconsideration stages, and Ms. P.S. appealed. In April of 1991, Ms. P.S. had a hearing with an administrative law judge. The judge found Ms. P.S. to be disabled, 2 years after her initial application.

Case History V

- Ms. B.L. --is a 42-year-old woman who resides in Brooklyn, New York. Ms. B.L. is HIV positive and suffers from chronic diarrhea, recurrent bacterial pneumonia, pelvic inflammatory disease, chronic cervicitis, herpes zoster, seborrheic dermatitis, oral thrush, night sweats, ulcers on her legs and arms, weakness, fatigue, and shortness of breath. Ms. B.L. rarely leaves the house because of these conditions, and her physician has ordered an ambulette to transport her to her medical appointments due to her various disabling conditions.

- On November 23, 1989, Ms. B.L. applied for DI and SSI but her application was denied. Ms. B.L. requested reconsideration of the denial

- In May of 1990, Ms. B.L. submitted evidence of her medical status to the SSA, including evidence of HIV infection, a 5-month history of diarrhea, skin rashes, night sweats, fatigue, and abnormal bruising. She provided SSA with a letter dated October 30, 1989, from her physician at Woodull Hospital, which indicated that she had large bilateral leg ulcers that caused her considerable pain and rendered her unable to work. She also advised SSA that in 1989 she was treated for leg ulcers at the Emergency Room at Boston City Hospital as well as at St. Luke's Hospital. SSA did not obtain medical records from these hospitals. Ms. B.L. also had an accident in which her hands and wrists were severely burned resulting in the limited use of her right wrist. She notified SSA in October of 1989, that, in May 1989, she had an operation and a skin graft on her right wrist at St. Luke's Hospital. In January of 1990 the consultative examination physician retained by SSA to examine Ms. B.L. noted a limited range of motion and fibrosis in her right wrist. Ms. B.L.'s Social Security file also contained records dated from April of 1990 which document a rash on the mid-abdomen, back, and vagina. In June of 1990, an "AIDS or AIDS Related Complex Medical Report" completed by Woodhull Hospital showed her $CD4^+$ lymphocyte count to be 37 cells/mm^3.

- Ms. B.L. was denied benefits on reconsideration in October of 1990.

- At a hearing before a administrative law judge on April 16, 1991, Ms. B.L. submitted a form filled out by Woodhull Hospital showing her $CD4^+$ lymphocyte count to be 37 cells/mm^3; she also submitted a medical report from her physician at St. Vincent's Hospital reporting that she suffered from hepatitis B, herpes zoster, gynecological problems, a $CD4^+$ lymphocyte count of 20 cells/mm^3, chronic cervicitis, and seborrheic dermatitis.

- An administrative law judge denied Ms. B.L.'s disability application on May 31, 1991, and on June 20, 1991, Ms. B.L. requested that the Appeals Council review the administrative law judge's decision. The Appeals Council remanded the case to the administrative law judge, and as of December of 1991, the case was still pending.

Case History VI

- Mr. E.A. --is a 33-year-old male who resides in Brooklyn, New York. Mr. E.A. suffers from many HIV-related symptoms and conditions, including a $CD4^+$ lymphocyte count below 200 cells/mm^3, anemia, thrombocytopenia (low platelet count), oral thrush, extreme weakness, night sweats, nausea, and bronchitis.

- From March 26, 1991, to April 31, 1991, Mr. E.A. was hospitalized at Lutheran Hospital for severe anemia. At the time he was admitted, Mr. E.A. had difficulty breathing and weakness in both legs, and he underwent 10 blood transfusions. In May of 1991, Mr. E.A. had a $CD4^+$ lymphocyte count of 335 cells/mm^3. Because he could not longer work, Mr. E.A. applied for SSI benefits in June 1991 and received presumptive SSI benefits for 3 months, from June through September.

- By September, Mr. E.A.'s $CD4^+$ lymphocyte count had decreased to 193 cells/mm^3. On September 9, 1991, Mr. E.A.'s application was denied by the State DDS.

- On September 30, 1991, Mr. E.A.'s treating physician of 1 year filled out a Medical Report for Determination of Disability for the SSA, which documented his low $CD4^+$ lymphocyte count, thrombocytopenia, recent hospitalization due to severe anemia, oral thrush, and an inability to tolerate AZT. Mr. E.A.'s treating physician also informed the SSA that Mr. E.A. tested high positive for exposure to toxoplasma, the protozoa that causes toxoplasmosis, an AIDS-defining condition. Nonetheless, his request for reconsideration was denied on October 22, 1991.

- On October 28, 1991, Mr E.A. requested a hearing before an administrative law judge. No hearing had been scheduled as of December 1991.

Case History VII

- Ms. K.P. --is a 37-year-old woman living in Brooklyn, New York. She tested positive for HIV in 1988. Her impairments included pneumonia, anemia, pancreatitis, an enlarged liver due to chronic hepatitis, a positive rheumatoid factor, an elevated erythrocyte sedimentation rate, endocarditis, reduced white blood and red blood cell counts, a suppressed $CD4^+$ lymphocyte count in the range of 200 to 300+ cells/mm^3, a reduced $CD4^+/CD8^+$ ratio, a low platelet count, chronic bronchitis, fatigue, and nausea.

- Ms. K.P. applied for disability benefits in April of 1989. Her application was denied after the disability determination review classified her primary diagnosis as HIV positive and her secondary diagnosis as 'none." According to K.P. 's attorneys, at a hearing before the administrative law judge in February of 1990, a medical adviser employed by the SSA testified that a $CD4^+$ lymphocyte count in the range of 200 cells/mm^3 and a $CD4^+/CD8^+$ cell ratio of 0.47 were not objective medical support for symptoms of chronic fatigue and weakness. The medical adviser attributed these symptoms to depression. He also testified that the endocarditis and pneumonia were completely resolved and were not AIDS-related and that the objective evidence did not support a finding of symptomatic HIV infection.

Appendix J--The Social Security Administration's New "HIV Infection Listing" for Use in Disability Determinations

Human Immunodeficiency Virus (HIV) Infection Listing[1]

The following conditions and symptoms of HIV infection will prevent a person from performing any gainful activity.

(Conditions with a * to the left are also included in whole or in part in the CDC's 1987 case definition of AIDS):

A. If there is no documentation of HIV Infection:

*1. Candidiasis of the esophagus, trachea, bronchi, or lungs (demonstrated by biopsy microscopy of a "wet" preparation or culture); or

*2. Cryptococcosis, extrapulmonary (demonstrated by culture, antigen detection in the cerebrospinal fluid (CSF), India ink preparation of the CSF, or by biopsy); or

*3. Cryptosporidiosis with diarrhea for over 1 month (documented by intestinal biopsy or fecal microscopy); or

*4. Cytomegalovirus disease of an organ other than liver, spleen, or lymph nodes (demonstrated by culture or histology); or

*5. Herpes simplex virus infection causing a mucocutaneous ulcer that persists longer than 1 month; or bronchitis, pneumonititis, or esophagitis for any duration (demonstrated by culture, histology, or cytology); or

*6. Lymphoma of the brain (primary) affecting a patient less than 60 years of age; or

*7. *Mycobacterium avium* complex or M. *kansasii* disease, disseminated (at a site other than or in addition to lungs, skin, or cervical or hilar lymph nodes) demonstrated by culture; or

*8. Pneumocystis *carinii* pneumonia (documented by lung biopsy, microscopy of a "touch" preparation, bronchial washings, or induced sputum); or

*9. Progressive multifocal leukoencephalopathy; or

*IO. Toxoplasmosis of the brain.

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1 For ease of presentation, the format of the listing has been changed and therefore designations of sections may differ from original.

OR

B. Documentation of HIV Infection (e.g., serum specimen that contains HIV antibodies detected by a screening test (e.g., ELISA) and confirmed by a more definitive test (e.g. , Western blot, immunoflourescence assay); and

*1. Intestinal cryptosporidiosis (documented by intestinal biopsy or fecal microscopy) that has caused diarrhea for 1 month or more;

*2. *Pneumocystis* carinii pneumonia (documented by lung biopsy, microscopy of a 'touch" preparation, bronchial washings, or induced sputum); or

*3. Toxoplasmosis (documented by histology or microscopy of a 'touch" preparation) with involvement of an organ other than the liver, spleen, or lymph nodes; or

*4. Isosporiasis (documented by intestinal biopsy or fecal microscopy) that has caused diarrhea for a month or more; or

*5. Extra-intestinal strongyloidiasis;

*6. Candidiasis, disseminated (beyond the skin, urinary tract, intestinal tract, or oral or vulvovaginal mucous membranes) or involving the esophagus, trachea, bronchi, or lungs (and demonstrated by microscopy of a 'wet" preparation, or observation on endoscopy of white plaques on an erythematous . base); or

*7. Cryptococcosis, disseminated (beyond the lungs), *or* involving the central nervous system and demonstrated by culture, antigen detection in the CSF, India ink preparation of the CSF, or by biopsy); or

*8. Disseminated histoplasmosis (beyond the lungs or or lymph nodes and demonstrated by culture or biopsy); or

*9. Disseminated coccidioidomycosis (beyond the lungs or lymph nodes and demonstrated by culture or histology); or

*10. Mycobacterial infection, disseminated (beyond the lungs, lymph nodes, or skin) and demonstrated by culture or by microscopy showing acid fast bacilli of a species not identified by culture; or

*11. Cytomegalovirus, causing infection of organs other than the liver, spleen, or lymph nodes demonstrated by culture or histology; or

*12. Herpes simplex virus, causing chronic continuous (longer than 1 month) mucocutaneous infection or infection of the pulmonary gastrointestinal tracts or encephalitis or disseminated infection demonstrated by culture, histology, or cytology; or

*13. Progressive multifocal leukoencephalopathy; or

*14. Recurrent non-typhoid salmonella bacteremia; or

15. Norcardiosis (demonstrated by culture); or

*16. HIV encephalopathy; or

*17. HIV wasting syndrome, characterized by involuntary weight loss (more than 10 percent of baseline body weight) and either chronic diarrhea (2 or more loose stools per day for 2 months or more) or chronic weakness and documented fever (greater than 100.4'F for the majority of 2 months or longer) in the absence of a concurrent illness that could explain the findings; or

*18. Lymphoma of the brain; or

*19. Other non-Hodgkin's lymphoma of B-cell or unknown phenotype and histology indicating either:
a. Burkitt's or other small noncleaved lymphoma; or
b. Immunoblastic sarcoma; or

*20. Non-Hodgkin's lymphoma or Hodgkin's disease; or

21. Invasive carcinoma of the cervix, FIGO stage 11 and beyond; or

22. Anal squamous cell carcinoma; or

23. Cardiomyopathy as described under the criteria in Listing of Impairments sections 4.02, 4.04, or 4.05; or

24. Nephropathy as described under the criteria in Listing of Impairments sections 6.02, or 6.06.

C. Documentation of HIV Infection, as described in B, above, with the criteria listed below. (The level of severity is met when the requirements for both 1 and 4, both 2 and 4, or both 3 and 4 are satisfied.):

1. Impaired cellular immunity as manifested by a $CD4^{+}$ (T4) lymphocyte count of less than or equal to 200 cells/mm^{3} (or 14 percent or less lymphocytes);

OR

2. Documentation of one or more of the following persistent and /or resistant to therapy:

a) Pneumonia; or
b) Pulmonary tuberculosis; or
c) Bacterial or fungal sepsis; or
d) Meningitis; or
e) Septic arthritis; or

f) Endocarditis; or
g) Peripheral neuropathy; or
*h) Kaposi's sarcoma;

OR

3. TWO or more of the following persisting over a two month period:

a) Anemia (hematocrit (HCT) value less than 30 percent); or
b) Granulocytopenia (absolute neutrophil count less than or equal to 1000/mm^3); or
c) Thrombocytopenia (less than or equal to 40,000/mm^3); or
d) Documented fever (greater than or equal to 100.4'F or 38'C); or
e) Weight loss of greater than or equal to 10 percent of baseline body weight; or
f) Mucosal (including vulvovaginal) candidiasis other than listed in A.1 or B.6 above; or
g) Oral hairy leukoplakia; or
h) Recurrent or chronic herpes zoster; or
i) Persistent dermatological conditions such as eczema or psoriasis; or
j) Persistent, unresponsive diarrhea; or
k) Persistent or recurring radiographically documented sinusitis.

AND

4. At least two of the following:

a) Marked restriction of activities of daily living; or
b) Marked difficulties in maintaining social functioning; or
c) Marked difficulties completing tasks in a timely reamer due to deficiencies in concentration, persistence or pace; or
d) Repeated episodes of decompensation, averaging 3 times a year or once every 4 months, lasting 2 or more weeks each, which cause the individual to deteriorate (which may include a loss of adaptive functioning).

SOURCE: U.S. Department of Health and Human Services, Social Security Administration, "Federal Old Age, Survivors, and Disability Insurance; Determining Disability and Blindness; Revision of Part A and Part B of the Listing of Impairments; Endocrine and Multiple Body Systems; Immune System-Proposed Rules," 56 FR 65702.

APPENDIX K--THE SOCIAL SECURITY ADMINISTRATION'S PRESUMPTIVE DISABILITY FORM FOR PHYSICIANS

PHYSICIAN'S REPORT ON ADULT WITH ALLEGATION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

DO-BO CODE:

The individual named below has filed an application for a period of disability and/or disability payments. If you complete this form, your patient may be able to receive early payments. (This is not a request for an examination but for existing medical information.)

MEDICAL RELEASE INFORMATION

☐ Form SSA-827 "Authorization To Release Medical Information to the Social Security Administration" attached.

☐ I hereby authorize the medical source named below to release or disclose to the Social Security Administration or State agen any medical records or other information regarding my treatment for Human Immunodeficiency Virus (HIV) Infection.

CLAIMANT'S SIGNATURE *(Required only if Form SSA-827 is NOT attached)* | Date

PHYSICIAN'S NAME | CLAIMANT'S NAME

A. PLEASE CHECK APPROPRIATE BLOCK

☐ HIV Test(s) Performed

☐ HIV Test(s) Not Performed

CLAIMANT'S SSN

CLAIMANT'S DATE OF BIRTH

B. PLEASE INDICATE RESULTS OF HIV TESTS(S)

☐ POSITIVE ☐ NEGATIVE

C. PLEASE INDICATE HERE:

CD4 (T4) LYMPHOCYTE COUNT: _____

or percent _____ if count not available

D. OPPORTUNISTIC AND INDICATOR DISEASES: ***Please Check, If Present***

1. ☐ HIV encephalopathy
2. ☐ HIV wasting syndrome
3. ☐ Carcinoma of the cervix, FIGO stage II and beyond
4. ☐ Anal squamous cell carcinoma
5. ☐ Cardiomyopathy
6. ☐ Nephropathy
7. ☐ Lymphoma of the brain
8. ☐ Hodgkin's disease
9. ☐ Non-Hodgkin's lymphoma (including Burkitt's lymphoma)
10. ☐ M. kansasii disease, disseminated other than or in addition to the lungs, skin, or cervical or hilar lymph nodes
11. ☐ Mycobacterium avium complex
12. ☐ Mycobacterial infection, disseminated beyond the lungs, lymph nodes

Protozoan or Helminthic Infections

13. ☐ Cryptosporidiosis, intestinal with diarrhea for 1 month or more
14. ☐ Isosporiasis, with diarrhea over 1 month
15. ☐ Pneumocystis carinii pneumonia
16. ☐ Strongyloidiasis, extra-intestinal
17. ☐ Toxoplasmosis of the brain
18. ☐ Toxoplasmosis, of an organ other than the liver, spleen, or lymph nodes

Fungal Infections

19. ☐ Candidiasis, of the esophagus, trachea, bronchi, or lungs
20. ☐ Candidiasis, disseminated beyond the skin, urinary or intestinal tract, or oral or vulvovaginal mucous membranes
21. ☐ Coccidioidomycosis, disseminated beyond the lungs, or lymph nodes
22. ☐ Cryptococcosis, disseminated beyond the lungs, or involving the central nervous system
23. ☐ Histoplasmosis, disseminated beyond the lungs or lymph nodes

Viral Infections

24. ☐ Cytomegalovirus, of an organ other than the liver, spleen, or lymph nodes
25. ☐ Herpes simplex virus, causing bronchitis
26. ☐ Herpes simplex virus, causing chronic continuous mucocutaneous infection, or infection of the pulmonary or gastrointestinal tract or encephalitis
27. ☐ Herpes simplex virus causing esophagitis
28. ☐ Herpes simplex virus, causing a mucocutaneous ulcer persistent over 1 month
29. ☐ Herpes simplex virus, causing pneumonitis
30. ☐ Progressive multifocal leukoencephalopathy

Bacterial Infections

31. Salmonella bacteremia, non-typhoid, recurrent
32 E I Nocardiosis

NOTE: IF YOU HAVE CHECKED ANY ITEM IN BLOCK D, SKIP BLOCKS E, F, & G, GO TO BLOCKS I & J.

E. OTHER MANIFESTATIONS OF HIV INFECTION PERSISTING OVER A 2 MONTH PERIOD, AND/OR RESISTANT TO THERAPY
(If one or more of the following is checked, block G must also be completed.)

33. ☐ Bacterial sepsis
34. ☐ Fungal sepsis
35. ☐ Endocarditis
36. ☐ Kaposi's sarcoma
37. ☐ Meningitis
38. ☐ Peripheral neuropathy
39. ☐ Pneumonia
40. ☐ Pulmonary tuberculosis
41. ☐ Septic arthritis

NOTE: IF YOU HAVE CHECKED ANY ITEM IN BLOCK E, YOU NEED NOT COMPLETE BLOCK F, GO TO BLOCK G.

OTHER MANIFESTATIONS OF HIV INFECTION PERSISTING OVER A 2 MONTH PERIOD, AND/OR RESISTANT TO THERAPY
(If two or more of the following are checked, block G must also be completed.)

2. ☐ Anemia—Hct. less than or equal to 30%
3. ☐ Granulocytopenia (absolute neutrophil count less than or equal to 1000/mm^3)
4. ☐ Thrombocytopenia (less than or equal to 40,000/mm^3)
5. ☐ Dermatological conditions, persistent
6. ☐ Diarrhea, persistent and unresponsive
7. ☐ Documented temperature of 100.4^{0}F (38^{0}C) or greater
48. ☐ Herpes zoster, chronic
49. ☐ Herpes zoster, recurrent
50. ☐ Oral hairy leukoplakia
51. ☐ Mucosal candidiasis (including vulvovaginal)
52. ☐ Sinusitus, persistent or recurrent
53. ☐ Weight loss of greater than or equal to 10% of baseline

. FUNCTIONAL LIMITATIONS: *(If any of the items in block E or F are checked, each of the following items must also be completed.)*

4. Restriction of activities of daily living including, but not limited to, such activities as doing household chores, grooming and hygiene, using a post office, taking public transportation, and paying bills.
☐ Extreme ☐ Marked ☐ Moderate ☐ Mild ☐ None

5. Difficulties in maintaining social functioning, i.e., capacity to interact appropriately and communicate effectively with others. These restrictions could result from HIV- or treatment- induced fatigue or other symptoms or could result from a pattern of exacerbation and remission caused by the illness itself or its treatment.
☐ Extreme ☐ Marked ☐ Moderate ☐ Mild ☐ None

6. Difficulties in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace, i.e., the ability to sustain focused attention sufficiently long to permit the timely completion of tasks commonly found in work settings. This could result from symptoms such as extended or intermittent depression, fatigue, or physical functioning or both.
☐ Extreme ☐ Marked ☐ Moderate ☐ Mild ☐ None

7. Repeated episodes of deterioration or decompensation (averaging three times a year or once every four months, lasting two or more weeks each) in work or work-like settings. This may be caused by manifestations of HIV infection itself, such as its symptoms, or by the frequency and intrusiveness of treatment for the disease.
☐ Extreme ☐ Marked ☐ Moderate ☐ Mild ☐ None

. DISCUSSION: *(Please use this space to indicate any other medical conditions of your patient, or to provide any other comments you wish about your patient.)*

REPORTING PHYSICIAN'S NAME AND ADDRESS

TELEPHONE NUMBER *(Area Code)*

DATE

PHYSICIAN'S SIGNATURE
▶ **SIGN HERE**

☐ FIELD OFFICE DISPOSITION: ☐ DISABILITY DETERMINATION SERVICES DISPOSITION:

RIVACY ACT NOTICE: The Social Security Administration is authorized to collect the information on this form under sections 205(a), 223(d) and 1633(e)(1) the Social Security Act. The information, on this form is needed by Social Security to make a decision on the named claimant's claim. While giving us the formation on this form is voluntary, failure to provide all or part of the requested information could prevent an accurate or timely decision on the named claimant's aim. Although the information you furnish is almost never used for any purpose other than making a determination about the claimant's disability, such formation may be disclosed by the Social Security Administration as follows: (1) to enable a third party or agency to assist Social Security in establishing rights Social Security benefits and/or coverage; (2) to comply with Federal laws requiring the release of information from Social Security records (e.g., to the General ccounting Office and the Department of Veterans Affairs); and (3) to facilitate statistical research and audit activities necessary to assure the integrity and nprovement of the Social Security programs (e.g., to the Bureau of the Census and private concerns under contract to Social Security).

/e may also use the information you give us when we match records by computer. Matching programs compare our records with those of other Federal, State, local government agencies. Many agencies may use matching programs to find or prove that a person qualifies for benefits paid by the Federal government. he law allows us to do this even if you do not agree to it.

hese and other reasons why information about the claimant may be used or given out are explained in the *Federal Register*. If you want to learn more about is, contact any Social Security office.

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/e estimate that it will take you about 10 minutes to complete this form. This includes the time it will take to read the instructions gather the necessary facts and l out the form. If you have comments or suggestions on how long it takes to complete this form or on any other aspect of this form, write to the Social Security dministration. ATTN: Reports Clearance Officer, 1-A-21 Operations Bldg., Baltimore, MD 21235, and to the Office of Management and Budget, Paperwork eduction Project (0960-0057), Washington, D.C. 20503. **DO NOT SEND COMPLETED FORMS OR INFORMATION CONCERNING THIS CLAIM TO THESE FFICES. SEND THEM TO THE OFFICE THAT REQUESTED THE INFORMATION.**

NOWING THAT ANYONE MAKING A FALSE STATEMENT OR REPRESENTATION OF A MATERIAL FACT FOR USE IN ETERMINING A RIGHT TO PAYMENT UNDER THE SOCIAL SECURITY ACT COMMITS A CRIME PUNISHABLE UNDER FEDERAL AW, I CERTIFY THAT THE ABOVE STATEMENTS ARE TRUE.

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