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U.S. Department of Justice

Office of Legal Counsel

OCT - 6 1988

Office of the
Assistant Attorney General

Washington, D.C. 20530

In response to the AIDS Commission, the White House Counsel requested an opinion from the Department of Justice, Office of Legal Counsel on the scope of the existing anti-discrimination provisions in the federal Rehabilitation Act. We have prepared the opinion and delivered it to the White House Counsel. In light of the controversial nature and complexity of legal issues raised by the AIDS virus, the White House Counsel has directed us to release this opinion and to be responsive to questions you may have about it.

I should also note at the outset that our legal opinion is consistent with the President's policy statement of last August, namely that federal employers should treat HIV-infected individuals on a case by case basis so they do not pose health and safety dangers or performance problems. Otherwise, they should be treated like any other employee. In particular, our opinion focuses on two issues: (1) whether persons with AIDS are protected by the Rehabilitation Act as an "individual with handicaps," even though AIDS is a contagious disease, and (2) whether so-called "asymptomatic" HIV-infected persons are also "individuals with handicaps" for purposes of the Act.

We answer both questions in the affirmative. We believe the first question was largely answered by the Supreme Court's decision in School Board of Nassau County, Fla. v. Arline (1987). While Arline concerned tuberculosis rather than AIDS, it clearly held that "[a]llowing discrimination based on the contagious effects of a physical impairment would be inconsistent with the basic purpose of [the Rehabilitation Act]."

As to asymptomatic HIV-infected individuals, our legal conclusions have been largely guided by recent medical clarification from the Surgeon General that even these individuals are, from a medical standpoint, physically impaired. The Surgeon General advises us that the impairment of HIV infection cannot be meaningfully separated from clinical AIDS, and that it is medically "inappropriate to think of this disease as composed of discrete conditions." Given this medical information that HIV infection is a physical impairment, the only legal issue remaining to us was to determine whether a court could in a given case determine that such a person is substantially limited in a major life activity. Because HIV infection may limit the likelihood of bearing a healthy child and may adversely affect intimate sexual relations, we believe that an individual proving these facts to a court could fairly be found to be an individual with handicaps for purposes of the Act.

The Supreme Court has also indicated in Arline that if a person is perceived by others as having a handicapping condition that substantially limits a major life activity -- that in itself could bring the person within the terms of the Act. We believe that, as a factual matter, many HIV-infected individuals would likely be included within the Act on this basis as well.

As both our opinion and the Supreme Court's opinion indicate, however, saying that it is possible for HIV-infected individuals to be found within the terms of the Act does not mean that federal employers or federally-conducted or financed programs and activities cannot in individual circumstances exclude an HIV-infected individual from the workplace or such program. If that individual poses a threat to the health or safety of others or is unable to perform the job or satisfy the requirements of the program, that individual can be excluded if there is no reasonable way to accommodate these health and safety and performance concerns.

In short, so long as HIV-infected individuals do not on a case-by-case basis pose these health and safety dangers or performance problems, they should be treated in the federal workforce and in federally-conducted or financed programs and activities like everyone else. By the terms of the Act, and our construction of it, we believe that similar anti-discrimination protections extend to federally-conducted or financed programs and activities.

I will be happy to try to answer any questions you may have.

Douglas W. Kmiec



Department of Justice

FOR IMMEDIATE RELEASE
THURSDAY, OCTOBER 6, 1988

AG
202-633-2007
(TDD) 202-786-5731

Attorney General Dick Thornburgh today issued the following statement:

I have reviewed the opinion prepared by the Office of Legal Counsel on the application of federal anti-discrimination laws to victims of the AIDS virus. The opinion concludes that the necessary result of the Supreme Court's decision in School Board of Nassau County v. Arline, recent legislative action, and the medical views of the Surgeon General, is to extend the protection of federal anti-discrimination laws to individuals when they become infected with the virus. It also concludes that if the infection is a direct threat to the health or safety of others or renders the individual unable to perform the duties of the job, the employer is not required to retain or hire that person. It is by no means clear that much of the existing law designed to protect handicapped members of our society was ever intended specifically to protect AIDS victims. For example, Section 504, with which this opinion deals, was adopted in 1973, well before the advent of AIDS. There are, I believe, legitimate questions as to whether existing law can adequately and appropriately serve these most unfortunate victims. Those concerns will be discussed with other members of the Administration and Congress who are considering this question.

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Office of the
Assistant Attorney General

Washington, D.C. 20530

SEP 27 1988

Memorandum for Arthur B. Culvahouse, Jr.
Counsel to the President

Re: Application of Section 504 of the
Rehabilitation Act to HIV-Infected Individuals

Introduction and Summary

This memorandum responds to your request for an opinion on the application of section 504 of the Rehabilitation Act of 1973 (Act), 29 U.S.C. 794, to individuals who are infected with the Human Immunodeficiency Virus ("HIV" or "AIDS virus"). You specifically asked us to consider this subject in light of School Board of Nassau County v. Arline, 107 S. Ct. 1123 (1987) (Arline). Congress has also sought to clarify the law in this area by amending the Rehabilitation Act to address directly the situation of contagious diseases and infections in the employment context. See Civil Rights Restoration Act of 1987, Pub. L. No. 100-259, sec. 9, 102 Stat. 28, 31 (1988) (Civil Rights Restoration Act). Although your opinion request was limited to the application of section 504 in the employment context, we have also considered the non-employment context because the President has directed the Department of Justice to review all existing federal anti-discrimination law applicable in the HIV infection context and to make recommendations with respect to possible new legislation.¹ See Memorandum for the Attorney General from President Ronald Reagan (Aug. 5, 1988).

For the reasons stated below, we have concluded, with respect to the non-employment context, that section 504 protects symptomatic and asymptomatic HIV-infected individuals² against

¹ We defer to others in the Department to make the policy determinations necessary to recommend legislation, and, in keeping with the tradition of this Office, confine our analysis to matters of legal interpretation.

² In this opinion, individuals who are infected with the AIDS virus and have developed the clinical symptoms known as Acquired Immune Deficiency Syndrome ("AIDS") or AIDS-Related Complex ("ARC") will sometimes be referred to as "symptomatic HIV-infected individuals." Individuals who are infected with the
(continued...)

discrimination in any covered program or activity on the basis of any actual, past or perceived effect of HIV infection that substantially limits any major life activity³ -- so long as the HIV-infected individual is "otherwise qualified" to participate in the program or activity, as determined under the "otherwise qualified" standard set forth in Arline. We have further concluded that section 504 is similarly applicable in the employment context, except for the fact that the Civil Rights Restoration Act replaced the Arline "otherwise qualified" standard with a slightly different statutory formulation. We believe this formulation leads to a result substantively identical to that reached in the non-employment context: namely, that an HIV-infected individual is only protected against discrimination if he or she is able to perform the duties of the job and does not constitute a direct threat to the health or safety of others.⁴

²(...continued)

AIDS virus but do not have AIDS or ARC will sometimes be referred to as "asymptomatic HIV-infected individuals." References to AIDS should be understood to include ARC, except where a distinction between the two is expressly drawn. Finally, where we intend to refer to all HIV-infected individuals, whether symptomatic or not, we either refer to "HIV-infected individuals" or to "HIV infection" (without any "symptomatic" or "asymptomatic" modifier) or clearly indicate in the text that the discussion refers to both categories.

³ The medical information available to us indicates that HIV infection is a physical impairment which in a given case may substantially limit a person's major life activities. See infra at 6-11. In addition, others may regard an HIV-infected person as being so impaired. See infra at 12-13. Either element in a given case, we believe, would be sufficient for a court to conclude that an HIV-infected person is an "individual with handicaps" within the terms of the Act. By virtue of the fact that the handicap here, HIV infection, gives rise both to disabling physical symptoms and to contagiousness, it is unnecessary to resolve with respect to any other infection or condition which gives rise to contagiousness alone whether that singular fact could render a person handicapped. In other words, the medical information available to us undermines the accuracy of the assumption or contention referenced in Arline that carriers of the AIDS virus are without physical impairment. 107 S. Ct. at 1128 n.7.

⁴ These conclusions differ from, and supersede to the extent of the difference, a June 20, 1986 opinion from Charles J. Cooper, Assistant Attorney General, Office of Legal Counsel, for Ronald E. Robertson, General Counsel, Department of Health and

(continued...)

I. Statutory Framework Under Section 504

Section 504 was intended to proscribe discrimination against the handicapped in programs or activities that are conducted by federal agencies or that receive federal funds. In relevant part, the statute provides:

No otherwise qualified individual with handicaps in the United States, as defined in section 706(8) of this title, shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service.

29 U.S.C. 794.⁵

There are two definitions of "individual with handicaps," one or both of which may be applicable to HIV-infected

⁴(...continued)

Human Services (Cooper Opinion). The conclusions herein incorporate subsequent legal developments (the Supreme Court's decision in Arline and Congress' passage of the Civil Rights Restoration Act) and subsequent medical clarification (see July 29, 1988 letter from C. Everett Koop, M.D., Surgeon General, to Douglas W. Kmiec, Acting Assistant Attorney General, Office of Legal Counsel (Koop Letter) (attached)).

⁵ Section 504 thus has five elements. First, an individual claiming discriminatory treatment must be an "individual with handicaps," as defined in the Act. Second, the individual must be "otherwise qualified" for the benefit or program participation being sought. Third, the individual must be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under a covered program or activity. Fourth, the contested treatment must be "solely by reason of . . . handicap." And fifth, the discrimination must occur in a program or activity conducted or funded by the federal government.

The definition of "program or activity" is set forth in a new section 504(b), which was added by section 4 of the Civil Rights Restoration Act. In general, the term is to be given an institution-wide scope rather than the program- or activity-specific scope called for by Grove City College v. Bell, 465 U.S. 555 (1984). Grove City was superseded by the Civil Rights Restoration Act. See sec. 2, Pub. L. No. 100-259.

individuals depending upon the context in which the discrimination occurs. The generally-applicable definition is "any person who (i) has a physical or mental impairment which substantially limits one or more of such person's major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment." 29 U.S.C. 706(8)(B). Thus, an individual can qualify as handicapped under the general definition if he actually suffers from a disabling impairment, has recovered from a previous such condition, was previously misclassified as having such a condition, or is regarded as having such a condition, whether or not he actually has it.

The Civil Rights Restoration Act amended the definitions section of the Rehabilitation Act to provide, in the employment context, a qualification of the definition of an "individual with handicaps" with respect to contagious diseases and infections. This provision qualifies rather than supplants the general definition of "individual with handicaps".⁶ The amendment provides as follows:

For the purpose of sections 503 and 504, as such sections relate to employment, [the term "individual with handicaps"] does not include an individual who has a currently contagious disease or infection and who, by reason of such disease or infection, would constitute a direct threat to the health or safety of other individuals or who, by reason of the currently contagious disease or infection, is unable to perform the duties of the job.

Pub. L. No. 100-259, sec. 9, 102 Stat. 28, 31-32 (1988).

II. Application of Section 504 in Contexts Other Than Employment

Section 504, as interpreted by the Supreme Court in Arline, has two primary elements: the definition of "individual with

⁶ The Civil Rights Restoration Act amended 29 U.S.C. 706(8) to add the qualification as a new subparagraph (C), to follow subparagraph (B), which contains the generally-applicable definition of "individual with handicaps." The new subparagraph thus constitutes a specific qualification of the preceding general definition. The qualification operates in the same way as the qualification Congress enacted in 1978 with respect to alcohol and drug abuse, on which the contagious disease provision was modeled. See note 19, infra, and accompanying text. Both provisions are structured as exclusions from the general definition. The natural implication of both statutory exclusions is that persons who do not fall within the specified grounds for exclusion are covered by section 504 to the extent that they meet the general requirements of that section.

handicaps" and the "otherwise qualified" requirement. We will first determine whether in the non-employment context an HIV-infected individual, whether symptomatic or asymptomatic, is an "individual with handicaps," and then discuss the application of the "otherwise qualified" requirement to such an individual.⁷

A. Symptomatic HIV-Infected Individuals

As discussed below, Arline requires the conclusion that persons with AIDS (i.e., symptomatic HIV-infected individuals) are within the section 504 definition of handicapped individual notwithstanding their contagiousness. Contagiousness, by itself, does not obviate the existence of a handicap for purposes of section 504. Arline, 107 U.S. at 1128.

Arline involved an elementary school teacher who had been discharged after suffering a third relapse of tuberculosis within two years. All parties conceded, and the Court found, that the plaintiff was handicapped because her tuberculosis had adversely affected her respiratory system, requiring hospitalization. Id. at 1127-1128. Plaintiff's respiratory ailment thus was a physical impairment that substantially limited one of her major life activities. Id. The Court concluded that the defendant's action came within the coverage of section 504, notwithstanding the fact that Ms. Arline was dismissed not because of any disabling effects of her tuberculosis but because of her employer's fear that her contagiousness threatened the health of her students. The Court concluded that "the fact that a person with a record of physical impairment is also contagious does not suffice to remove that person from coverage under § 504." Id. at 1130 (emphasis added).

⁷ Arline was also concerned with a third element: namely, whether the contagiousness of a handicapped individual covered by the Act could be used as a justification for discrimination against that individual. Subject to the "otherwise qualified" limitation, the Court held that contagiousness cannot be used for this purpose. The Court stated: "We do not agree with petitioners that, in defining a handicapped individual under § 504, the contagious effects of a disease can be meaningfully distinguished from the disease's physical effects on a claimant. . . . It would be unfair to allow an employer to seize upon the distinction between the effects of a disease on others and the effects of a disease on a patient and use that distinction to justify discriminatory treatment." Arline, 107 S. Ct. at 1128. In light of the Court's holding, we conclude that the contagiousness of an HIV-infected individual cannot be relied upon to remove that individual from the coverage of the Act. Contra Cooper Opinion at 27 and n.70.

We believe that symptomatic HIV-infected individuals are handicapped under section 504. For these individuals, the disease has progressed to the point where the immune system has been sufficiently weakened that a disease such as cancer or pneumonia has developed, and as a result, the individual is diagnosed as having clinical AIDS. Because of the substantial limiting effects these clinical symptoms have on major life activities, such a person is an "individual with handicaps" for purposes of section 504. This same conclusion should also apply to a person with ARC, who also has serious disabling physical effects caused by HIV infection, although the physical symptoms are not the particular diseases that the Centers for Disease Control have included in its list of the clinical symptoms that constitute AIDS. As with the tuberculosis that afflicted Ms. Arline, AIDS (or ARC) is often "serious enough to require hospitalization, a fact more than sufficient [in itself] to establish that one or more . . . major life activities [are] substantially limited" *Id.* at 1127. Therefore, assuming they are otherwise qualified, contagiousness does not excuse or justify discrimination against individuals handicapped by symptomatic HIV infection. As will be seen, the consideration of the "otherwise qualified" standard allows for a reasonable determination of whether contagiousness threatens the health or safety of others or job performance, and in those events, permits the exclusion of the individual from the covered program or activity.

B. Asymptomatic HIV-Infected Individuals

Arline did not resolve the application of section 504 to asymptomatic HIV-infected individuals.⁸ The Court left open the

⁸ Since the plaintiff had disabling physical symptoms and thus was clearly a handicapped individual under section 504, the Court declined to reach the question of whether a person without such an impairment could be considered handicapped by virtue of a communicable disease alone. As the Court stated, "[t]his case does not present, and we therefore do not reach, the questions whether a carrier of a contagious disease such as AIDS [who suffers no physical impairment] could be considered to have a physical impairment, or whether such a person could be considered, solely on the basis of contagiousness, a handicapped person as defined by the Act." *Id.* at 1128 n.7. Subsequent to Arline, the Surgeon General informed this Office that even an asymptomatic HIV-infected individual is physically impaired, stating that "from a purely scientific perspective, persons with HIV infection are clearly impaired. They are not comparable to an immune carrier of a contagious disease such as Hepatitis B." Koop Letter at 2. In light of Dr. Koop's letter, this Office has no occasion to determine whether a contagious, but not impaired

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question of whether such individuals are "individuals with handicaps" under section 504, a question which turns on whether an asymptomatic HIV-infected individual "(i) has a physical or mental impairment which substantially limits one or more of such person's major life activities, (ii) has a record of such impairment, or (iii) is regarded as having such an impairment." 29 U.S.C. 706(8)(B). These determinations primarily focus upon: (1) whether HIV infection by itself is a physical or mental impairment; and (2) whether the impairment substantially limits a major life activity (i.e., whether it has a disabling effect); or (3) whether someone with HIV infection could be regarded as having an impairment which substantially limits a major life activity.

1. Asymptomatic HIV-Infected Individuals Are Physically Impaired

The Department of Health and Human Services regulations implementing section 504 define "physical impairment" as:

[A]ny physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive, digestive, genito-urinary; hemic and lymphatic; skin; and endocrine.

45 C.F.R. 84.3(j)(2)(i) (1987). In addition, an appendix to the regulations provides an illustrative (but not exhaustive) list of diseases and conditions that are "physical impairments" for purposes of section 504: "such diseases and conditions as orthopedic, visual, speech, and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, [and] emotional illness, and . . . drug addiction and alcoholism." 45 C.F.R. Pt. 84, App. A, p. 344 (1987).

The first question is whether an asymptomatic HIV-infected individual is physically impaired for purposes of section 504. For this factual determination we necessarily must rely heavily on the views of the Public Health Service of the United States. In this respect, Dr. C. Everett Koop, the Surgeon General of the Public Health Service, has indicated that it is

⁸(...continued)
individual, such as a Hepatitis B carrier, would be protected by the Act. See note 3, supra. Cf., Kohl by Kohl v. Woodhaven Learning Center, 672 F. Supp. 1226, 1236 (W.D. Mo. 1987) (finding a Hepatitis B carrier to be within the Act).

inappropriate to think of [HIV infection] as composed of discrete conditions such as ARC or "full blown" AIDS. HIV infection is the starting point of a single disease which progresses through a variable range of stages. In addition to an acute flu-like illness, early stages of the disease may involve subclinical manifestations i.e., impairments and no visible signs of illness. The overwhelming majority of infected persons exhibit detectable abnormalities of the immune system.

Koop Letter at 1-2. On the basis of these facts, the Surgeon General concluded that

from a purely scientific perspective, persons with HIV infection are clearly impaired. They are not comparable to an immune carrier of a contagious disease such as Hepatitis B. Like a person in the early stages of cancer, they may appear outwardly healthy but are in fact seriously ill.

Id. at 2.

In our view, the type of impairment described in the Surgeon General's letter fits the HHS definition of "physical impairment" because it is a "physiological disorder or condition" affecting the "hemic and lymphatic" systems.⁹ We therefore

⁹ Moreover, it would also appear that the impairment affects the brain and central nervous system as well. Medical evidence indicates that the AIDS virus, apart from any effect it has on the immune system, also attacks the central nervous system and may result in some form of mental deficiency or brain dysfunction in a significant percentage of persons infected with the virus. "Mental disease (dementia) will occur in some patients who have the AIDS virus before they have any other manifestation such as ARC or classic AIDS." U.S. Department of Health Services, Surgeon General's Report on Acquired Immune Deficiency Syndrome 32 (1986) (Surgeon General's Report). See also id. at 12 ("The AIDS virus may also attack the nervous system and cause delayed damage to the brain. This damage may take years to develop and the symptoms may show up as memory loss, indifference, loss of coordination, partial paralysis, or mental disorder. These symptoms may occur alone, or with other symptoms mentioned earlier.").

In addition, as discussed below with respect to the effects of HIV infection on major life activities, infection with the virus affects the reproductive system because of the significant danger that the virus will be transmitted to a baby during

(continued...)

believe that, in light of the Surgeon General's medical assessment, asymptomatic HIV-infected individuals, like their symptomatic counterparts, have a physical impairment.

2. Asymptomatic HIV-Infected Individuals and Limits on Major Life Activities

The second question, therefore, is whether the physical impairment of HIV infection substantially limits any major life activities.

Under the HHS regulations implementing section 504, "'major life activities' means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working." 45 C.F.R. 84.3(j)(2)(ii) (1987) (emphasis added). Although the definition is illustrative and not exhaustive, it does provide a helpful starting point for our analysis. We would expect that courts will resolve the factual question of whether the impairment of HIV infection limits a major life activity by reviewing this list for guidance in ascertaining whether a particular activity constitutes a basic function of life comparable to those on the list.

As indicated earlier, the disabling effects of HIV infection are readily apparent in the case of symptomatic HIV infection. The salient point with respect to symptomatic HIV-infected individuals is not that they have AIDS or ARC but rather that their impairment has manifest disabling effects. Again, as noted above, we believe that the courts will find that such individuals are limited in a number of major activities. Due to the weakness of their immune system and depending on the nature of the particular disease afflicting symptomatic HIV-infected individuals, any and perhaps all of the life activities listed in the HHS regulations could be substantially limited.

The question with respect to asymptomatic HIV-infected individuals is more difficult because such individuals would not appear at first glance to have disabling physical effects from their infection that substantially affect the type of life activities listed in the HHS regulations. Their ability, for example, to work, to care for themselves, to perform manual tasks, or to use their senses are usually not directly affected.

⁹(...continued)

pregnancy. Also bearing on whether HIV infection is a physical impairment under the HHS regulations is the Surgeon General's statement in his letter that HIV infection in its early stages is comparable to cancer -- a disease that is listed in the HHS regulations as a physical impairment -- in that infected individuals "may appear outwardly healthy but are in fact seriously ill." Koop Letter at 2.

Nevertheless, we believe it is likely that the courts will conclude that asymptomatic HIV-infected individuals have an impairment that substantially limits certain major life activities. While the Supreme Court explicitly refrained from answering this precise question in Arline, because HIV infection was not before it and perhaps in the mistaken understanding that asymptomatic HIV infection was not accompanied by an impairment,¹⁰ the logic of the decision cannot fairly be said to lead to a different conclusion. This conclusion, we believe, may be based either on the effect that the knowledge of infection will have on the individual or the effect that knowledge of the infection will have on others. With respect to the latter basis, the Court observed, "[i]t would be unfair to allow an employer to seize upon the distinction between the effects of a disease on others and the effects of a disease on a patient and use this distinction to justify discriminatory treatment." Arline, 107 S. Ct. at 1128.

a. Limitation of Life Activities Traceable to Knowledge of Infection by Asymptomatic HIV-Infected Individual

Turning first to the effect knowledge of infection may have on the asymptomatic individual, it can certainly be argued that asymptomatic HIV infection does not directly affect any major life activity listed in the HHS regulations. 45 C.F.R. 84.3(j)(2)(ii) (1987). However, since the regulatory list was not intended as an exhaustive one, we believe at least some courts would find a number of other equally important matters to be directly affected. Perhaps the most important such activities are procreation and intimate personal relations.

Based on the medical knowledge available to us, we believe that it is reasonable to conclude that the life activity of procreation -- the fulfillment of the desire to conceive and bear healthy children -- is substantially limited for an asymptomatic HIV-infected individual. In light of the significant risk that the AIDS virus may be transmitted to a baby during pregnancy,¹¹ HIV-infected individuals cannot, whether they are male or female, engage in the act of procreation with the normal expectation of bringing forth a healthy child. Because of the infection in their system, they will be unable to fulfill this basic human desire. There is little doubt that procreation is a major life

¹⁰ Compare Arline, 107 S. Ct. at 1128 n.7 (suggesting that HIV infection is a disease without physical impairment) with Koop Letter at 2 (HIV infection is a physical impairment).

¹¹ Surgeon General's Report at 20-21 ("Approximately one third of the babies born to AIDS-infected mothers will also be infected with the AIDS virus.").

activity and that the physical ability to engage in normal procreation -- procreation free from the fear of what the infection will do to one's child -- is substantially limited once an individual is infected with the AIDS virus.

This limitation -- the physical inability to bear healthy children -- is separate and apart from the fact that asymptomatic HIV-infected individuals will choose not to attempt procreation. The secondary decision to forego having children is just one of many major life decisions that we assume infected individuals will make differently as a result of their awareness of their infection. Similarly, some courts can be expected to find a limitation of a major life activity in the fact that an asymptomatic HIV-infected individual's intimate relations are also likely to be affected by HIV infection. The life activity of engaging in sexual relations is threatened and probably substantially limited by the contagiousness of the virus.¹²

Finding limitations of life activities on the basis of the asymptomatic individual's responses to the knowledge of infection might be assailed as not fully persuasive since it depends upon the conscience and good sense of the person infected. The causal nexus, it would be argued, is not between the physical effect of the infection (as specified in the Koop Letter) and life activities, but between the conscience or normative judgment of the particular infected person and life activities. Thus, it might be asserted that there is nothing inherent in the infection which actually prevents either procreation or intimate relations.¹³

It is undoubtedly true that some HIV-infected individuals have not or will not change their behavior after learning they are infected, thereby exhibiting disregard for the health of their offspring or sexual partners. Nonetheless, in any case where the evidence indicates that the plaintiff HIV-infected individual has in fact changed his or her behavior -- as, for example, where the plaintiff represents that procreation has been foregone -- the court might well find a limitation of major life activity. Moreover, courts may choose to pass over such factual questions since the Supreme Court has stated an alternative rationale for finding a life activity limitation based on the reaction of others to the infection. We turn to that rationale next.

¹² Id. at 14-18.

¹³ As indicated in the text, we think this argument is disingenuous at least insofar as infection physically precludes the normal procreation of healthy children.

b. Limitation of Life Activities Traceable to
Reaction of Others to Asymptomatic HIV Infection

The Arline Court relied on the express terms of the statute for the proposition that a handicapped individual includes someone who is regarded by others as having a limitation of major life activities whether they do or not. 29 U.S.C. 706(8)(B)(iii). This provision was added by Congress in 1974. The Court cited the legislative history accompanying this textual expansion to show that an impaired person could be protected even if the impairment "in fact does not substantially limit that person's functioning," S. Rep. No. 1297, 93rd Cong., 2d Sess. 64 (1974), and observed that such an impairment "could nevertheless substantially limit that person's ability to work as a result of the negative reactions of others to the impairment." 107 S. Ct. at 1129.

This construction by the Court of the statutory definition of the term "handicapped individual" has particular significance for the application of section 504 to asymptomatic HIV-infected individuals. The Court found that in order "[t]o combat the effects of erroneous but nevertheless prevalent perceptions about the handicapped," id. at 1126, Congress intended by its 1974 amendment to expand the section's scope to include persons who are regarded as handicapped, but who "may at present have no actual incapacity at all." Id. at 1126-1127 (quoting Southeastern Community College v. Davis, 442 U.S. 397, 405-406 n.6 (1979)). Stressing this point, the Court repeated later in the opinion that the amended definition covers persons "who, as a result [of being incorrectly regarded as handicapped], are substantially limited in a major life activity." Id. at 1129. The effect of this interpretation is that the perceived impairment need not directly result in a limitation of a major life activity, so long as it has the indirect effect, due to the misperceptions of others, of limiting a life activity (in Arline, the activity of working).¹⁴ Thus, at least one district court

¹⁴ The Arline Court appears not to accept the distinction between being perceived as having an impairment that itself limits a major life activity (the literal meaning of the statutory language) and having a condition the misperception of which results in limitation of a life activity. This may have been the distinction the Solicitor General was attempting to draw by suggesting there was a difference between being perceived as having a handicap that precludes work and being perceived as contagious, which does not physically preclude work, except that because of the perception, no work is offered. As recited by the Court, the Solicitor General stated at oral argument "that to argue that a condition that impaired only the ability to work was a handicapping condition was to make 'a totally circular argument (continued...)"

following Arline has held that if an individual or organization limits an HIV-infected individual's participation in a section 504 covered activity because of fear of contagion, a major life activity of the individual is substantially limited.¹⁵

C. Application of the "Otherwise Qualified" Requirement

The Supreme Court's opinion in Arline concluded by remanding the case for consideration by the district court of whether the plaintiff was "otherwise qualified." The Court indicated more generally that section 504 cases involving persons with contagious diseases should turn on the "otherwise qualified" issue, that such individuals must "have the opportunity to have their condition evaluated in light of medical evidence and a determination made as to whether they were 'otherwise quali-

¹⁴(...continued)
which lifts itself by its bootstraps.' [Citation omitted] The argument is not circular, however, but direct. Congress plainly intended the Act to cover persons with a physical or mental impairment (whether actual, past, or perceived) that substantially limited one's ability to work." Id. at 1129 n.10. This last statement, of course, returned the Court to the statute's literal meaning. The only justification for departing from that meaning occurs not in footnote 10 of Arline, but in footnote 9, where the Court relied on legislative history which does indicate that at least some members of Congress believed that the perception of a physical disability by others does not have to include the belief that the perceived condition results in a limitation of major life activities, but simply that the perception of the condition by others in itself has that effect. Id. at 1128 n.9 (physically repulsive aspects of cerebral palsy, arthritis, and facial deformities).

¹⁵ Doe v. Centinela Hospital, Civ. 87-2514 (C.D. Cal. June 30, 1988) (holding HIV-infected individual to be "individual with handicaps" because he was perceived as such by the defendant). The district court wrote that a person is an individual with handicaps if he "has a physiological disorder or condition affecting a body system that substantially limits a 'function' only as a result of the attitudes of others toward the disorder or condition; . . ." Slip op. at 12. The HHS regulations are in accord with this view. 45 C.F.R. section 84.3(j)(2)(iv)(B) (1987). Although as indicated in the previous footnote we think this aspect of the Supreme Court's reasoning departs from the literal meaning of the statutory text in favor of legislative history, we do not question that the district court in Centinela Hospital fairly reads Arline to support a finding that the reaction of others to the contagiousness of an HIV-infected individual in itself may constitute a limitation on a major life activity.

fied.'" 107 S. Ct. at 1130. The Court stressed that before making this determination the trial court must

conduct an individualized inquiry and make appropriate findings of fact. Such an inquiry is essential if § 504 is to achieve its goal of protecting handicapped individuals from deprivations based on prejudice, stereotypes, or unfounded fear, while giving appropriate weight to such legitimate concerns of grantees as avoiding exposing others to significant health and safety risks In the context of the employment of a person handicapped with a contagious disease . . . this inquiry should include "[findings of] facts, based on reasonable medical judgments given the state of medical knowledge, about (a) the nature of the risk (how the disease is transmitted), (b) the duration of the risk (how long is the carrier infectious), (c) the severity of the risk (what is the potential harm to third parties) and (d) the probabilities the disease will be transmitted and will cause varying degrees of harm." (Quoting Brief for American Medical Association as Amicus Curiae 19.) In making these findings, courts normally should defer to the reasonable medical judgments of public health officials. The next step in the "otherwise-qualified" inquiry is for the court to evaluate, in light of these medical findings, whether the employer could reasonably accommodate the employee under the established standards for that inquiry.

Id. at 1131 (footnotes omitted).

It is important to emphasize that the Court recognized that "[a] person who poses a significant risk of communicating an infectious disease to others in the workplace will not be otherwise qualified for his or her job if reasonable accommodation will not eliminate that risk." Id. at 1131 n.16. The Court has thus made it clear that persons infected with the AIDS virus will not be "otherwise qualified" to perform jobs that involve a significant risk of transmitting the virus to others. In addition, an "otherwise qualified person is one who is able to meet all of a program's requirements in spite of his handicap." Southeastern Community College v. Davis, 442 U.S. 397, 406 (1979).¹⁶

¹⁶ In ascertaining whether a person is otherwise qualified, the court considers "whether any 'reasonable accommodation' by the employer would enable the handicapped person to perform those functions. Accommodation is not reasonable if it either imposes 'undue financial and administrative burdens' on a grantee, . . . , or requires 'a fundamental alteration in the

(continued...)

Based on current medical knowledge, it would seem that in most situations the probability that the AIDS virus will be transmitted is slight, and therefore as a matter of health and safety there will often be little, if any, justification for treating infected individuals differently from others.¹⁷ Similarly, mere HIV infection involving only "subclinical manifestations" will generally also not render an individual unqualified to participate in a covered program or activity on the basis of inability to perform. As the disease progresses, however, and conditions such as ARC or "full blown" AIDS affect the physical or mental capacity of the individual, it may well be that an "individualized inquiry" will reveal that such person is not otherwise qualified to participate.

In addition, current medical knowledge does suggest the possibility of specialized contexts where, even with respect to a person in the early stages of the disease, a court might find an individual to be not otherwise qualified. These situations are very likely to involve individuals who have responsibility for health or safety, such as health care professionals or air traffic controllers. In these and similar situations where there is a greater possibility that the AIDS virus could be transmitted (see generally, Surgeon General's Report), or the consequences of a dementia attack could be especially dangerous (see note 9, supra), we believe a court could find, within the scope of "otherwise qualified" standard, a justification for treating HIV-infected individuals differently from uninfected individuals.

In brief, whether HIV-infected individuals will be found after the individualized inquiry required by Arline to be otherwise qualified will often depend on how far the disease has progressed. At the early stages of the disease, it is likely that neither health and safety nor performance will provide a justification for excluding an HIV-infected person. Moreover, while current medical knowledge suggests that safety should not be a concern in most contexts even as the disease progresses, an individualized assessment of performance may result in those with AIDS or ARC being found not otherwise qualified. Finally, courts may find in certain specialized contexts that an HIV-infected individual is not otherwise qualified at any stage of the disease because infection in itself presents an especially serious health or safety risk to others because of the nature of

¹⁶(...continued)
nature of [the] program.'" 107 S. Ct. at 1131 n.17 (citations omitted).

¹⁷ See Surgeon General's Report at 13 ("No Risk from Casual Contact").

the position. The inquiry in each case will be a factual one, and because of that, we are unable to speculate further.

III. Application of Section 504 in the Employment Context

A. Introduction and Summary

The Civil Rights Restoration Act included a provision, the Harkin-Humphrey amendment,¹⁸ which amended the definitions section of the Rehabilitation Act to provide, with respect to employment, a specific qualification of the definition of an "individual with handicaps" in the context of contagious diseases and infections:

For the purpose of sections 503 and 504, as such sections relate to employment, [the term "individual with handicaps"] does not include an individual who has a currently contagious disease or infection and who, by reason of such disease or infection, would constitute a direct threat to the health or safety of other individuals or who, by reason of the currently contagious disease or infection, is unable to perform the duties of the job.

As discussed below, application of the Harkin-Humphrey amendment in the employment context should result in substantially the same conclusions as result from application in the non-employment context of section 504 as interpreted in Arline. Specifically, we conclude that Harkin-Humphrey provides that HIV-infected individuals (regardless of whether or not they are symptomatic) are protected against discrimination in the employment context so long as they fall within the general section 504 requirements defining an "individual with handicaps" and do not contravene the specific qualification to the general requirements that the amendment provides: namely, that they do not "constitute a direct threat to the health or safety of other individuals" and they can "perform the duties of the job." In our judgment, this qualification merely codifies the "otherwise qualified" standard discussed by the Court in Arline and discussed above in this memorandum, including the provision of a means of reasonable accommodation that can eliminate the health or safety threat or enable the employee to perform the duties of the job, if it is provided for under the employer's existing personnel policies and does not impose an undue financial or administrative burden.

¹⁸ Pub. L. No. 100-259, sec. 9, 102 Stat. 28, 31-32 (1988). Since this amendment to section 504 was jointly sponsored by Senators Harkin and Humphrey, we will refer to the amendment in this opinion as "Harkin-Humphrey."

Because Harkin-Humphrey was a floor amendment that was not developed by a committee, there is no committee report explaining it. The only explanatory statement that accompanied its introduction was a one-sentence statement of purpose -- "Purpose: To provide a clarification for otherwise qualified individuals with handicaps in the employment context", 134 Cong. Rec. S256 (daily ed. Jan. 28, 1988) -- and a brief colloquy between the two sponsors. Id. at S256-257.

The sponsors' colloquy made three basic points. First, the amendment was designed to do in the contagious disease and infection context what the comparably phrased 1978 amendment to section 504 did in the context of alcohol and drug abuse¹⁹ -- "assure employers that they are not required to retain or hire individuals with a contagious disease or infection when such individuals pose a direct threat to the health or safety of other individuals, or cannot perform the essential duties of a job." Id. at S256-57. Second, the amendment "does nothing to change the current laws regarding reasonable accommodation as it applies to individuals with handicaps." Id. at S257. Finally, "as we stated in 1978 with respect to alcohol and drug abusers, . . . the two-step process in section 504 applies in the situation under which it was first determined that a person was handicapped and then it is determined that a person is otherwise qualified." Id.

With that description of Harkin-Humphrey's principal legislative history as background, we now discuss the amendment's impact on two aspects of the application of section 504 to HIV infection cases in the employment context: (1) whether section 504 applies to both asymptomatic and symptomatic HIV-infected individuals; and (2) the manner in which the section's "otherwise qualified" requirement is to be applied, including whether employers must provide "reasonable accommodation" to infected individuals.

B. Coverage of All HIV-Infected Individuals (Subject to the Stated Limitations)

We have no difficulty concluding that the Harkin-Humphrey amendment, and thus section 504 in the employment context,

¹⁹ "For purposes of sections 503 and 504 as such sections relate to employment, [the term "handicapped individual"] does not include any individual who is an alcoholic or drug abuser whose current use of alcohol or drugs prevents such individual from performing the duties of the job in question or whose employment, by reason of such current alcohol or drug abuse, would constitute a direct threat to property or the safety of others." Pub. L. No. 95-602, sec. 122(a), 92 Stat. 2955, 2985 (1978), codified at 29 U.S.C. 706(8)(B).

includes within its coverage both asymptomatic and symptomatic HIV-infected individuals. The amendment's language draws no distinction between asymptomatic and symptomatic individuals and, notably, applies to a "contagious disease or infection." It therefore applies to all HIV-infected individuals, whether or not they are symptomatic. It is true that the amendment is phrased in the negative in that it says who is not handicapped, rather than defining who is handicapped. Nevertheless, we believe the natural implication of this statutory exclusion is that persons who do not fall within the specified grounds for exclusion are covered by section 504 to the extent that they meet the general requirements of that section. Accordingly, in light of our previous discussion of the application of the general provisions of section 504 to HIV-infected persons, we conclude that all HIV-infected individuals who are not a direct threat to the health or safety of others and are able to perform the duties of their job are covered by section 504.

Harkin-Humphrey's legislative history reinforces this reading of the amendment.²⁰ There was no disagreement expressed concerning the amendment's applicability to asymptomatic HIV-infected individuals, and a number of legislators expressly stated that such persons were covered. Senator Harkin described the purpose of the amendment in a letter, dated February 26, 1988, to Representatives Hawkins and Edwards. Senator Harkin explained that

[t]he objective of the amendment is to expressly state in the statute the current standards of section 504 so as to reassure employers that they are not required to hire or retain individuals with contagious diseases or infections who pose a direct threat to the health or safety of others or who cannot perform the duties of a job.

The basic manner in which an individual with a contagious disease or infection can present a direct threat to the health or safety of others is when the individual poses a significant risk of transmitting the contagious disease or infection to other individuals. The Supreme Court in Arline explicitly recognized this necessary limitation in the protections of section 504. The amendment is consistent with this standard.

²⁰ Moreover, the model for the Harkin-Humphrey amendment -- the 1978 amendment to section 504 concerning drug addicts and alcoholics -- was intended to include within section 504 those covered persons not possessing the deficiencies identified in the statute. See generally, 124 Cong. Rec. 30322-30325 (1978) (statements of Senators Cannon, Williams, and Hathaway).

134 Cong. Rec. H1065 (daily ed. Mar. 22, 1988) (emphasis in original).²¹

During the subsequent debate in the House of Representatives, the Representatives who commented on the amendment indicated their understanding that persons with contagious diseases or infections were covered. For example, referring to the dissenting opinion in Arline, see 107 S. Ct. at 1132-1134, Representative Weiss observed:

[Chief] Justice Rehnquist stated that Congress should have stated explicitly that individuals with contagious diseases were intended to be covered under section 504. Congress has done so now with this amendment, stating clearly that individuals with contagious diseases or infections are protected under the statute as long as they meet the "otherwise qualified" standard. This clarity is particularly important with regard to infections because individuals who are suffering from a contagious infection -- such as carriers of the AIDS virus or carriers of the hepatitis B virus -- can also be discriminated against on the basis of their infection and are also individuals with handicaps under the statute.

134 Cong. Rec. H573 (daily ed. Mar. 2, 1988). Representative Coelho stated that the amendment

provides that individuals with contagious diseases or infections are protected under the statute unless they pose a direct threat to the health or safety of others or cannot perform the duties of the job.

* * * * *

People with contagious diseases and infections, such as people with AIDS or people infected with the AIDS virus, can be subject to intense and irrational discrimination. I am pleased that this amendment makes clear that such individuals are covered under the protections of the Rehabilitation Act.

Id. at H560-61. Representative Owens commented:

I am glad to see that [the amendment] refers to individuals with contagious infections, thus clarifying

²¹ See also 134 Cong. Rec. S1739 (daily ed. Mar. 2, 1988) ("The purpose of the amendment was to clarify for employers the applicability of section 504 of the Rehabilitation Act of 1973 to persons who have a currently contagious disease or infection.") (statement of Sen. Harkin).

that such infections can constitute a handicapping condition under the Act.

Id. at H574. The record is replete with similar comments.²²

In summary, we believe that under the Harkin-Humphrey amendment, section 504 applies in the employment context to all HIV-infected individuals, which necessarily includes both asymptomatic and symptomatic HIV-infected individuals. This parallels our conclusions with respect to HIV-infected individuals, both symptomatic and asymptomatic, outside the employment context. The difference between the employment and non-employment contexts because of the Harkin-Humphrey amendment is thus more apparent than real. Specifically, it is our view that the Harkin-Humphrey amendment merely collapses the "otherwise qualified" inquiry applicable outside the employment context into the definition of "individual with handicaps" in the employment text. Thus, whether outside the employment context a particular infected person is deemed to be handicapped but ultimately receives no protection under the statute because that person poses a danger to others and is thereby not "otherwise qualified" or whether that same person is not deemed to be handicapped under the Harkin-Humphrey amendment in the employment context for the same reason is of only semantic significance. In either case, if the infection is a direct threat to the health or safety of others or renders the individual unable to perform the duties of the job, the grantee or employer is not required to include that person in the covered program or activity or retain or hire him in a job. Indeed, the legislative history suggests that the principal purpose of the Harkin-Humphrey amendment was the codification of the "otherwise qualified" limitation as discussed in Arline.²³

²² See, e.g., 134 Cong. Rec. H584 (daily ed. Mar. 2, 1988) (statement of Rep. Edwards) ("I commend the Members of the Senate for fashioning this amendment in such a way that the courts will continue to adjudicate cases involving AIDS, HIV infection and other communicable conditions on a case by case basis."); id. at E487 (statement of Rep. Hoyer) (referring to "people with AIDS and people infected with the AIDS virus" as equally subject to the amendment); id. at H580 (statement of Rep. Dannemeyer) (opposing amendment because it covers "asymptomatic carriers").

²³ "Purpose: To provide a clarification for otherwise qualified individuals with handicaps in the employment context." 134 Cong. Rec. S256 (daily ed. Jan. 28, 1988). See also the sponsors' colloquy, discussed supra in the text, as well as the comments of individual members. E.g., 134 Cong. Rec. H584 (daily ed. Mar. 2, 1988) (statement of Rep. Edwards) ("This amendment . . . codif[ies] the 'otherwise qualified' framework (continued...)")

C. Is There a "Reasonable Accommodation" Requirement Under Harkin-Humphrey?

The Department of Health and Human Services (HHS) regulations implementing section 504, first issued in 1977, reflect HHS' determination that a "reasonable accommodation" requirement is implicit in the "otherwise qualified" element of section 504. 42 Fed. Reg. 22676, 22678 (May 4, 1977). Then, as now, the regulations provided the following statement of the "otherwise qualified" requirement: "'Qualified handicapped person' means . . . [w]ith respect to employment, a handicapped person who, with reasonable accommodation, can perform the essential functions of the job in question."²⁴ In Arline, the Supreme Court endorsed the "reasonable accommodation" requirement of the regulations, explaining that when a handicapped person is not able to perform the essential functions of the job, and is therefore not "otherwise qualified," "the court must also consider whether any 'reasonable accommodation' by the employer would enable the handicapped person to perform those functions."²⁵

²³(...continued)
for courts to utilize in these cases."); id. at H573 (statement of Rep. Weiss) ("In such circumstances [significant risk of communicating a contagious disease], the individual is not 'otherwise qualified' to remain in that particular position. The Supreme Court in Arline explicitly recognized this necessary limitation in the protections of section 504. The Senate amendment places that standard in statutory language"); id. at E487 (statement of Rep. Hoyer) ("[T]his amendment essentially codifies the existing standard of otherwise qualified in section 504, as explicated by the Supreme Court in Arline.").

²⁴ 45 C.F.R. 84.3(k)(1) (1987) (emphasis added). See also 45 C.F.R. 84.12 (1987) (setting forth the "reasonable accommodation" requirements).

²⁵ Arline, 107 S. Ct. at 1131 n.17. The Court suggested that two factors, originally employed by the Court in Davis, should be used to ascertain the reasonableness of an employer's refusal to accommodate a handicapped individual: "Accommodation is not reasonable if it either imposes 'undue financial and administrative burdens' on a grantee, Southeastern Community College v. Davis, supra, at 412, 99 S. Ct. at 2370, or requires a 'fundamental alteration in the nature of [the] program' id. at 410. See 45 C.F.R. § 84.12(c) (1985) (listing factors to consider in determining whether accommodation would cause undue hardship)" Id.

As noted above, the Harkin-Humphrey amendment includes within it the "otherwise qualified" standard. We must determine whether a "reasonable accommodation" requirement is implicit in Harkin-Humphrey's special section 504 formulation, just as HHS and the Supreme Court found such a requirement to be implicit in section 504 prior to this amendment. More specifically, was Harkin-Humphrey intended to require reasonable accommodation of a contagious individual who, absent such accommodation, poses a "direct threat to the health or safety of other individuals or . . . is unable to perform the duties of the job?" The amendment's legislative history convinces us that Congress intended that consideration of "reasonable accommodation" should be factored into an employer's determination of whether an infected employee poses a direct threat or can perform the job.

The legislative history of the Harkin-Humphrey amendment indicates that Congress was quite aware that administrative and judicial interpretation had added the "reasonable accommodation" gloss to section 504, and Congress understood and intended that such a gloss would be put on Harkin-Humphrey. The first evidence of this is found in the colloquy between Senators Harkin and Humphrey upon the introduction of the amendment. The colloquy stressed that the amendment "does nothing to change the current laws regarding reasonable accommodation as it applies to individuals with handicaps." 134 Cong. Rec. S257 (daily ed. Jan. 28, 1988). More expansively, Senator Harkin subsequently stated that

the amendment does nothing to change the requirements in the regulations regarding providing reasonable accommodations for persons with handicaps, as such provisions apply to persons with contagious diseases and infections. Thus, if a reasonable accommodation would eliminate the existence of a direct threat to the health or safety of others or eliminate the inability of an individual with a contagious disease or infection to perform the essential duties of a job, the individual is qualified to remain in his or her position.

134 Cong. Rec. S1740 (daily ed. Mar. 2, 1988).

Senator Harkin's statement cannot be given dispositive weight because it was not joined by his co-sponsor, Senator Humphrey, and it was not made before the Senate voted on the amendment. However, Senator Humphrey never directly challenged this statement, or said that reasonable accommodation was not intended, and unchallenged statements to the same effect were made by members of the House speaking in favor of and against the amendment prior to the House vote on the amendment and by members of the Senate speaking in favor of and against the amendment

prior to the vote to override the President's veto of the Civil Rights Restoration Act.

Prior to the House vote, for example, Representative Weiss remarked that

[a]s the Senate amendment now restates in statutory terms, [individuals with contagious diseases or infections] are also not otherwise qualified if, without reasonable accommodation, they would pose a direct threat to the health or safety of others or could not perform the essential functions of a job.

Id. at H573. Representative Waxman said the same thing:

the Court went on to say [in Arline] that if [persons with contagious diseases] pose a significant risk of transmitting their diseases in the workplace, and if that risk cannot be eliminated by reasonable accommodation, then they cannot be considered to be "otherwise qualified" for the job. The amendment added by the Senate to this bill places that standard in law.

Id. at H575 (emphasis added). Many other Representatives supporting the amendment agreed.²⁶ Opposing the amendment, Representative Dannemeyer stated that "[i]f this bill is passed as presently written, employers will be required to accommodate

²⁶ E.g., 134 Cong. Rec. E501 (daily ed. Mar. 3, 1988) (statement of Rep. Miller) ("[T]he new language added by the Senate changes nothing with respect to current law and is not intended to displace the . . . reasonable accommodations requirement under section 504."); 134 Cong. Rec. H584 (daily ed. Mar. 2, 1988) (statement of Rep. Edwards) ("The colloquy in the Senate between the two cosponsors of the amendment clarifies that it is the intent of Congress that the amendment result in no change in the substantive law with regard to assessing whether persons with this kind of handicapping condition are 'otherwise qualified' for the job in question or whether employers must provide 'reasonable accommodations' for such individuals."); id. at H561 (statement of Rep. Coehlo) ("[I]ndividuals with contagious diseases and infections are not otherwise qualified -- and thus are not protected in a particular position -- if, without reasonable accommodation, they would pose a direct threat to the health or safety of others or cannot perform the duties of the job."); id. at E487 (statement of Rep. Hoyer) (not "otherwise qualified" if risk of communicating contagious disease "cannot be eliminated by reasonable accommodation"); id. at H571 (statement of Rep. Jeffords) (same); id. at H574 (statement of Rep. Owens) (same).

victims of this fatal disease despite potential health threats to other employees." Id. at H580.

Prior to the Senate vote to override the President's veto of the Civil Rights Restoration Act, Senator Harkin reiterated his intent and understanding that reasonable accommodation was required:

I say to this body this bill does not I repeat does not require an employer to hire or retain in employment all persons with contagious diseases. An employer is free to refuse to hire or fire any employee who poses a direct threat to the health or safety of others who cannot perform the essential functions of the job if no reasonable accommodation can remove the threat to the safety of others or enable the person to perform the essential functions of the job. This determination must be made on an individualized basis and be based on facts and sound medical judgment.

134 Cong. Rec. S2435 (daily ed. Mar. 17, 1988) (emphasis added). Moreover, in arguing that the President's veto should be sustained, a number of Senators stated their understanding that Harkin-Humphrey would require reasonable accommodation. Senator Hatch included in his list of objectionable features of the Civil Rights Restoration Act "the requirement to attempt to accommodate persons with infectious diseases, such as tuberculosis and AIDS." Id. at S2403. Senator Symms made the same point, arguing that "[t]he equality-of-result rather than equality-of-opportunity standards [in the Civil Rights Restoration Act] can lead to . . . the need to attempt to accommodate infectious persons" Id. at S2410.

Moreover, in addition to this direct evidence of congressional intent concerning the Harkin-Humphrey amendment, we also find illuminating the evidence that the 1978 drug and alcohol abuse amendment, on which Harkin-Humphrey is modeled,²⁷ was intended to require reasonable accommodation. During the Senate debate on Harkin-Humphrey, Senator Cranston observed that the drug and alcohol abuse amendment

did not result in any basic change in the process under section 504 by which it is determined whether the individual claiming unlawful discrimination is handicapped and whether that individual is "otherwise qualified," taking into account -- as in the case of all other handicapped persons -- any reasonable accommodations

²⁷ See sponsors' colloquy, 134 Cong. Rec. S256-57 (daily ed. Jan. 28, 1988).

that should be made to enable him or her to perform the job satisfactorily.

134 Cong. Rec. S724 (daily ed. Feb. 4, 1988) (emphasis added).

The legislative history of the drug and alcohol abuse amendment supports Senator Cranston's assertion that "reasonable accommodation" was required under that amendment. That legislative history is clear that the amendment was designed to codify the existing "otherwise qualified" standard, as interpreted by the Attorney General and the Secretary of HEW, which included the "reasonable accommodation" requirement.²⁸ In explaining the amendment, one of its sponsors specifically cited the "reasonable accommodation" requirement:

Regulations implementing sections 503 and 504 already address [the concerns of employers and others seeking the amendment]. They make clear that the protections of sections 503 and 504 only apply to otherwise qualified individuals. That means . . . that distinction on the basis of qualification is perfectly justifiable. Regulations implementing section 503 define "qualified handicapped individual" as a handicapped person who is capable of performing a particular job with reasonable accommodation to his or her handicap.²⁹

²⁸ 43 Op. Atty' Gen. No. 12, at 2 (1977) (section 504 does not "require unrealistic accommodations" for drug addicts or alcoholics); 42 Fed. Reg. 22676, 22678 (May 4, 1977) (promulgating "otherwise qualified" definition, which is identical to current definition and thus includes reasonable accommodation).

²⁹ 124 Cong. Rec. 30324 (1978) (statement of Sen. Hathaway) (emphasis added). The sponsors of the amendment believed that it "simply [made] explicit what prior interpret[at]ions of the act -- including those of the Attorney General and the Secretary of Health, Education, and Welfare -- have found" *Id.* at 37510 (statement of Sen. Williams). They did not believe that a change in law was necessary, but they were willing to provide a clarification in order to "reassure employers that it is not the intent of Congress to require any employer to hire a person who is not qualified for the position or who cannot perform competently in his or her job." *Id.* at 30323. The amendment used an "otherwise qualified" formulation to clarify how existing law applied to drug and alcohol abusers. As explained by Senator Williams, "while the legislative history of the 1973 act, as authoritatively interpreted by the Attorney General, made clear that qualified individuals with conditions or histories of alcoholism or drug addiction were protected from discrimination by covered employers, this amendment codifies that intent." *Id.*

(continued...)

Our final reason for believing that Congress intended the Harkin-Humphrey amendment to preserve the "reasonable accommodation" requirement of existing law is that a contrary conclusion would entail overruling a specific holding of Arline. After holding that the plaintiff in Arline was a "handicapped individual," the Supreme Court remanded the case to the district court for the "otherwise qualified" determination, which the Court said should include "evaluat[ing], in light of [a series of medical findings], whether the employer could reasonably accommodate the employee under the established standards for that inquiry." 107 S. Ct. at 1131.

Any reading of the Harkin-Humphrey amendment that precluded reasonable accommodation would be inconsistent with that Arline holding. Applying Harkin-Humphrey without reasonable accommoda-

29 (...continued)
at 37509.

Senator Williams' reference to the Attorney General was to an opinion Attorney General Bell provided to HEW Secretary Califano a month before HEW's promulgation (on May 4, 1977) of its regulations implementing section 504. 43 Op. Att'y Gen. No. 12 (1977). While concluding that drug and alcohol abusers were "handicapped individuals" subject to the same protections under section 504 as were all other handicapped individuals, the Attorney General stressed the applicability of the "otherwise qualified" requirement:

[O]ur conclusion that alcoholics and drug addicts are "handicapped individuals" for purposes of section 504 does not mean that such a person must be hired or permitted to participate in a federally assisted program if the manifestations of his condition prevent him from effectively performing the job in question or from participating adequately in the program. A person's behavior manifestations of a disability may also be such that his employment or participation would be unduly disruptive to others, and section 504 presumably would not require unrealistic accommodations in such a situation.

Id. at 2 (emphasis added). As Senator Williams noted (124 Cong. Rec. 30324 (1978)), Secretary Califano's statement accompanying issuance of the regulations agreed with the Attorney General's interpretation and his emphasis on the "otherwise qualified" requirement. 42 Fed. Reg. 22676, 22686 (May 4, 1977). The regulations issued by Secretary Califano included the "otherwise qualified" regulation requiring reasonable accommodation. Id. at 22678.

tion to an individual like the plaintiff in Arline would probably result in a finding that the individual is a direct threat to the health and safety of her students without any meaningful consideration of non-burdensome ways to alleviate the danger. Thus, under that reading, an individual with tuberculosis (or an HIV-infected individual) would receive less individualized scrutiny under the amendment than under Arline. However, it is clear that Congress did not intend to overrule Arline. Indeed, supporters of Harkin-Humphrey repeatedly and unequivocally spoke of codifying Arline and acting consistently with Arline, including specifically Arline's approach to "otherwise qualified" and "reasonable accommodation."³⁰ Only a single statement by Senator Humphrey is arguably somewhat to the contrary, and even this remark does not undermine our conclusion, or the overwhelming evidence of legislative intent on which it is based.³¹ Senator Humphrey merely stated that the amendment must result in some change or it would have been "pointless." However, codifying a Supreme Court holding in a manner designed to reassure those infected with a contagious disease of the law's protection and employers of the law's limits has a point.

For the foregoing reasons, we conclude that implicit in Harkin-Humphrey's statement of the "otherwise qualified" standard for the contagious disease context is a "reasonable accommodation" requirement.³² Accordingly, before determining that an HIV-infected employee is not an "individual with

³⁰ E.g., 134 Cong. Rec. S2435 (daily ed. Mar. 17, 1988) (statement of Sen. Harkin); 134 Cong. Rec. S1739 (daily ed. Mar. 2, 1988) (statement of Sen. Harkin, concurred in by Sen. Kennedy and Sen. Weicker); 134 Cong. Rec. S725 (daily ed. Feb. 4, 1988) (statement of Sen. Cranston); 134 Cong. Rec. H560-61 (daily ed. Mar. 2, 1988) (statement of Rep. Coelho); id. at H567 (statement of Rep. Hawkins); id. at H571 (statement of Rep. Jeffords); id. at H574 (statement of Rep. Owens); id. at H575 (statement of Rep. Waxman); id. at H584 (statement of Rep. Edwards).

³¹ 134 Cong. Rec. S970 (daily ed. Feb. 18, 1988) (statement of Sen. Humphrey) ("If the Humphrey-Harkin amendment had not resulted in some substantive change in the law, it would have been a pointless exercise. . . . [The amendment was not] intended merely to codify the status quo in this area. The language of these measures is quite clear, and post facto interpretations should not be construed to alter their actual intent or effect.").

³² The American Law Division of the Library of Congress' Congressional Research Service has reached the same conclusion. CRS Report for Congress, Legal Implications of the Contagious Disease or Infections Amendment to the Civil Rights Restoration Act, S. 557 18-23 (March 14, 1988).

handicaps," an employer must first consider whether, consistent with the employer's existing personnel policies for the job in question, a reasonable accommodation would eliminate the health or safety threat or enable the employee to perform the duties of the job.

Arline's discussion of the HHS regulations' "reasonable accommodation" requirement presents a useful point of reference for considering what "reasonable accommodation" should be provided for HIV-infected individuals in the employment context. As noted by the Court, the HHS regulations provide that "[e]mployers have an affirmative obligation to make a reasonable accommodation for a handicapped employee. Although they are not required to find another job for an employee who is not qualified for the job he or she was doing, they cannot deny an employee alternative employment opportunities reasonably available under the employer's existing policies." 107 S. Ct. at 1131 n.19. However, "where reasonable accommodation does not overcome the effects of a person's handicap, or where reasonable accommodation causes undue hardship to the employer, failure to hire or promote the handicapped person will not be considered discrimination." 45 C.F.R., Part 84, App. A., p. 350 (1987).

While reasonable accommodation is part of the individualized factual inquiry and therefore difficult to discuss in the abstract, it clearly does not require allowing an HIV-infected individual to continue in a position where the infection poses a threat to others. This would appear to be the case with infected health care workers who are involved in invasive surgical procedures, and it may also be the case with respect to other infected health care workers or individuals employed in jobs that entail responsibility for the safety of others. Limited accommodations might be required if alternative employment is reasonably available under the employer's existing policies. For example, a surgeon in a teaching hospital might be restricted to teaching or other medical duties that do not involve participation in invasive surgical procedures, or a policeman might be reassigned to duties that do not involve a significant risk of a physical injury that would involve bloodshed. In contrast, given the evolving and uncertain state of knowledge concerning the effects of the AIDS virus on the central nervous system, it may not be possible, at least if the disease has sufficiently progressed, to make reasonable accommodation for positions, such as bus driver, airline pilot, or air traffic controller, that may allow very little flexibility in possible job assignment and where the risk of injury is great if the employer guesses wrongly and the infected person is not able to perform the duties of the job.

Conclusion

We have concluded, with respect to the non-employment context, that section 504 protects symptomatic and asymptomatic HIV-infected individuals against discrimination in any covered program or activity on the basis of any actual, past or perceived effect of HIV infection that substantially limits any major life activity -- so long as the HIV-infected individual is "otherwise qualified" to participate in the program or activity, as determined under the "otherwise qualified" standard set forth in Arline. We have further concluded that section 504 applies in substance in the same way in the employment context, since the statutory qualification set forth in the Civil Rights Restoration Act merely incorporates the Arline "otherwise qualified" standard for those individuals who are handicapped under the general provisions of section 504 by reason of a currently contagious disease or infection. The result is the same: subject to an employer making reasonable accommodation within the terms of his existing personnel policies, the symptomatic or asymptomatic HIV-infected individual is protected against discrimination if he or she is able to perform the duties of the job and does not constitute a direct threat to the health or safety of others.


Douglas W. Kmiec
Acting Assistant Attorney General
Office of Legal Counsel

Attachment



July 29, 1988

The Surgeon General of the
Public Health Service
Washington DC 20201

Douglas Kamiec, Esq.
Acting Assistant Attorney General
Office of Legal Counsel
Department of Justice
Washington, D.C.

Dear Mr. Kamiec:

I was pleased to be able to convey to you, at our meeting of July 20, 1988, our medical and public health concerns regarding discrimination and the current HIV epidemic. These concerns will be greatly affected by the extent to which HIV infected individuals understand themselves to be protected from discrimination on account of their infection.

Protection of persons with HIV infection from discrimination is an extremely critical public health necessity because of our limited tools in the fight against AIDS. At this time, we have no vaccine to protect against HIV infection and only one treatment which appears to extend the lives of some persons with AIDS but does not cure the disease. Consequently, the primary public health strategy is prevention of HIV transmission.

This strategy requires extensive counseling and testing for HIV infection. If counseling and testing are to work most effectively, individuals must have confidence that they will be protected fully from HIV related discrimination.

During our meeting you and members of your staff raised a number of perceptive questions concerning the nature of HIV infection including the pathogenesis of the virus and its modes of transmission. Your interest in the scientific aspects of HIV infection is welcome, since it is our belief that any legal opinion regarding HIV infection should accurately reflect scientific reality. As I sought to emphasize during our meeting, much has been learned about HIV infection that makes it inappropriate to think of it as composed of discrete conditions such as ARC or "full blown" AIDS. HIV infection is the starting point of a single disease which progresses through a variable range of stages. In addition to an acute flu-like illness, early stages of the disease may involve subclinical manifestations i.e., impairments and no visible signs of illness. The overwhelming

majority of infected persons exhibit detectable abnormalities of the immune system. Almost all, HIV infected persons will go on to develop more serious manifestations of the disease and our present knowledge suggests that all will die of HIV infection barring premature death from other causes.

Accordingly, from a purely scientific perspective, persons with HIV infection are clearly impaired. They are not comparable to an immune carrier of a contagious disease such as Hepatitis B. Like a person in the early stages of cancer, they may appear outwardly healthy but are in fact seriously ill. Regrettably, given the absence of any curative therapy for AIDS, a person with cancer currently has a much better chance of survival than an HIV infected individual.

Please do not hesitate to contact me if I can be of any further assistance to you in this matter.

Sincerely,

A handwritten signature in dark ink, appearing to read "C. Everett Koop", written in a cursive style.

C. Everett Koop, M.D.
Surgeon General

Drug Abuse Policy Office

FOR IMMEDIATE RELEASE

(DATE)

SUMMARY OF ACCOMPLISHMENTS IN COMBATTINGTHE HUMAN IMMUNODEFICIENCY VIRUS (HIV)

Not until 1982 did researchers in France and the United States isolate and identify the Human Immunodeficiency Virus (HIV). The urgency and breadth of the nation's HIV research effort is without precedent in the history of the Federal government's response to an infectious disease crisis. In the 7 years since the first reports of AIDS cases, the virus has been identified; the ways in which it is spread have been pinpointed; an AIDS antibody screening test has been developed and is being used to protect blood supplies; the first steps toward development of a protective vaccine have been taken; and promising drugs to fight the HIV and its manifestations are being synthesized and tested. And, in order to promote even greater understanding, the President commissioned two major reports on the epidemic: the Surgeon General's Report on AIDS and the Report of the Presidential Commission on the HIV.

The HIV epidemic will be an international threat for years to come. Knowledge is a critical weapon against HIV -- knowledge about the virus and how it is transmitted, and knowledge of how to protect one's health. It is critical also that knowledge lead to individual responsibility. Toward that end, it is the responsibility of each individual to learn about HIV and to treat those infected with HIV with respect and compassion. And it is the responsibility of infected individuals not to infect others.

The President established a 10-point action plan to advance the U.S. battle against AIDS and HIV. The plan, based on recommendations of the Presidential Commission on the HIV Epidemic, calls for actions to assure compassion towards those with HIV infection, to allow for their care with dignity and kindness, and to inform and educate citizens to prevent further spread of the disease. The President further instructed the Federal government to take the lead in protecting HIV-infected persons against discrimination in the Federal workplace.

Accomplishments in Combatting HIV

HIV will continue to pose a great public health threat to the world community -- it is estimated that 65,000 people will die because of HIV in the year 1992 alone. However, extensive efforts by Government and the private sector as well as the international community are underway in the fight against AIDS and HIV infection, and great strides have been made.

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- o As the first cases of AIDS were identified, nationwide surveillance activities were initiated to monitor the spread of the disease. Disease surveillance began early in the epidemic, before the HIV had been identified or isolated, and before it was known that there could be a lengthy period of infection prior to illness.
- o There has been unprecedented progress in identifying and describing how HIV is structured and how it works. The Federal government continues to probe the inner workings of the immune system and its function during HIV infection to find ways to halt the progress of the virus. Continued research is also being pursued to expand our knowledge of the factors and causes of progression to clinical disease.

Public Health Measures

In 1982, scientists determined that AIDS could be transmitted through transfusion of contaminated blood or blood products. Some two years later, HIV was identified as the agent that causes AIDS. This discovery allowed scientists to develop screening tests to detect antibodies to HIV in blood. This breakthrough provided the opportunity to essentially eliminate one form of HIV transmission, that is, through blood transfusions or blood products.

- o Since the approval of these screening tests, all donated blood and plasma throughout the U.S. is screened for HIV.
- o Individuals whose blood is found to be infected with HIV are referred for appropriate medical treatment and counseling.
- o The U.S. blood supply is now among the safest in the world - since 1985, only 13 new cases of HIV infection have been associated with the transfusion of blood.
- o Although the risk of transmission of HIV by transfusion has been almost eliminated, the Federal government continues to initiate activities to further reduce the remaining risk.
- o A series of consensus conferences are being held to intensify public/private sector collaboration of public health measures to reduce the spread of AIDS.

Approximately 30 percent of all AIDS cases are associated with intravenous (IV) drug use. HIV infected drug users are a source of infection not only to other IV drug users through needle sharing, but also to their sexual partners and their unborn children. Currently, most heterosexual HIV infections are indirectly related to people who are IV drug users. Over 70 percent of the HIV infection in newborns is related to the use of intravenous drugs by the mother or her sexual partner.

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- o Research aimed improving the treatment for IV drug abuse and the most effective approaches for changing this behavior has been expanded.
- o A data base is being developed on which research can be built to improve information about the extent and nature of IV drug use.
- o Additional research is being conducted on the effects of all drugs, particularly illicit drugs, on the immune and nervous systems, and how treatment for drug abuse affect AIDS disease progression.

Education and Public Information

The Reagan Administration has placed a high priority on programs to strengthen the level of understanding in the general public about AIDS, HIV infection and effective prevention measures. The education programs are geared towards increasing the prevention-specific knowledge in the general public so as to reduce misinformation, allay unfounded fears, and increase levels of support for AIDS/HIV prevention and control efforts.

- o In 1982, a toll-free national AIDS hotline was established.
- o An HIV prevention program has been established in every State.
- o An educational brochure, Understanding AIDS, was distributed in the spring of 1988 to every household in the United States.
- o OPM has established an AIDS clearinghouse to make information on AIDS and HIV available to all Federal agencies seeking assistance. The clearinghouse contains, among other things, education and training materials, results of periodic surveys regarding extent and status of AIDS policies and programs, and specific AIDS education activities.
- o The Federal government increased funding for community-based organization involved with AIDS education and prevention -- from _____ in 1982 to _____ in 1989.
- o Public policy and prevention efforts are now based on understanding the extent and distribution of HIV in the population and on the rate at which new infections occur.

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International Cooperation

The U.S. has committed itself internationally to lead the effort to control the spread of HIV infection and find a cure. Working with the World Health Organization, the Department of State has developed a three-year plan for international efforts against HIV infection. The strategy includes: enhanced coordination to control the spread of HIV and further research; support for multi- and bilateral programs to reduce the spread of infection; and strengthened research and research cooperation to control the spread of infection and treat those already infected.

- o _____ countries [All countries with which the U.S. is working] have implemented HIV public information campaigns, including education programs targeted at reducing high risk behavior.
- o Blood transfusion screening programs has been implemented in _____ countries and most are now working to ensure that their national blood supply in free from HIV infection.
- o Simple and rapid HIV diagnostics are being tested for use in developing countries.
- o Incidence and prevalence studies are being conducted to assess the scope of the world's HIV epidemic.

Antidiscrimination and Confidentiality

In response to the President's request, the Attorney General reviewed Federal anti-discrimination laws in this area and issued a legal opinion clarifying the coverage of the Rehabilitation Act. The opinion clarifies that the act protects HIV-infected individuals in Federal employment and programs and activities receiving Federal funds (i.e. schools, hospitals). It also concludes that if the infection is a direct threat to the health or safety of others or renders an individual unable to perform the duties of his or her job, an employer is not required to retain or hire that person.

- o The 22 largest Federal agencies (96 percent of the Federal workforce), have instituted AIDS antidiscrimination guideline, per the OPM Guidelines.
- o These 22 Federal agencies have established Employee Assistance Programs which have been expanded to include counseling and referral services for AIDS-related issues.
- o OPM sent a letter to each of the Fortune 1000 companies telling them of the President's 10-point action plan and enclosed a copy of "AIDS in the Federal Workplace Guidelines." Positive response has been received from a number of companies thanking OPM for the mailing and announcing plans to implement the guidelines.

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Treatment

Success in treating HIV infection will depend on the discovery and testing of new drugs and treatments. The overall goal of the Federal government in therapeutics is to aid in these discoveries by developing and testing compounds, providing an extensive clinical trials network in which to test the efficacy of these compounds, and providing the regulatory framework for getting new drugs into the marketplace rapidly. Both the Federal government and the private sector are very active in preclinical drug development, clinical trials testing, and regulatory approval processes.

- o A comprehensive program has been established which fully supports all phases of drug discovery.
- o In 1987, Azidothymidine (AZT) was approved in record time and prolongs the life of some HIV infected individuals.
- o A massive drug screening program has been established to evaluate potential therapies from all possible sources.
- o The Federal government has made a cooperative arrangement with other research institutions and pharmaceutical companies to explore the range of drugs to treat infections that occur in or kill AIDS patients, such as Pneumocystis Carinii (PCP).
- o A large clinical trials network has been established at medical centers across the country to evaluate various drugs and treatment regimens in populations of HIV-infected individuals.
- o The Federal government, in collaboration with the pharmaceutical industry, is conducting extensive clinical trials to judge therapies efficacy in humans.
- o The FDA, in cooperation with the Vice President and the Presidential Task Force on Regulatory Relief, has approved a process which will speed approval of therapies to treat life-threatening illnesses such as AIDS.
- o The Federal government is expanding and improving treatment for IV drug users. Demonstration projects have been initiated to help identify and understand the behavior of IV drug abusers so that more effective treatment and prevention programs can be designed.
- o The methadone regulations and practices are being revised so that its use can be expanded to cause a reduction in IV use of opiates.

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- o The Federal government is pursuing a closer linkage between drug abuse treatment services and the primary health care services -- particularly because people with AIDS require special health and social services.
- o Outreach programs have been expanded to reach those drug users who are not currently in treatment.

Resources

State and local governments and our nation's charitable institutions have spent generously to fight the HIV epidemic. Since 1982, the Reagan Administration has committed more than \$5.4 billion to various measure to protect public health against HIV -- biomedical research, drug trials, prevention, education, treatment, financial assistance programs.

- o A consolidated office building is being constructed on the NIH campus to remove the administrative obstacles and to provide additional laboratory and office space for AID/HIV research.
- o Additional FTEs for HHS have been approve to assure that adequate human resources are available for HIV efforts.
- o [OPM is addressing the issue of recruitment and retention of science personnel.]

[insert chart]

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Bush Expected to Take Early Action on AIDS

By MARLENE CIMONS,
Times Staff Writer

WASHINGTON—Recently, about a dozen activists who have been working to achieve what they consider a compassionate federal AIDS policy met for more than an hour with officials from President-elect George Bush's transition team. They emerged extremely pleased.

"The Bush people were informed, they were engaged in this issue and they understood that it would be a high priority," said Jeff Levi, executive director of the National Gay and Lesbian Task Force, who participated in the meeting. "That moves us light years ahead of the current Administration."

Although AIDS was barely mentioned during the presidential campaign, it promises to become one of the most critical health issues facing the new Administration.

Crucial Decisions

With a total caseload expected to approach 365,000 before Bush finishes his first term, and a national health care system already straining under the weight of the burgeoning epidemic, the President-elect will almost certainly be forced to make some crucial health policy decisions early in his tenure.

AIDS activists expect Bush to be more aggressive and sympathetic in formulating an AIDS public policy than his predecessor, President Reagan.

"George Bush is an extremely fair guy," said Dr. Burton Lee, who served on the presidential AIDS commission and who is a Bush personal friend. "There is not going to be a hiding from this problem, or a putting it under the table because of the people affected by the disease."

A Bush transition team official
Please see AIDS, Page 14

Continued from Page 1

said that the Bush staff is "taking great pains to become as educated as we can on AIDS. Obviously, it's a priority—an issue we should be committed to. We are not yet in policy development. But the AIDS group was one of the first we had in the door for a meeting—that is some evidence of commitment and concern."

To be sure, much will depend on key appointments still to be made—most important among them that of secretary of health and human services. Nevertheless, there have already been some early signs that the Bush Administration will bring some long-sought-after changes in AIDS policy. Some months ago, at a private dinner, Bush met with Dr. Anthony Fauci, the director of AIDS programs for the National Institutes of Health,

such an important statement to me, personally, that I had not heard from anyone in the executive branch, that I was overwhelmed by it. I knew then there was hope."

Congressional sources involved in AIDS legislation agreed.

"Mr. Bush isn't going to push for national health insurance to pay for AIDS, but he's also not going to be silent when people talk about discrimination," one of them said. "That's a crucial change. He's either going to be someplace in the middle—or he may be as surprising as Adm. Watkins and Surgeon General Koop turned out to be. They came to this issue probably as conservative people—and came away from it changed."

Among the new President's first tests will be whether he pushes Congress to enact the anti-discrimination and confidentiality legisla-

'Bush isn't going to push for national health insurance to pay for AIDS, but he's also not going to be silent when people talk about discrimination.'

—congressional aide

and Surgeon General C. Everett Koop, who both briefed him extensively on AIDS. It was an encounter that reportedly so impressed Bush, that many believe it was one reason Bush called Fauci one of his "heroes" during the second presidential election campaign debate.

More importantly, the first real indication that Bush had broken from Reagan on AIDS came last summer after the release of the presidential commission report. The recommendations essentially were disregarded by the Reagan White House—even though the panel had been appointed and charged by the Reagan Administration to develop a national strategy on AIDS. But Bush endorsed the report immediately—specifically its centerpiece proposals, that strong anti-discrimination and confidentiality legislation be enacted to protect the ill and the infected.

'Right Thing'

"I called him up in Maine a few days later and I said: 'Mr. Vice President, I'm calling you to tell you what a courageous act you just performed. I wasn't anticipating that,'" said Adm. James D. Watkins, chairman of the commission, also a friend of the President-elect. "I said: 'You're going to lose a lot of right-wing votes because of this.' He said: 'Jim, I know it. But it was the right thing to do.'"

"When he said that, I broke down," Watkins continued. "It was

tion that many people feel is crucial to curbing the epidemic. The major bill in question would expand to the private sector an anti-discrimination law that protects the handicapped—including those with infectious diseases. The existing law affects only institutions that receive federal funds.

Additional legislation has been proposed to protect the ill and infected against violations of confidentiality.

"I cannot think of anything more important for the President to do early in his Administration than to work with the Congress to ensure early passage," Watkins said. "He can say: 'This is my first contribution to a kinder and gentler society.' This would be my fondest wish."

The public health community has been unified in calling for such protections, saying that they are essential to containing the epidemic. Most public health professionals believe that individuals will not voluntarily be tested for AIDS infection if they believe they will suffer social or economic repercussions as a result.

But the Reagan Administration opposed such measures and congressional attempts at legislation failed during the last session. Some conservative members viewed the bills as having a "hidden" gay rights agenda, while others felt uneasy supporting them without some endorsement from the President.

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"I'm optimistic that the Bush Administration will help us over some of the legislative barriers we've had in the past," said Rep. Henry A. Waxman (D-Los Angeles), chairman of the House Energy and Commerce subcommittee on health, and author of major AIDS legislation in the House. "There are lots of members of Congress who want to do the right thing but just don't want to be out on a limb by themselves."

He added: "With a President supporting the legislation, it will be clear that these policies are both needed and responsible. Strong leadership will make such legislation likely. Presidential support will be enough for moderates in both parties to rally behind these proposals."

Dr. Lee has proposed that Bush appoint someone to serve in the White House as "a point man" for AIDS.

"It would give some reassurance to the entire AIDS community that there was somebody there communicating with the executive branch," Lee said. "During the Reagan years, people were faulting the White House for a lack of leadership on this. If there was somebody in there, a liaison, an awful lot of criticism and weight would be taken off the President in his handling of the problem. There would be somebody for the critics to go to."

Another potential task facing Bush, which will also offer some clues to his approach to AIDS policy, will be how he handles amendments to the fiscal 1990 budget as they affect AIDS activities.

One drug has been approved thus far for AIDS therapy, but there is still no cure and no vaccine, although efforts on these fronts are accelerating. Further, there is the need for increased federally funded AIDS education programs, all of which require more money than has been appropriated thus far.

The Department of Health and Human Services requested \$1.9 billion for AIDS activities, but the Office of Management and Budget pared its figure back to \$1.6 billion, which the department felt was inadequate.

"The test of George Bush's commitment on this issue will be whether he will give the public health officials the resources they feel are necessary," said Levi, the gay and lesbian task force director.

Waxman agreed. "I hope that the Bush Administration will be more realistic in its budget request than we saw from the Reagan Administration," he said. "If not, Congress will have to come in as we've done for the last seven years and put in more money."

Moreover, Levi said, regardless of the "positive feelings we are

getting about [Bush] people working specifically on health issues, how the deficit is handled is going to have an impact ultimately on the resources available for health programs."

In other areas affected by AIDS, Bush will also be forced to confront the growing burden on the nation's health care delivery system, already overtaxed in areas most heavily afflicted by AIDS.

In a document given Bush tran-

sition people, a coalition of groups active in AIDS work wrote: "Reforms in health care financing and assistance to those systems are critical. We must improve access to care, not only for the growing numbers of men, women and children with . . . disease, but also for all who are catastrophically ill or inadequately served by existing public and private health care delivery systems."

Levi added: "There has to be a recognition that there are public hospital systems in the country that are collapsing under the weight of AIDS and they are going to have to address that, particularly in New York and California."

Although specific AIDS policy initiatives are still forthcoming, observers expect Bush to align himself with the public health community and to try to distance himself from the kind of political rhetoric—and arguments over values and morality—that has marked the AIDS debate in recent years.

"AIDS will become a lot less inflammatory during the Bush Administration," one congressional source predicted. However, he added: "But the problems are going to get a lot harder."

INFORMATION

DRAFT 12/14/88

MEMORANDUM FOR THE PRESIDENT

FROM: DONALD IAN MACDONALD, M.D.

SUBJECT: Progress Report: 10-Point Action Plan to Fight the Human Immunodeficiency Virus Epidemic

In June you asked me to review the report of your Commission on the Human Immunodeficiency Virus Epidemic (HIV) and make recommendations for its implementation. In this third and final review, I am pleased to report that much progress has been made. A number of important issues, however, are still unresolved, and I herewith make additional recommendations to you for transmission to the next administration.

Accomplishments and Status Since June 1988 The majority (64 percent) of the 354 Commission recommendations that fall within the Federal purview have already been completed or will be implemented with FY 1989 funds. Additionally, Federal leadership has been provided to stimulate implementation of many of the 243 recommendations that fall largely outside Federal jurisdiction.

Details of the Federal response to your 10-Point Action Plan are at Tab A. Highlights:

- o FDA has implemented a process which will speed approval of therapies to treat life-threatening illness such as AIDS.
- o The Public Health Service has set in place a plan that includes many of the more specific recommendations of your Commission.
- o Legislation you signed in November put in place the largest increase for ~~drug~~ drug abuse treatment ~~in recent years~~. The Commission identified this effort as critical to combatting the HIV epidemic.
- o The Department of State has begun implementation of a three-year plan to enhance international efforts to control the spread of HIV infection.
- o HHS has taken a number of steps to promote private sector participation in research and development of HIV-related products.

(2)

Unresolved Issues and Solutions At this point, several issues remain unresolved. In brief:

- o Management of HIV Issues The Commission suggested that larger organizational considerations may be necessary to alleviate the Government's perceived inability to respond to health emergencies in other than a "business as usual" manner. A number of the Commission's specific recommendations directed at management, resource, and coordination issues may be answered with organizational change. A proposal on this issue is included at Tab B. I recommend that further action on this issue be left to the next Administration.
- o Confidentiality The perception that protection of privacy of public health information is inadequate may be inhibiting the ability of States to move forward with implementing traditional public health prevention measures. Options, which include Federal confidentiality legislation, are discussed at Tab B. As this issue needs further study, I believe it is best left for consideration by the next Administration.
- o Discrimination The fear of discrimination against those who carry the AIDS virus is still of concern. Although the reach of the Federal Rehabilitation Act is broad, major areas remain uncovered. States have been moving to shore up their protections, but there are significant gaps. Options for Federal action are presented at Tab B.
- o Nursing Shortage The shortage of nurses which is affecting the ability of our medical system to care for sick people in general is having an especially acute effect on the care of AIDS patients. On December 12, a Commission, which was appointed by Secretary Bowen to study the nursing shortage, made its recommendations to him. He has set in motion a plan for implementing those recommendations, which in many instances overlap those of your Commission. I am recommending that we defer to HHS on resolution of this issue.
- o Financing of Health Care HHS has begun the one year study of the current system of health care financing, but the report will not be available until September 1989. I recommend that we leave resolution of this issue to HHS but that the next Administration continue to monitor this study.
- o National Commission on AIDS The Health Omnibus Programs Extension of 1988 (P.L. 100-607) establishes a two-year National Commission to promote the development of a consensus on AIDS policy and make recommendations regarding a consistent policy. Among its functions, the new Commission is to monitor the implementation of the recommendations of your Commission, modifying those recommendations as the Commission considers appropriate. I recommend that your two appointees to this Commission named as soon as possible.

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Tab 17

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DRAFT 12/14/88

THE PRESIDENT'S 10-POINT ACTION PLAN
AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Progress Report

December , 1988

3. The President emphasizes his concern about drug abuse and its relation to HIV infection and continues his call for bipartisan efforts to enact his anti-drug proposals.

Status

Drug and HIV/AIDS Legislation Many of your recent proposals concerning drug abuse and its relation to HIV infection were implemented with P.L. 100-690, the Omnibus Drug Initiatives Act. Included in P.L. 100-690 was \$500 million for expanding iv drug abuse treatment.

- o Prevention and Treatment of Intravenous Drug Abuse ADAMHA is implementing a provision of P.L. 100-690 that authorizes State use of funds for development, implementation and operation of IV drug abuse treatment programs, training of drug abuse counselors, and for outreach activities to bring persons into treatment.
- o Expansion of Demonstration Programs ADAMHA will be funding and evaluating three year demonstration projects to: (1) determine the feasibility and long-term efficacy of programs providing drug abuse treatment and vocational training in exchange for public service; (2) conducting out-reach activities to IV drug abusers to prevent transmission of HIV and (3) providing drug abuse treatment services to pregnant women, postpartum women, and their infants.

ADAMHA will be working with each State to establish demonstration projects to enable them to provide effective treatment, and referrals for treatment, to individuals who abuse drugs. The projects are to treat adolescents, minorities, pregnant women, female addicts and their children, residents of public housing projects, and centralized local referral units.

- o Banning of Butyl Nitrite P.L. 100-690 bans the use of Butyl Nitrate for inhaling or to produce a euphoric or physical effects.

MEMORANDUM FOR WHITE HOUSE CHIEF OF STAFF

FROM: DONALD IAN MACDONALD, M.D.

SUBJECT: Press coverage for December Update on
President's Ten point action plan for
combatting the AIDS/HIV epidemic

I will soon be submitting to the President the final update on his ten point action plan for combatting the AIDS/HIV epidemic. This report summarizes progress made by Federal agencies in responding to his plan as well as to the 597 recommendations of the Presidential Commission on the HIV Epidemic.

I recommend that highlights of my report to the President be released to the press to demonstrate that he has taken his Commission's recommendations seriously and that much work is accomplished or ongoing. I further recommend that the President devote one of his Saturday radio addresses to the overall issue of responding to HIV infection.

The address should focus on the enormous progress that has been made during this Administration in combatting the AIDS/HIV epidemic. The fact is that more scientific and public health advances have been made in a shorter time than for any other complex new disease in the history of medicine. AIDS was first recognized in 1981. By 1983, the Public Health Service had identified the major routes of transmission. By 1984, scientists had identified human immunodeficiency virus (HIV) as the cause of AIDS. A year later blood tests were licensed which allowed blood to be screened, greatly adding to the ability to protect the blood supply. By 1986, through Federal funding, every State has established an HIV prevention program. In 1987, a significant AIDS drug (AZT) was approved in record time. Over the past two years, the Federal government has continued to make enormous scientific strides as well as conducting a major AIDS information campaign which included the mailing of an educational booklet on AIDS to every household in the United States.

The radio address would provide an excellent opportunity for the President to summarize the progress in combatting this terrible epidemic as well reiterate the points he has made previously about compassion for individuals with HIV infection.

THE WHITE HOUSE
Office of the Press Secretary
(Los Angeles, California)

For Immediate Release

October 31, 1988

NATIONAL AIDS AWARENESS AND PREVENTION MONTH, 1988

- - - - -

BY THE PRESIDENT OF THE UNITED STATES OF AMERICA

A PROCLAMATION

Nearly 75,000 Americans have been diagnosed as having the fatal disease AIDS, and more than 41,000 have already died from it. The Public Health Service estimates that an additional one to one-and-a-half million Americans have been infected by the Human Immunodeficiency Virus (HIV), which causes AIDS. Most of the infected individuals now show no symptoms, but it is likely that over the next few years they will develop AIDS or AIDS-related illnesses.

Extensive efforts by Government and the private sector are underway in the fight against AIDS and HIV infection, and great strides have been made. In the 7 years since the first reports of AIDS cases, the virus has been identified; the ways in which it is spread have been pinpointed; an AIDS antibody screening test has been developed and is being used to protect blood supplies; the first steps toward development of a protective vaccine have been taken; and promising drugs to fight the HIV and its manifestations are being synthesized and tested.

Nevertheless, today we have neither a cure for AIDS nor a vaccine against HIV infection. For this reason, it is vital that every individual know how HIV infection is spread -- and that we understand how to prevent the spread. The virus is most commonly spread through sexual contact with an infected person, especially through homosexual practices; through intravenous drug use with contaminated needles; and through other transmissions of infected blood. The virus is not commonly spread through ordinary, everyday, nonsexual contact.

To prevent the further spread of AIDS and HIV infection, we must heed lessons taught by medicine and morality alike. The Surgeon General has reminded all of us that the best way to prevent AIDS and the HIV is to abstain from sexual activity until adulthood and then to restrict sex to a faithful, monogamous relationship. This wise counsel, along with saying "no" to illegal drugs, can prevent the spread of most AIDS and HIV cases. Parents should explain to their children the goodness and blessings of chastity before marriage, of solid family life, and of a drug-free way of life.

One of America's greatest strengths has always been our ability to work together in times of adversity. We must rely on this strength to sustain us as we work to prevent the spread of AIDS and the HIV and as we care for those already afflicted.

more

(OVER)

The Congress, by Senate Joint Resolution 192, has designated October 1988 as "National AIDS Awareness and Prevention Month" and authorized and requested the President to issue a proclamation in observance of this occasion.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim October 1988 as National AIDS Awareness and Prevention Month, and I call upon Americans to observe this occasion with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of October, in the year of our Lord nineteen hundred and eighty-eight, and of the Independence of the United States of America the two hundred and thirteenth.

RONALD REAGAN

#

FACSIMILE TRANSMISSION REQUEST

ADDRESSEE: (NAME, ORGANIZATION,
CITY, STATE & PHONE#)

Sue Daoulas
Drug Abuse Policy Office
White House
Room 220
Washington, D.C. 20500
456-6554

FROM: (NAME, ORGANIZATION & PHONE #)

Lorraine Fishback
PHS/OASH
Hubert Humphrey Building, 740G

245-6135

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Status of the Response to the Presidential Commission on the HIV
Epidemic and the President's Ten Point Action Plan

BACKGROUND: THE HIV EPIDEMIC

Since 1981, when the first cases of AIDS were reported, the size and scope of the HIV epidemic has grown rapidly, and the epidemic has had a major impact on our society.

As of December 19, 1988, 80,996 cases of AIDS have been reported to the Centers for Disease Control, and over 45,000 people have died. Because of the long latent period between infection and AIDS, the true size of the problem is more appropriately evaluated in terms of the number of persons with HIV infection. PHS currently estimates that 1 to 1.5 million people in the United States are infected with HIV.

The Public Health Service has projected that the cumulative number of reported AIDS cases in the United States will total 365,000 by the end of 1992. In that year alone, more than 80,000 new cases are expected to be reported and 65,000 persons expected to die. An estimated 172,000 persons with AIDS are expected to be alive in 1992.

Major advances in controlling HIV infection have been made:

- o The human immunodeficiency virus (HIV) has been identified as the cause of AIDS.
- o HIV antibody tests to screen blood have been licensed and adopted by all blood banks.
- o Federal funding has assisted every State in establishing an AIDS prevention program.
- o Drug therapies, azidothymidine (AZT) and interferon, have been approved.
- o HHS has mailed the brochure Understanding AIDS to every household in the United States as part of a major public information campaign.

Total Federal spending for HIV-related activities has grown from \$8 million in 1982 to \$1.5 billion in 1988. In Fiscal Year 1989, the Federal government has budgeted \$2.12 billion for HIV-related activities of which \$1.94 billion is for the Department of Health and Human Services.

THE PRESIDENTIAL COMMISSION ON THE HIV EPIDEMIC

Recognizing the complexity and impact of the HIV epidemic, in June 1987, President Reagan created by Executive Order a Commission to advise him on the public health issues of the HIV epidemic, including medical, legal, ethical, social and economic issues. The Commission was tasked to recommend measures that Federal, state, and local officials could take to protect the public from contracting HIV infection, assist in finding a cure for AIDS, and care for those who already have the disease. The President requested a final report within a year.

Admiral James D. Watkins chaired the Commission for most of the year. During that time, the Commission held a series of about 40 hearings and heard testimony from more than 600 witnesses. On June 27, 1988, Admiral Watkins submitted the Commission's report to the President. It contained 597 recommendations which covered all aspects of the epidemic and in many cases went beyond to identify the problems society faces--i.e., illegal drugs, inadequacies in the health care system--which are exacerbated by the AIDS epidemic.

The Commission recommended focusing efforts on HIV-infection rather than AIDS, the end stage of the disease. They emphasized expansion of testing and counseling and recommended Federal confidentiality legislation to protect the privacy of those tested and Federal legislation to protect HIV-infected individuals from discrimination. In general, the Commission's report was well received by the public and the health community.

DEVELOPMENT OF THE PRESIDENT'S 10 POINT ACTION PLAN

After receiving his Commission's report, the President asked Donald Ian Macdonald, M.D., Special Assistant and Director of the Drug Abuse Policy Office, to review the Commission's recommendations and present him with a "course of action that takes us forward" against HIV infection.

As a first step, copies of the Commission's report were sent to all Federal departments and agencies. Each was asked to review the report and identify those recommendations that fell within their purview and to submit a status report. More than 50 individuals representing private sector and voluntary organizations with an interest in AIDS and HIV infection were consulted and asked to comment on recommendations that affected their organization.

This review showed that 364 of the recommendations fell within the Federal purview for implementation. In August, when the review was first done, 44 percent of these recommendations were either completed, under implementation or planned for

1. "AIDS: Frontline Health Care" is a conference for health care workers jointly sponsored by the Department of Labor, the Department of Health and Human Services, and the National AIDS Network. It will be held in Washington, D.C., January 8, 9, and 10th.
2. A planning workshop for a Gubernatorial Consensus Conference on Federal-state strategies to address topics such as neighborhood resistance to drug abuse treatment facilities, alternative drug abuse service facilities and mainstreaming of drug abuse care with primary care is scheduled during the National Governor's Association winter meeting in February 1989.
3. The Department of Health and Human Services and the Department of Justice are planning a meeting (tentatively scheduled for May) that will address restrictive measures and criminal statutes directed to HIV-infected persons who knowingly persist in maintaining behaviors that transmit their infection and other legal issues.
4. The Department of Health and Human Services is planning a consensus conference on reporting of HIV infection. It is tentatively scheduled for May.

Community-Based Education Programs: In response to the President's 10-point action plan and in recognition of the importance of racial/ethnic minority community-based educational programs, funds for community based programs will double in FY 1989. This will include the direct funding of 15 to 20 community-based organizations in areas with the highest prevalence of AIDS.

Action Plan Point Two

Implement actions within 45 days that address: (a) prompt notification of transfusion recipients who are at increased risk of HIV infection; (b) steps to improve HIV laboratory quality and HIV screening tests; and, (c) ways to encourage the use of autologous transfusions in appropriate circumstances.

Status

In September, HHS submitted a plan in response to this item. It notified the President that HHS will take the following actions to address the three issues he raised related to safety of the blood supply:

Notification of transfusion recipients: HHS's intensified efforts for the prompt notification of transfusion recipients at increased risk of HIV infection include strengthening existing

implementation in FY 1989. The rest of the 233 recommendations fell primarily to the private sector for implementation. There was overlap in some areas where the Federal sector shares responsibility because it provides funding and technical assistance to States.

With this analysis in hand, and in consultation with members of Executive Branch agencies; the Office of Management and Budget, White House staff, and a cross-section of private groups and individuals, including the National Academy of Sciences which recently released an AIDS report with conclusions similar to those of the Commission, the 10 point action plan was developed. It attempted to identify those major issues raised by the Commission where further Federal action was needed.

On August 5, 1988, the 10-point action plan was announced to the public and directives were sent to heads of departments and agencies requesting they undertake a number of activities. The President requested follow-up reports in September and again in December on the both the status of the Commission's original 597 recommendations and on the actions taken in response to his 10 point plan.

10-POINT ACTION PLAN ITEMS AND THEIR STATUS

The ten action plan items and their status as of December:

Action Plan Point One

Develop a series of consensus conferences with representatives from all levels of government and the private sector to intensify public health measures to reduce the spread of HIV infection. Increase the number of community-based education programs directed to those at increased risk of HIV infection.

Status

Consensus Conferences HHS is sponsoring a series of 10 consensus conferences to intensify public health measures to reduce the spread of HIV infection. The first of this series, "The U.S. Health Summit on HIV Infection", was held in Washington, D.C., November 28-29. Key state and local public health officials discussed issues such as outreach programs to get IV drug users in treatment, management of public health agencies, testing issues such as counseling, reporting and partner notification, and health care worker safety and education. A series of 5 regional mini-Summits will be held between January and May in New York City, Chicago, San Francisco, Dallas, and Atlanta.

Four other meetings will address specific issues the President raised in his directive to HHS

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"look-back" programs by: a) promulgating regulations to make look back mandatory rather than voluntary when a donor is discovered to be seropositive; b) promulgating requirements to ensure that the blood industry and hospitals must notify either each recipient or the physician of each recipient that potentially infectious blood has been administered, ultimately ensuring that each recipient is offered appropriate testing and counseling; and c) for those individuals who live in high AIDS incidence areas and received multiple blood transfusion between 1977 and 1985 (before the HIV antibody screening test was available), HHS will intensify its efforts to encourage them to seek counseling and testing.

Improving laboratory quality: HHS has begun an intensified strategy to improve the accuracy of laboratory tests for HIV antibody that will include (a) proficiency testing requirements and development of standards for laboratory quality, (b) inspections of blood bank facilities annually rather than every other year, (c) enhanced training of FDA investigators who inspect blood banks, and (d) training programs for blood establishment staff.

Encouraging the Use of Self-Donated Blood Before Surgery: HHS has begun to implement a public education campaign that will include a public service message campaign for radio, television and print media as well as informational brochures. HHS will also work with health professionals to encourage the appropriate use of autologous transfusions.

Action Plan Point Three

The President emphasizes his concern about drug abuse and its relation to HIV infection and continues his call for bipartisan efforts to enact his anti-drug proposals.

Status

The Omnibus Drug Act of 1988 contained the single largest expansion of funding for drug abuse treatment and authorized the following activities which are being implemented:

- o Prevention and Treatment of Intravenous (IV) Drug Abuse
Funds will go to states for development, implementation, and operation of IV drug abuse treatment programs, training of drug abuse counselors, and outreach activities to bring persons into treatment.
- o Expansion of Demonstration Programs Three-year demonstration projects will be funded to: (1) study efficacy of providing drug treatment and vocational training in exchange for public service; (2) conduct outreach activities to IV drug users to prevent the spread of HIV, and (3)

provide drug treatment services to pregnant and postpartum women, and their infants.

Action Plan Point Four

Begins action in and out of Government that will accelerate development, approval and distribution of vaccines and drugs.

Status

HHS has taken several actions that address this point:

- o Expediting the Drug Approval Process: Working at the direction of Vice President Bush, head of the Presidential Task Force on Regulatory Relief, the Food and Drug Administration has implemented a proposal that will expedite approvals for those therapies intended to treat life-threatening illnesses such as AIDS. The proposal compresses the total premarket drug development time by having FDA work with the drug sponsor early in the course of the approval process to design and conduct controlled clinical trials that are capable of providing definitive data on the drug's safety and effectiveness. Other key elements of the proposal are: a) a means to provide patients with experimental drugs between the completion of promising clinical trials and the point of marketing approval; b) risk-benefit considerations appropriate for drugs intended to treat life-threatening illnesses; and c) post-marketing studies to gather additional information about the drug's risks and benefits.
- o Incentives for Drug Development The Public Health Service's Technology Management Advisory Board developed a report that surveyed existing Federal incentives to the private sector for developing HIV-related products. Among its recommendations to strengthen these incentives is a legislative proposal to assure that the important research and development incentives under the Orphan Drug Act (i.e. market exclusivity and R&D tax credits) will be available after the number of AIDS patients exceeds the 200,000 ceiling applied by the act. In order to assure that new products will be affordable to AIDS patients, PHS has recommended negotiation of equitable pricing assurances in cooperative R&D agreements when exclusive licenses are granted to industrial partners for HIV-related products.
- o Liability Issues In an analysis of the issue, HHS has found no indication that promising research on an AIDS vaccine has been delayed or foregone in the public or private sector because of fears about liability. HHS has, however, identified a series of options for continued attention to possible liability problems.

Action Plan Point 5

Reaffirms his commitment to provide adequate resources (dollars, staff, office and laboratory space) to combat the HIV epidemic, and directs the Office of Management and Budget to make certain there are no impediments to efficient use of these resources.

Status

Space Needs In September, at the President's request, Congress granted authority to the National Institutes of Health to initiate construction of a consolidated office building on NIH's Bethesda, Maryland, campus. The Commission recommended construction of such a building to remove "one of the most serious research administrative obstacles . . . encountered." Also, the Centers for Disease Control's construction to provide additional laboratory and office space is planned for FY 1989.

Resource Needs Because of the urgent need, additional FTEs for HHS were approved for FY 1989. The FY 1990 budget includes \$1.6 billion for Public Health Service programs to combat the HIV epidemic. This is a 24 percent increase over the FY 1989 appropriation. For 1990, OMB recommended an HHS allocation of 355 more FTEs than HHS proposed to allocate to PHS for HIV activities. These FTEs are to be reprogrammed from other PHS programs that OMB considers either overstaffed or plans to phaseout.

Science Personnel The recruitment and retention of science personnel remains a problem for HHS. Several sources, including the Commission on Executive, Legislative and Judicial Salaries, have recommended salary increases to make the Federal government more competitive.

Action Plan Point Six

Asks Congress to accelerate enactment of his FY 1989 HIV appropriations request and adopt the FY 1990 budget request for HIV activities as early as possible after the budget is submitted. The President will seek a special HIV emergency fund for unanticipated problems and opportunities in the FY 1990 budget request.

Status

On August 5, the President sent a letter to the Congress announcing his 10-point action plan to advance the national and international response to the public health threat caused by HIV. He asked Congress to take the important step of enacting the FY 1989 appropriations for HIV activities as expeditiously as possible and to adopt the FY 1990 budget request regarding HIV measures as soon as possible after the budget is submitted.

Much of the FY 1989 HIV appropriation request was contained in the Labor, Health and Human Services and Education Bill which the President signed on September 20. It included a \$1.29 billion appropriation to combat HIV infection, which was approximately the amount requested in the President's budget for the Public Health Service.

Status of FY 1990 Request: The President's budget will be sent to Congress in January. The chart below lists the government wide spending for HIV activities, including the FY 1990 request.

(OMB will be supplying an updated chart next week)

Action Plan Point Seven

The President instructs the Secretary of HHS to evaluate the current system of health care financing; and directs HHS to conduct specific studies of ways to promote out-of-hospital care; encourage states to establish insurance risk pools for medically uninsurable persons; and increase the public health response to HIV infected infants, children, adolescents and low income disabled individuals.

Status

Evaluation of Health Care Financing HHS begun a one-year evaluation of the health care system. The evaluation will concentrate on financing and insurance issues. In conducting the evaluation, HHS will use a Health Care Financing Administration (HCFA) team as well as an outside contract for needed expert information and research support. The study is to be completed by September 1989.

Alternatives to Acute Care HHS is encouraging states and other organizations to study the efficacy of care and to provide more cost-effective care through:

- o stimulating states to apply for the home and community-based services waiver program;
- o soliciting research and demonstration projects to study the effectiveness of out-of-hospital and case-managed care;
- o evaluating patterns of utilization and costs in AIDS service demonstration grant projects (due late summer 1989)
- o evaluating regional AIDS education and training centers (due late summer 1989).

Risk Pools In January, the Secretary of HHS will send an advisory letter to State Governors and legislative leaders to encourage replication of risk pools for the medically uninsurable in States which now lack such programs. The letter will suggest sources of technical information and assistance which interested States may wish to use.

Infants, Children and Adolescents The HHS Secretary's Task Force on Pediatric HIV Infection Report recommends specific studies regarding infants, children, and adolescents. HHS will be implementing many of the report's recommendations within the next year.

Action Plan Point Eight

Develop a multi-focused international initiative to combat HIV, particularly in less-developed countries; increase U.S. commitment to international technical assistance; and develop three-year plan for international efforts against HIV infection.

Status

In December, the Department of State submitted a three year plan to accomplish the following goals:

- o The 70 countries with which the U.S. is working will have implemented HIV public information campaigns;
- o All of these countries will have implemented, and most will have evaluated, educational programs aimed at the reduction of high risk behavior;
- o All of these countries will have implemented blood transfusion screening programs for HIV;
- o New HIV diagnostics appropriate for use in developing countries will have been field tested and will be in common use;
- o Vaccine field trial sites will have been established;
- o Better estimates of the number of HIV infected individuals in developing countries will have been completed.

Implementation of the plan assumes coordination between State, HHS, and the World Health Organization's Global Programme on AIDS (GPA). In FY 1989, Congress appropriated \$25.5 million for GPA.

Action Plan Point Nine

Requires the Public Health Service to update the 1986 Public Health Service plan for combatting HIV infection.

Status

PHS has published its Report of the second Public Health Service AIDS Prevention and Control Conference. It is based upon a meeting convened by the Assistant Secretary for Health in early June 1988 in Charlottesville, Virginia, to develop an updated plan for combatting HIV infection. Experts in various fields, including basic research scientists, clinicians, epidemiologist, public health policy makers, pharmaceutical manufacturers, health care providers, minorities and consumers provided advice and guidance to the Federal scientists who attended the conference.

The Charlottesville report is intended as a guide for the Public

Health Service to manage its \$1.29 billion HIV program. The issues, goals and objectives are divided among nine areas:

- o epidemiology and surveillance
- o clinical manifestations and pathogenesis
- o prevention, information, education, and behavior change
- o patient care/health care needs
- o blood and blood products
- o intravenous drug abuse
- o neuroscience and behavior
- o therapeutics
- o vaccines

Although the Charlottesville Report is not a response to the Report of the Presidential Commission on the HIV Epidemic, it was developed within the same time frame and after a year of close interaction of PHS staff with the Commissioners. Consequently, many of the elements in the Charlottesville Report address specific recommendations of the Presidential Commission. PHS will begin a quarterly reporting of progress in carrying out the plan's goals in January. Each goal will be cross referenced to similar recommendations in the Presidential Commission Report.

Action Plan Point Ten

Calls on all sectors of society to respond equitably and compassionately to those with HIV infection and to their families. In addition to directing all Federal agencies to adopt a policy based on OPM guidelines, the President requests that American businesses, unions and schools examine and consider adopting education and personnel policies based on the OPM and Centers for Disease Control guidelines.

Status

Antidiscrimination In October, the Attorney General issued a legal opinion clarifying the coverage of the Rehabilitation Act. The opinion clarifies that the act protects HIV-infected individuals in Federal employment and programs and activities receiving Federal funds (i.e. schools, hospitals). It also concludes that if the infection is a direct threat to the health or safety of others or renders an individual unable to perform the duties of his or her job, an employer is not required to retain or hire that person.

Federal Agencies Implement OPM Guidelines The Office of Personnel Management's (OPM) Agency of Compliance and Evaluation staff conducts periodic telephone surveys of the largest 22 Federal agencies (representing 96 percent of the work force):

- o All 22 agencies are putting AIDS policy guidelines in place. Thirteen agencies have issued AIDS policies. The nine others are presently drafting policies/guidelines to be issued by the end of this year or early in 1989.
- o Twenty-one agencies have initiated formal training/education programs on AIDS-related issues for employees, supervisors and managers. The one remaining agency is currently developing a program and plans to have it in place by December.
- o All 22 agencies now offer counseling and referral services for AIDS-related issues through their Employee Assistance Programs or medical services facilities.

OPM AIDS Clearinghouse OPM has established a clearinghouse of specific policy statements, educational materials, and training manuals developed by Federal agencies for their AIDS in the workplace programs.

Conference Sponsored: In September, OPM sponsored a very successful conference on "AIDS in the Workplace". Presenters discussed issues concerning implementation of an effective AIDS education program. More than 120 Federal managers and personnel specialists attended the conference.

STATUS OF THE COMMISSION'S 597 RECOMMENDATIONS

Federal Responsibility

<u>August 4</u>		<u>September 18</u>		<u>December 9</u>		<u>Status</u>
126	34.8%	137	38.4%	168	47.0%	Completed/Ongoing
32	8.9%	44	12.3%	61	17.2%	Planned: FY89
108	29.9%	81	22.7%	72	20.3%	Under Consideration: FY90
36	10.0%	40	11.2%	53	14.9%	Disagree
62	17.1%	55	15.4%	0		Other
364	61.0%	357	59.8%	354	59.3%	Total Federal

Non-Federal Responsibility

<u>August 4</u>	<u>September 18</u>	<u>December 9</u>	<u>Status</u>
210 89.4%	216 90.0%	219 90.1%	Agree
3 1.3%	3 1.3%	3 1.2%	Disagree
9 3.8%	9 3.8%	9 3.7%	Neutral
<u>11 4.7%</u>	<u>12 5.0%</u>	<u>12 5.0%</u>	Other
233 39.0%	240 40.2%	243 40.7%	Total Non-Federal
597	597	597	TOTAL

The Health Omnibus Programs Extension of 1988 (P.L. 100-607) establishes a two-year National Commission on AIDS which is intended to be a successor to the Presidential Commission on the HIV Epidemic. Its purpose is to promote the development of a consensus on AIDS policy and make recommendations regarding a consistent policy. Among its functions, the new Commission is to monitor the implementation of the recommendations of the Watkin's Commission, modifying those recommendations as the Commission considers appropriate. Five members are to be appointed by the President. Three of those members are specified by the legislation as the Secretary of Health and Human Services, the Secretary of Defense, and the Administrator of Veterans' Affairs. Five members are to be appointed by the Speaker of the House and Five others by the President pro tempore of the Senate.

UNRESOLVED ISSUESOrganizational Issues Raised by the Commission

Issue In a number of places in the report and especially in Chapter 12, the Commission expressed frustration over the Federal Government's seeming inability to respond to health emergencies in other than a "business as usual" manner. In their critique, the Commission focused most heavily on resource and management issues such as: overall budget levels; adequate personnel, space and equipment; grant and contracting policies; and need for communication among various levels of government with different responsibilities for responding to the HIV epidemic. Up to this point, the President's response to the Commission's recommendations on this issue has treated the resource and management issues largely from the perspective of the "direct and immediate" items. The larger organizational considerations have been left for the President and the President-elect to consider in a more studied fashion.

The Department of Health and Human Services bears the primary responsibility for the Federal response to the HIV epidemic and

receives most of the HIV budget. Understandably, many of the management and organizational questions are targeted at HHS and raise issues of micro-management and unresponsiveness to requests from science and health officials. Improvements in these areas should be possible without eliminating or by-passing the important oversight and management functions of the current system.

Option for Consideration Strengthen the leadership position of the Department of Health and Human Services. The Commission wanted the public health functions of HHS to be more visible and more capable of commanding attention from both the public and the resource and management agencies. One possible way to accomplish this is to reorganize the Department of Health and Human Services so that line health officials report more directly to the Secretary and have the authority to deal directly with OMB and the White House.

This option would produce the least amount of perturbation in the system and would retain the day-to-day decisionmaking authority from the Department with most of the responsibility and expertise.

Federal Privacy Legislation Regarding Health Records of HIV Infected Individuals

Issue A key recommendation of the Commission was enactment of Federal legislation governing the use and disclosure of information obtained in HIV testing and counseling, with criminal penalties for improper disclosures. The recommended legislation would apply only to HIV information, held by virtually anyone in the country. It would permit certain disclosures, under controlled conditions, including to public health agencies and for notification of sexual partners.

Since the beginning of the HIV epidemic, the confidentiality of personally-identifiable records about AIDS patients and HIV-positive individuals has been of major concern. Since the illness affects, in large part, persons who are socially stigmatized, these persons have been at pains to see that information about them was not widely disseminated. The concern is both about casual or inadvertent disclosure to a landlord, employer, or neighbor, resulting in discrimination, loss of job, denial of services, ostracism, or the like, and about legally-compelled disclosure in private litigation or in governmental proceedings of one kind or another against the individual, with undesired consequences for the individual.

In general, the key legal enactments on use and disclosure of medical information are State laws. An increasing number of States have strengthened their confidentiality protections, some

specifically for HIV-related data. The strength and breadth of these protections vary widely, however.

The 100th Congress considered HIV confidentiality legislation similar to that recommended by the Commission, but did not enact it. Congress did direct the Secretary of HHS to study existing State law governing confidentiality of HIV-related information.

Option for Consideration There is precedent for Federal action in certain cases where public health goals are better served when additional protection would reassure people that private information about them will not be spread around. The existing Federal confidentiality law for drug and alcohol abuse patient information is such a case. Federal action on confidentiality of HIV-related records would provide the reassurance needed by those who are worried and might encourage them to be tested for HIV, would better protect HIV records, would offer uniformity across States and would be a symbol of Federal attention to HIV and the social and human problems related to it.

Federal Leadership Regarding Protection of HIV-infected Individuals Against Discrimination

Issue Many consider the key recommendation of the Presidential Commission to have been Federal legislation protecting those who are HIV-infected against discrimination. Action taken by the Department of Justice in October assured that Federal law treats HIV infection as a disability and thus protects infected persons. However the reach of the Federal Rehabilitation, although broad, leaves major areas uncovered.

States have been moving to shore up their protections, but still there are significant gaps. The Department of Justice is reviewing options for additional Federal action. The Department of Health and Human Services, as required by Congress, is conducting a six month study on the adequacy of existing State laws.

Option for Consideration

Health Care Financing Issues and the Nursing Shortage

Issue The Public Health Service projects that 172,000 persons with AIDS are expected to be alive in 1992 and they will require medical care at a cost expected to range from \$5 billion to \$13 billion. Current trends suggest that the epidemic is spreading more rapidly in populations unable to pay for their medical care. Large metropolitan areas, such as New York City and Miami, are likely to bear a major burden. Caring for AIDS patients will become more difficult even though case managed care and other new

approaches toward less reliance on hospitals are likely to be adopted.

Providing adequate numbers of health care workers, especially nurses, available to treat HIV-infected patients is a major problem recognized by two Commissions--the Presidential Commission on the HIV Epidemic and the Secretary of HHS's Commission on the Nursing Shortage. Both have made recommendations to alleviate the problem. The report of the Commission on the Nursing Shortage was released on December 12.

Option for Consideration The issue of adequate health care facilities and personnel to care for the 172,000 persons with AIDS in 1992 is being addressed by HHS. It will become one of the major issues around the HIV epidemic in the next four years as there is unlikely to be curative therapy available. Increased attention to the problem now might be warranted.