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December 20, 2007

Dr. Elizabeth M. Duke
Administrator, Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Duke:

Last year, the Centers for Disease Control and Prevention (CDC) issued revised guidelines for HIV testing that recommended routine “opt-out” testing for Americans aged 13-64 in health care settings.¹ In response to questions I asked, CDC provided additional details about the guidelines, but even so, many important questions remain. I am therefore writing to you and to CDC Director Dr. Julie Gerberding to request that the Health Resources Services Administration (HRSA) and CDC conduct additional analysis to answer questions about estimated numbers of new infections; increased demand on government services; and mechanisms for linking patients to care.

Number of New Infections

I asked CDC for an estimate of the number of new cases that would be diagnosed through expanded testing. In its response, CDC cited an analysis based on 2002 data, the most recent available, indicating that between 16-22 million people are tested for HIV annually in the

¹ 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, (Sept. 22, 2006).

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U.S.² Of these, approximately 3.8 million are tested through CDC-funded programs.³ In total, approximately 40,000 people are identified as HIV positive in the U.S. annually.⁴

CDC then provided estimates of how many new infections will be found through expansion of the agency's own testing programs. According to CDC's response letter, pending funding requests for FY 2008, the number of HIV tests administered by CDC will increase to 5.3 million in 2007 and 5.8 million in 2008. Due to this expanded screening, CDC projects an additional 20,000 HIV cases will be identified in 2007, and an additional 31,000 new diagnoses in 2008.⁵

While these estimates are useful, they do not incorporate any information of how many infections will be diagnosed outside of CDC testing programs. As indicated above, CDC-funded tests represent less than a quarter of total annual tests. The new guidelines provide recommendations to healthcare settings across the country, regardless of whether they are CDC-funded, and the goal is to increase testing not only by existing providers but also those who have not conducted routine testing before. CDC wrote that the agency's experience with earlier prenatal screening guidelines suggests that projections of total infections diagnosed would be premature.⁶ However, while I understand the difficulty involved in predicting the number of new HIV infections, an estimated projected range would aid policy-makers in understanding potential impacts.

Increased Need for Government Services

In my first letter, I also requested an estimated breakdown of the insurance status of people expected to be diagnosed under the new screening guidelines. According to CDC's response, a 2003 CDC assessment of the insurance status of patients recently diagnosed with

² Centers for Disease Control and Prevention, *Number of persons tested for HIV — United States, 2002*, Morbidity and Mortality Weekly Report (2004) (online at www.cdc.gov/mmWR/preview/mmwrhtml/mm5347a4.htm).

³ Letter from Dr. Julie Louise Gerberding to Rep. Henry A. Waxman (July 18, 2007).

⁴ Centers for Disease Control and Prevention. *Cases of HIV infection and AIDS in the United States and Dependent Areas, 2005*. HIV/AIDS Surveillance Report (17) Revised Edition (June 2007) (online at www.cdc.gov/hiv/topics/surveillance/resources/reports/2005_report/default.htm). Estimated numbers of cases of HIV/AIDS by year of diagnosis and selected characteristics, 2001-2005-33 states and U.S. dependent areas with confidential name-based HIV infecting report. Totals ranged from 40,007 in 2001 to 37,367 in 2005.

⁵ Dr. Julie Louise Gerberding, *supra* note 4.

⁶ Dr. Julie Louise Gerberding, *supra* note 4.

HIV/AIDS found that 31.2% were covered by Medicaid, 17% were covered by private insurance, 5.7% were covered by Medicare, the Veterans Administration, or TriCare, and 30% chose "other" to indicate their coverage status. As CDC notes, however, since almost all the survey participants were receiving medical care, people with insurance might be overrepresented. While the number of uninsured patients was not measured in this survey, 22.1% of patients did not identify with any of the coverage options.⁷

CDC also cited a study conducted by HRSA in 2006 that provides a broader and perhaps more accurate assessment of patient insurance status. This study, which targeted a hard-to-reach population that was not necessarily in care, estimated that 50.6% of patients were covered by Medicaid and 5.9% were covered by Medicare.⁸ Another 14.7% of the study's patients had private insurance coverage, and 28.8% were uninsured.

These two studies give some sense of what the insurance status of future populations of people diagnosed with HIV might be. However, I believe that a more detailed analysis or model of projected increased demands on the healthcare system would be a useful tool for both program providers and policymakers.

Monitoring Linkage to Care and Treatment

Finally, I have concerns about the actual mechanism of "linking" newly diagnosed patients with appropriate follow-up care and treatment. While some settings that have experience with HIV testing might have well-established systems for referral, others which have just begun to screen based on the new guidelines may not. In addition, it is unclear how providers, and CDC itself, will monitor the effectiveness of any referral systems that are put into place.

Conclusion

In order to help providers, the community, and policymakers prepare for the consequences of the expanded testing program, I ask that HRSA and CDC provide the following information:

1. An estimate of the number of people who will be identified as HIV positive annually under the new guidelines, incorporating estimates based on both CDC and non-CDC funded efforts.

⁷ *Id.*

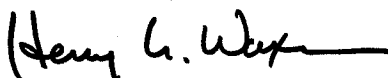
⁸ Cunningham, W.E. et al. Health services utilization for people with HIV infection: Comparison of a population targeted for outreach with the U.S. population in care. *Medical Care* 2006; 44:1038-1047.

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2. An analysis of increased demand for HIV/AIDS services within Medicaid, Medicare, the Indian Health Service, and the VA system.
3. An analysis of increased demand for Ryan White and AIDS Drug Assistance Program (ADAP) services and other HIV/AIDS services among people without insurance.
4. Information regarding how newly identified HIV positive patients will be linked into care and treatment, including any variation among different healthcare settings, and whether and how CDC will monitor the effectiveness of such linkage. Please include any guidelines that have been developed for specific healthcare settings.

I thank HRSA for your continued collaborative efforts along with CDC to address the identification and treatment of Americans with HIV/AIDS. Please provide your response by January 16, 2008. If you have any questions, please contact Jesseca Boyer or Naomi Seiler at (202) 225-5056.

Sincerely,



Henry A. Waxman
Chairman

Enclosure

cc: Tom Davis
Ranking Minority Member