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May 2, 2007

The Honorable Julie Gerberding, M.D., M.P.H. Director Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30333

Dear Dr. Gerberding:

For 25 years, the Centers for Disease Control and Prevention (CDC) have been at the core of our government's efforts to fight the AIDS epidemic in the United States. Because of this role, CDC's recommendations to states, while nonbinding, have a profound impact on the way HIV is addressed. I am writing to request information regarding CDC's new guidelines for HIV testing.

After peaking at more than 150,000 in the 1980's, annual HIV incidence rates in the United States fell steadily as nationwide prevention efforts took effect.<sup>1</sup> In 1993, it was estimated that there were approximately 40,000 new infections.<sup>2</sup> However, in the decade since, the estimated number of new infections has remained steady.<sup>3</sup> Already disproportionately impacted, African-Americans and Latinos, particularly women, are experiencing increasing infection rates.<sup>4</sup>

<sup>3</sup> The HIV/AIDS Epidemic in the United States, supra note 1 at 3.

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<sup>&</sup>lt;sup>1</sup> The Henry J. Kaiser Family Foundation, *The HIV/AIDS Epidemic in the United States* (Nov. 2006).

<sup>&</sup>lt;sup>2</sup> The Henry J. Kaiser Family Foundation, *Facts on HIV/AIDS: AIDS Public Information Project* (Mar. 26, 1996).

<sup>&</sup>lt;sup>4</sup> The Henry J. Kaiser Family Foundation, *Black Americans and HIV/AIDS* (Dec. 2006); The Henry J. Kaiser Family Foundation, *Latinos and HIV/AIDS* (Dec. 2006); The Henry J. Kaiser Family Foundation, *Women and HIV-AIDS in the United States* (Dec. 2006).

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In September of 2006, the CDC issued new guidelines for HIV testing in the United States.<sup>5</sup> The most notable change in the guidelines is the recommendation that routine "opt-out" testing be provided to all Americans aged 13-64 in health care settings. Additional recommendations include:

- Annual screening for those at high risk for HIV infection;
- Elimination of the requirement of separate consent for HIV testing in addition to general consent for medical care; and
- Elimination of a pre-test prevention counseling requirement in health-care settings.

These guidelines represent efforts to reach the estimated 25% of HIV-positive Americans who do not know that they are infected.<sup>6</sup> This is of crucial importance because an awareness of one's HIV status is essential to seeking appropriate care and treatment. Moreover, data indicate that people who know their HIV status are less likely to engage in risk behaviors that may expose others to the virus.<sup>7</sup>

Since the guidelines were announced, however, concerns have been raised about their feasibility and possible impact. Limited resources will likely pose challenges to states' implementation of increased testing. Also, an increased number of diagnosed HIV infections can be expected to lead to increased demand for care and treatment resources. Already, in recent years, some states have rolled back eligibility for Medicaid and have implemented limits on Medicaid covered AIDS drugs.<sup>8</sup> Similarly, excess demand has led numerous states to implement caps or waiting lists on the AIDS Drug Assistance Program, which provides free AIDS drugs to qualified patients.<sup>9</sup> Finally, because data indicate that counseling and testing together can reduce

<sup>7</sup> G. Marks et al., *Meta-analysis of High-Risk Sexual Behavior in Persons Aware and Unaware They are Infected with HIV in the United States: Implications for HIV Prevention Programs.* Journal of Acquired Immune Deficiency Syndrome 39:446-53 (2005).

<sup>8</sup> The Henry J. Kaiser Family Foundation and the National Alliance of State and Territorial AIDS Directors, *National ADAP Monitoring Project Annual Report*, 10 (Apr. 2007), (online at www.kff.org/hivaids/upload/7619.pdf).

<sup>9</sup> *The ADAP Watch*, National Alliance of State & Territorial AIDS Directors (Feb. 7, 2007), (online at www.nastad.org/Docs/highlight/2007212\_NASTAD\_ADAP\_Watch\_2-07-07\_FINAL.pdf.).

<sup>&</sup>lt;sup>5</sup> Centers for Disease Control and Prevention, *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, Morbidity and Mortality Weekly Report 55(RR14); 1-17, (Sep. 22, 2006).

<sup>&</sup>lt;sup>6</sup> Glynn M., Rhodes P., *Estimated HIV Prevalence in the United States at the End of 2003, National HIV Prevention Conference Abstract 595* (June 2005).

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risk behaviors for the HIV-negative, the de-linking of counseling and testing has elicited concerns about the potential missed opportunity for HIV prevention.<sup>10</sup>

These questions should be explored now, so that the impacts of the new testing guidelines are anticipated and addressed. I therefore ask that you, in coordination with relevant agencies including the Health Resources and Services Administration, provide the following:<sup>11</sup>

- 1. An update on the implementation of the new guidelines since their introduction in September 2006. Please describe all major steps taken at the federal and state levels, including consultations or collaborations with other agencies and stakeholders. In addition, please describe challenges to implementation that have arisen and steps that are being taken or planned to address them.
- 2. An analysis of the cost-effectiveness of the new testing recommendations, based on resources required and infections detected. Please provide a comparison to alternative testing strategies that were or could have been considered.
- 3. An estimate or estimated range of the number of new HIV infections expected to be diagnosed under the new guidelines, with a comparison to the most recent data on newly diagnosed infections.
- 4. An estimated breakdown of the insurance status of people expected to be diagnosed under the new screening guidelines. Please include estimates of the number of people who would be eligible for Medicaid, Medicare, Veterans' Administration Health Services, and ADAP benefits, as well as those expected to be covered by private insurance.
- 5. Current HIV testing reimbursement policies for Medicaid, Medicare, Veterans' Administration Health Services, and private insurers.
- 6. Current and planned funding for federal or state purchase of HIV rapid tests and other testing supplies, including any central bulk purchases.
- 7. Any patient or healthcare provider educational materials on HIV testing issued by federal agencies based on the new guidelines.

<sup>&</sup>lt;sup>10</sup> Kamb M.L., Fishbein M., Douglas J.M., et al. *Efficacy of Risk-Reduction Counseling* to Prevent Human Immunodeficiency Virus and Sexually Transmitted Diseases: A Randomized Controlled Trial, JAMA; 1397-1405, 1998.

<sup>&</sup>lt;sup>11</sup> The Health Resources and Services Administration (HRSA) administers the AIDS Drug Assistance Program.

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- 8. A compilation of the behavioral data relied on by CDC in making its new recommendations on prevention counseling for people who test negative.
- 9. A description of how CDC plans to assess the programmatic and behavioral impact of the new recommendations on prevention counseling.

I thank CDC for your continued efforts in the fight against HIV in America and look forward to receiving your response by May 23<sup>rd</sup>. If you have any questions, please contact Jesseca Boyer or Naomi Seiler at 202-225-5056.

Sincerely,

Heya. Warman

Henry A. Waxman Chairman

cc: Elizabeth M. Duke
Administrator, Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857