Testimony Presented to the New York State Assembly Health Committee

On Proposals to Amend State Law Provisions Governing HIV Testing and Informed Consent

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We are pleased to have the opportunity to offer testimony on behalf of The Center for HIV Law and Policy and the HEAT Program of SUNY Downstate Medical Center in Brooklyn on the pending proposals before the Assembly Health Committee to change fundamental aspects of HIV testing and informed consent in New York State.

The Center for HIV Law and Policy (CHLP) is the first and only national legal resource and support center for HIV advocates around the country, taking a multidisciplinary, back-up center approach to resource development and legal policy analysis affecting marginalized communities affected by HIV. CHLP's team consists of lawyers, nurses, physicians, dentists and people living with HIV, all dedicated to development of legally and scientifically-sound approaches to the continuing epidemic of HIV and HIV-related discrimination.

The HEAT (Health and Education Alternatives for Teens) Program, created in 1992, is a comprehensive multi-disciplinary adolescent AIDS Clinic combining medical, mental health, case management and nutrition services with access to research, and serves young people ages 13-24. HEAT and FACES , a program that treats perinatally-infected youth from birth to age 24, and their families, are both directed by Dr. Jeffrey Birnbaum, Assistant Professor of Pediatric Preventive Medicine with SUNY Downstate Medical Center. Dr. Birnbaum is the founder of the HEAT program and has been treating pediatric HIV patients for nearly 15 years. Dr. Birnbaum also is an Advisory Board member of CHLP.

SUMMARY OF TESTIMONY

CHLP's & HEAT's testimony addresses three basic points:

1) Pending proposals to change NY law on HIV test counseling and proof of consent, particularly without clear plans for linkage to care, may expose providers to liability under a variety of other governing laws and legal/ethical principles;

2) The available evidence indicates that existing racial disparities in HIV care are likely to be exacerbated by elimination of pre-test counseling and proof of informed consent as a predicate to HIV testing;

3) There are multiple models demonstrating the efficacy and feasibility of HIV pre- and post-test counseling and informed, written proof of consent as routine components of HIV testing regimens.

CHLP & HEAT also respond to queries posed in the Assembly Health Committee Chair's hearing announcement, as follows:

- NYSDOH's "2005 Guidance for HIV Counseling and Testing and New Laboratory Reporting Requirements" has, in many respects, improved the counseling and testing process and promoted more testing, by making it clear that while informed consent is central to HIV testing, the counseling that is part of the testing process can and should be streamlined and tailored as dictated by individual needs, i.e., one size does not fit all.
- There still is no evidence that statutory requirements for written informed consent and counseling in Article 27-F create a real barrier to testing. The elimination of counseling and documentation of informed consent is a response to limited anecdotal evidence of provider *preferences*, not to any evidence of patient/consumer desires or needs.
- In New York State and across the nation, there are models of high-volume care providers that have successfully expanded testing in accordance with the informed consent standards of Article 27-F that can be replicated in other settings, such as at Kings County Hospital adult outpatient clinics, in adolescent HIV programs such as HEAT in Brooklyn, and in large, multi-state HMOs such as Kaiser Permanente.
- The current proposals have failed to demonstrate that systems, programs and funding are in place to assure that individuals who test HIV-positive have access to necessary health care and case management services.
- There are specific legal and ethical concerns, and a significantly increased potential for liability, posed by the proposed statutory amendments to Article 27-F in A.11075 and A.11958, and the CDC's September, 2006 revised guidelines on HIV testing in health care settings.

In further support of our testimony, we are appending two additional documents to this testimony:

1. ***HIV Testing Policies & Racial Disparities In HIV Care: A Call For An Evidence-Based Response***, prepared by The Center for HIV Law and Policy, May, 2006.

2. ***Delivering on the Promise: The Managed Care View***, a slide presentation prepared by Dr. Michael Horberg, MD, MAS, FACP, Director, HIV/AIDS Policy, Quality Improvement, Research, Kaiser Permanente/The Permanente Federation, and November, 2006.

Part I. ELMINATION OF INFORMED CONSENT, AND WRITTEN PROOF OF CONSENT, HAS MULTIPLE LEGAL AND ETHICAL IMPLICATIONS BEYOND NEW YORK'S HIV TESTING AND CONFIDENTIALITY LAW, ARTICLE 27F

State HIV testing laws are only one type of a variety of laws that are applicable to the issue of informed consent to HIV testing. The legal issues related to HIV testing, confidentiality and access to care are governed by a range of federal and state laws as well as common law principals and constitutional provisions.

Ethical considerations and professional licensing regulations also come into play. State and federal guidelines are not legally binding, but can be indicative of the standard of care. Finally, international human rights law also applies and is of special relevance to the treatment of women, children and the incarcerated when addressing HIV testing.

Changing Article 27 F will have no impact on most of these other applicable laws, regulations and principles, a number of which create special liability considerations in the context of HIV testing, care, patient autonomy and informed consent.

A. *Applicable Federal and State Laws and Ethical Considerations*

1. THE REHABILITATION ACT OF 1973, THE AMERICAN WITH DISABILITIES ACT, AND STATE DISABILITY ANTIDISCRIMINATION LAWS

The Rehab Act prevents disability-based discrimination by federal agencies and recipients of states funds, while the Americans with Disabilities Act (ADA) extends this protection to private employment, services offered to the public, and state and local governments.3 Treating positive HIV test results differently than other patient diagnostic tests -- e.g., as something other than a basis for entry into care c -- could violate these laws. Both the ADA & the Rehab Act apply to HIV, a history of substance abuse, and to correctional facilities.

2. THE CONSTITUTIONAL RIGHT TO PRIVACY, AND THE RIGHT OF PRISONERS TO CARE FOR SERIOUS MEDICAL NEEDS

Federal and state constitutional privacy protections apply to individuals' rights to consent to, and keep confidential, HIV testing. Federal courts across the country also confirm that prison inmates have a federal constitutional right to medical care that reflects community standards and a right to privacy regarding their HIV-positive status.4

3. BAN ON DISCRIMINATION BASED ON RACE OR GENDER

Title VII of the Civil Rights Act ensures the right to be offered the highest standard of care without regard to race or gender. However, recent research confirms widespread racial and gender disparities in the use of antiretrovirals to treat HIV disease. In fact, even after they present for testing, many women and people of color with HIV/AIDS are not offered antiretroviral therapy and other clinically appropriate care.5 Focused HIV screening of minority populations that does not include arrangements for linkage to may be suspect under the Civil Rights Act.

4. ETHICAL ISSUES

The ultimate objective of screening is to reduce the morbidity or mortality from a disease among the people screened.6 However, public health ethics dictate that the primary beneficiary of the screening be those who are screened. In the context of HIV screening, ethics dictate that screening programs include sufficient funding and case management to ensure that everyone with a positive HIV test is offered linkage to care and treatment as part of that screening.7

5. INFORMED CONSENT

The provider-patient communications process is a legal and an ethical obligation spelled out in the statutes and case law of all 50 states.8 A general consent is not the same legal concept as informed consent. 9 General consent covers procedures whose risks and benefits are generally well-known, while, as the AMA makes clear, "Informed consent is … a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention."10 Informed consent also is central to values of individual autonomy and dignity.11

The invented concept of "general informed consent" contained in the CDC's September, 2006 HIV testing guidelines is a legal anomaly. Either consent is general or it is specific informed consent. The process defined in the pending proposals and in the CDC guidance – which explicitly makes clear that the patient's silence is to be construed as consent – could not be characterized as informed consent under any accepted definition of the term. Unlike testing for most other infectious diseases, testing for HIV involves risks and benefits generally not well-known; and HIV is a disease that, unlike tuberculosis and sexually transmitted diseases, is life-long, typically requires decades of management with highly-toxic drugs, causes death, and results in social and economic exclusion unparalleled by most other current health conditions.

6. THE INFORMATION NECESSARY TO ENSURE THAT CONSENT IS INFORMED IS CONTEXTUAL

- Capacity = ability, without regard for age, to understand the nature and consequences of a proposed health service
- Emotional and mental health consequences of a medical procedure are part of related health risks that should be addressed as part of securing legally-adequate consent
- Courts and medical ethicists alike agree that informed consent requires that the health care provider convey that information that a layperson might not otherwise be expected to know
- The Convention on Human Rights and Biomedicine: a patient must be given the correct information about the nature and purpose of a medical intervention, its consequences and risks.
- “The potential harms of screening may also include ‘labeling’ effects and the psychological impact of test results or a diagnosis.”13

B. Stigma And Discrimination: The Continuing Consequences Of Testing HIV Positive Are An Important Element In Assessing The Legal And Ethical Relevance Of Informed Consent

Civil rights violations against people with HIV/AIDS are still widespread.15 Survey of 43 community-based ASO’s in 11 states documented denials of medical treatment, loss of parental rights, workplace discrimination, exclusions from nursing homes and residential facilities, and frequent medical privacy violations. 16 Studies continue to document both the continued social ostracism of those with HIV, and reports from many respondents that concerns about stigma, and fears that a breach in confidentiality could lead to discrimination or rejection in their families and communities, would affect their personal decisions to get tested.17

A 2004 study of violence against young gay men found they were more likely to experience verbal harassment, discrimination, and physical violence if they were HIV positive.18 Discrimination also persists in federal and state agencies that maintain exclusionary policies lacking a sound scientific rationale, for example:

- Current CDC guidelines recommend significant restrictions on health care workers with HIV.19
- Multiple federal agencies continue to exclude or restrict the employment or licensing of people with HIV.20
- A number of states prohibit the licensing of people with HIV in professions such as barbering, massage therapy, home health care, and nursing.
- 27 states have laws that criminalize the sexual conduct of those who have tested positive for HIV, most imposing significant terms of imprisonment regardless of mutual consent, whether prophylaxis was used or transmission occurred.21

Studies to determine attitudes about HIV testing at urban public hospitals indicate that people of color favor routinely-offered HIV testing but have concerns about privacy, and also found that distrust and misconceptions, particularly about the importance of testing, are very common.22 Other research confirms that many HIV positive adults believe that their clinicians have discriminated against them. 23 In fact, a study released December 1, 2006 by the UCLA's Williams Institute documented that one-fourth to one-half of skilled nursing facilities, obstetricians, and cosmetic surgeons in LA County deny treatment to HIV positive patients.

C. Potential Legal Pitfalls Caused By The Elimination Of Counseling And Proof Of Consent, And By A Focus On Testing Without Assured Linkage To Treatment

1. <u>While current state HIV testing laws typically are discussed in terms of patient protections, compliance with existing law also can help protect providers from liability on privacy, malpractice and other potential claims.</u>

2. <u>Amending state HIV testing law can be a protracted process, and other provisions of the law generally viewed as essential to patient confidence, such as confidentiality guarantees, become vulnerable.</u>

3. <u>Institutional patterns of testing without linkage to care, or patterns of racial disparities in linkages to care for those who test positive, could prompt claims of disability or race-based discrimination.</u>

4. <u>Absent proof of patient consent, health care providers could face liability on claims of failure to get informed consent in settings, or with populations, for whom general capacity to consent may be questionable, e.g.:</u>

- Adolescents
- Emergency room patients dealing with health trauma
- Other individuals with compromised capacity to consent
- Language barriers
- Prisoners, when there is either explicit or tacit pressure to "consent" to testing, or who are subjected to mandatory testing

5. <u>Truncated pre-test counseling & consent process can reinforce a claim of medical malpractice; One of the most common factors in patients' decision to file claims is inadequate physician communication. 24</u>

6. <u>Legal liability and ethical issues might be raised by individuals disputing they had sufficient knowledge to give general consent to HIV testing after experiencing negative fallout of a positive test, such as:</u>

   - Domestic violence
   - Loss of housing
   - Loss of employment or employment opportunities; loss of insurance
   - Exclusion from training, school and day care programs
   - Psychological trauma exacerbated by failure to assess test readiness or to sufficiently counsel after testing
   - Special issues for adolescents and other vulnerable individuals

7. <u>Research literature indicates that physicians have relatively limited knowledge regarding state law and institutional policies and procedures on confidentiality issues specific to patients with HIV. 25 This could lead to both individual and institutional liability for privacy violations, e.g.:</u>

   - Health care facilities could incur liability from inappropriate disclosures to family members, police, prison personnel;
   - The constitutional right to privacy also could be asserted in the case of inappropriate disclosures by doctors in state hospitals.

8. <u>People in correctional settings may have claims about inadequate medical care or privacy violations based on HIV testing without :</u>

   - Parallel diagnostic evaluation for Hepatitis C
   - Follow through on other CDC/NIH guidelines for treatment of HIV and Hepatitis C

- Procedures to ensure that prisoners can test, and ask questions, in privacy and without subsequent disclosure of their HIV status to staff and inmates
- Providing reliable access to medications during incarceration and prior to release

D. Alternatives That Protect Providers And Patients

1. Health providers who are, or should be, involved in HIV testing should be trained:

   - One size does not fit all regarding pretesting information needs;
   - Informed consent can be secured through multiple means and, in most situations, with modest time investment;
   - It is legally impossible to determine capacity to consent without pre-test patient/provider communication;
   - It is a continuing reality that many patients still fear being ostracized by their communities; many fear rejection or violence by their partners;
   - Written proof of consent is an important provider protection in situations where capacity to consent may be in question.
   - Documentation of a well-conducted process helps protects health care providers from exposure to liability

2. Short-staffed health care providers should engage with local ASOs and legal service providers to:

   - Assist with test-related counseling;
   - Ensure real informed consent;
   - Assist with immediate linkage to additional counseling, care and other core services.

3. In correctional settings, ensure that:

   - Resources are in place to provide standard-of-care treatment to HIV+/Hepatitis C+ inmates before launching routine test offering; routine testing without confirmation from health officials and/or outside monitors that prisoners have consistent access to appropriate care could turn prisons into breeding grounds for MDR virus that is further spread in the communities to which most inmates return;
   - Confidentiality is protected at and subsequent to time of testing;

- Testing and treatment protocol guarantees that information about inmates' HIV status can be used only for the purposes for which it is originally obtained, i.e., for diagnosis and treatment;
- Non-medical, security staff plays no role in diagnosis, treatment or partner notification activities.

Part II. AVAILABLE EVIDENCE STRONGLY SUGGESTS THAT PROPOSALS TO ELIMINATE COUNSELING, INFORMED CONSENT AND WRITTEN PROOF OF CONSENT ARE LIKELY TO WORSEN, RATHER THAN IMPROVE, NEW YORK'S RESPONSE TO HIV IN COMMUNITIES OF COLOR

Recent proposals to change HIV counseling and testing protocols rest on claims that current laws incorporating informed, written consent as a predicate to testing are outdated barriers to care. Public health officials in New York City have gone so far as to insist that these laws are a primary cause of racial disparities in HIV testing.

Will eliminating counseling and informed consent requirements before testing, counseling for all who test negative, and written proof of informed consent – in short, abandoning modern approaches to public health and patient autonomy in favor of "traditional" public health philosophy -- result in earlier, better and sustained access to HIV treatment and medical care, and better outcomes for people of color?

The available evidence strongly indicates that the elimination of pre-test counseling, informed consent, written proof of consent, and post-test counseling for all who are offered an HIV test as a response to racial disparities in care is both unsupported and unsound. This is so because 1) the plan is *no*t evidence-based, i.e., based on demonstrable evidence that counseling, consent and confidentiality procedures are in fact discouraging patient testing or care; and 2) the evidence suggests that in fact the proposals will *worsen* racial disparities in access to, and initiation and maintenance of, appropriate and life-prolonging treatment.

As documented in the attached CHLP report, there is substantial, long-standing evidence of racial disparities in initiation and ongoing access to state of the art HIV/AIDS treatments that are mirrored across a variety of health conditions, all across the U.S.. None of the evidence suggests that pre-test counseling and written proof of informed consent perpetuate stigma or are a barrier to care. However, *most of the evidence – even that produced by health provider interviews – shows that health care provider conduct, and the extent to which physicians establish a trusting relationship with patients, is closely connected to racial disparities in the initiation and continuation of life-saving HIV care.*

Attempting to address the problem of racial disparities by promoting some of the very views and behaviors underlying the problem is, to say the least, counterproductive.

Counseling and working with patients to assess potential exposure to HIV and to encourage appropriate testing and voluntary care for themselves and their children are essential for ensuring effective continuum of care. Removing all counseling and informed consent requirements, as a trade-off for the promise of streamlining and speeding introduction to care, is short-sighted. Building physician trust in the most hard-hit communities is a public health imperative. For people who already mistrust medical providers, elimination of pre-test counseling and proof of consent eliminates a critical juncture for fostering patient trust of a provider and the larger health care system. Eliminating the requirement for pre-test provider-patient communication likely will further delay real progress on the complex, continuing problem of racial disparities in HIV/AIDS diagnosis, care and outcomes.

Part III. PRE AND POST-TEST COUNSELING ARE A CRITICAL PART OF HIV CARE AND PREVENTION, AND THERE ARE MULTIPLE MODELS OF HIV TESTING AND CARE THAT HAVE INCREASED HIV TESTING AND ENTRY INTO CARE USING COUNSELING AND WRITTEN PROOF OF INFORMED CONSENT

A. Defining Success and Best Practices

Much of the discussion around increased HIV testing – as evidenced, for example, in the CDC's new guidelines – dedicates significant discussion to scaling up HIV testing while remaining vague on the specifics of linkage to care. It is very important to agree at the outset on how we define the "success" of a particular HIV testing regimen.

If we accept that any HIV screening program must, at minimum, benefit the person screened, then an increase in numbers tested is not a alone a valid measure of success. HIV testing is not an end point, but an entry point in the continuum of care. Consequently, while the numbers of newly-identified persons with HIV may be a central component of progress, success must be measured in significant part by the percentage of people tested who *enter care* (including simple regular monitoring of CD4 cells and viral loads, as not all who test will or should immediately initiate ART or other chemotherapy) and *remain in care for a sustained period*.

The evidence supports HIV test counseling before testing, and for those who test negative -- to explain the meaning of test results and the importance of regular testing and care -- as central to success, and to sound public health practice. This is particularly crucial as the most frequently used HIV screening tests do not detect acute infection.

Primary or acute HIV infection is the period immediately following a patient's initial infection with HIV, and before development of HIV antibodies that are detectable by ELISA and Western Blot assays. Traditional antibody assays typically cannot detect the virus until a minimum of four to six weeks into infection. However, a person with acute HIV infection is an important public health concern, as it is during this period when a person's viral load spikes and the person is probably the most infectious.26

By definition, a person experiencing primary or acute HIV infection has engaged recently in risk activity that caused the HIV infection. Without some intervention, that person, armed with a negative HIV test, is likely to continue that activity. A policy which focuses its care and prevention efforts exclusively on those who test positive on a rapid test is effectively giving up on this critical cause of the further spread of HIV. It is estimated that 40% of HIV-infected patients acquired HIV from someone who was in the primary infection stage.26 Particularly without a broad program of viral load testing (coupled with nucleic acid amplification testing) that is capable of picking up primary infection, effective counseling that engages such a person in continued testing and that promotes protective sexual practices must be retained as an important part of preventive HIV care.

This view actually is consistent with a 2003 CDC research report showing that compared with early testers (those who test $\geq$ 5 years before an AIDS diagnosis), later testers (those who test ≤ 1 year before an AIDS diagnosis) are significantly more likely to have tested negative for HIV previously, before their first positive test.27 As the CDC concluded in their report, "**[P]ersons who tested negative might have assumed they were safe and therefore did not retest for a long time.**"

B. Kings County Hospital and the HEAT Program

Successful programs recognize that there is such a thing as inappropriate HIV testing. Inappropriate testing includes testing people in emergency rooms at hours that preclude linkage to care or access to adequate counseling. Inappropriate testing also includes HIV testing of adolescents that does not include a real assessment of each youth's readiness to test, and the availability of services to support a teen who tests positive.

Proposals that fail to realize that HIV testing and introduction to care is a process, and that minimize the importance of counseling and informed consent as part of this process, fail to grasp that counseling is most important with populations prone to mistrust. This is precisely the population seen at Kings County Hospital and in the HEAT program, an adolescent HIV clinic recognized as a model of care. Years of experience have taught us that development of trust between health care staff and patient is essential to keeping adolescents in care. Scaling back provider-patient communication to accommodate physician preference is likely to worsen the chronic factor of mistrust, a risk that is unacceptable. HIV is like no other disease this population has been forced to deal with, and treating HIV differently than gonorrhea is not "exceptionalist," it is a medical and public health necessity.

The same principles apply to the importance of separate written consent forms. All patients are handed multiple forms – medical history, HIPAA, insurance, etc. – and burying the issue of HIV in a general medical consent form only risks suspicion if the person tests positive. When dealt with separately, people who might be suspicious are given the opportunity to ask questions and address concerns; experience also shows that many people, particularly teens and those already mistrustful of the health care system, will avoid subsequent care if they are unhappy with the way they are told they are HIV positive. Even as recently streamlined, the HIV testing and counseling process – making use of multiple media from videos to take-home information sheets to tailored counseling sessions – is an important, necessary opportunity to engage youth in care.

Kings County Hospital's recent program of scaled-up HIV testing proves that obtaining written consent is not a barrier to care. Over a period of several months, Kings County phased in and scaled up HIV testing until every patient seen in each of its adult outpatient programs was offered an HIV test. Regardless of the health care condition triggering the clinic visit, eventually every patient having blood drawn was seated in an area with a video explaining HIV, the testing process and meaning of results, and related transmission and prevention information. Using parts A and B of the NY State Department of Health's streamlined HIV testing information and consent forms, each patient was then asked at the time their blood was drawn whether they were interested in being tested for HIV. Patients signed consent forms and were tested, demonstrating the ease with which written consent can be secured even in a large-scale system.

Similarly, while the HEAT program operates a clinic that is both extremely busy and extremely demanding, we have never found the counseling process, or the simple process of having a patient sign a consent form, to be a barrier to care. To the contrary, we see the process as an indispensable tool to engage patients in a continuum of care. With youth in particular, linkage to care and retention in care is directly affected by the quality of pre-test counseling.

C. Kaiser Permanente/Permanente Federation/Group Health Cooperative

Kaiser Permanente, the nation's larges HMO, and a leading integrated health care system of 30 medical centers, 431 medical offices and 12,000 physicians, provides another compelling refutation of the position that counseling and informed written consent are a time-consuming barrier to HIV diagnosis and care.28 With over 16,000 active HIV positive patients in care, including more than 200 patients 19 years old or younger, Kaiser Permanente (KP) is the second largest provider of HIV care in the U.S.

As outlined recently at a national summit by Dr. Michael Holtgrave, KP's Director of HIV/AIDS Policy, Quality Improvement, and Research, KP's philosophy is that HIV testing is a process that includes an antibody test with pre- and post-test counseling, patient education, and procedures to handle newly identified cases, convey test results, and discuss risk behavior, sexuality, and STD testing; counseling and the frequency of testing are determined individually. Ninety percent of KP's HIV patients are in care within 120 days of diagnosis, and their mortality rate is lower than the national average.29

Part IV. CONCLUSION

Pending state and federal legislative recommendations and guidelines calling for the amendment of Article 27F are unsupported by the evidence, raise multiple legal, medical and public health concerns, and give short shrift to existing programs that successfully integrate increased testing with patient needs for provider communication and trust.

REFERENCES

1. See Health Research & Educational Trust, Laws of Individual States, (providing a map, and text, for state statutes related to HIV testing, consent, training, etc.), accessed 11/17/06 at www.hret.org/hret/about/hivmap.html. [Note: Spot checking of most of HRET's charts on aspects of the HIV laws posted at this sight revealed significant inaccuracies; in fairness, the lack of uniformity on basic definitions such as what constitutes HIV related information, or how informed consent or counseling are defined, create challenges in accurately summarizing state law in this regard. In addition, these charts do not include state regulations which may expand upon or clarify statutory provisions on HIV testing and confidentiality. The site is useful, however, for its collection of the actual text of individual state statutes on HIV testing.
2. Id.
3. See M. Crossley, Becoming Visible: The ADA's Impact on Health Care for Persons With Disabilities, 52 Ala. L. Rev. 51 (2000).
4. See Powell v. Schriver, 175 F.3d 107 (2d Cir. 1999); Faison v. Parker, 823 F. Supp. 1198 (E.D. Pa. 1993); Albrecht v. Lehman, 1993 WL 346216 (E.D. Pa. 1993); Hilaire v. Arizona Dept. of Corrections, 934 F.2d 324 (9th Cir. 1991); A.L.A. v. West Valley City, 26 F.3d 989 (10th Cir. 1994).
5. For example, recent data produced by a multistate sample of HIV patients already in care in major HIV primary care sites, including New York City, revealed that many eligible women and African American patients still did not receive antiretroviral therapy. Kelly A. Gebo, M.D., Richard D. Moore, M.D., and John A. Fleishman, Ph.D., Racial and Gender Disparities in Receipt of Highly Active Antiretroviral Therapy Persist in a Multistate Sample of HIV Patients in 2001, http://hopkins-aids.edu/publication/report/nov03_2.html. See also W.E. Cunningham, L.E., Markson, R.M. Andersen, et al, Prevalence and Predictors of Highly Active Antiretroviral Therapy Use in Patients With HIV Infection in the United States, 25 J. AIDS 115-123 (Oct. 2000); V.E.Stone, MD, MPH, Dir., Women's HIV/AIDS Program, Assoc. Chief, G.M.U, Massachusetts General Hospital, Assoc. Prof. of Med., Harvard Medical School, Disparities in HIV/AIDS by Race/Ethnicity, (2006), http://www.med.unc.edu/ome/Zollicoffer_Presentation_2006.pdf; Betancount M.D., M.Ph.,"Unequal Treatment": The Institute of Medicine's Finding and Recommendations on Health Care Disparities, 3 Harv. Hlth Policy Rev., No. 2 (Fall 2002).
6. Coughlin, S., Ethical Issues in Epidemiological Research and Public Health Practice, 3 Emerg. Themes Epidemiol. (Oct. 2006).
7. See id.

8. See American Medical Association, Office of the General Counsel, Division of Health Law, Informed Consent, http://www.ama-assn.org/ama/pub/category/4608.html
9. See, *e.g.*, Dr. Antonia Novello, Commissioner of the NY State Dept. of Health, *En guardia contra el estigmadel SIDA*, El Diario/La Prensa, 10/24/2006, http://www.hwadvocacy.com/update/El%20Diario.pdf
10. American Medical Association, Office of the General Counsel, Division of Health Law, *Informed* Consent, http://www.ama-assn.org/ama/pub/category/4608.html; B. L. Atwell, *The Modern Age of Informed Consent*, 40 U. Rich. L. Rev. 591 (Jan. 2006).
11. G.P. Smith, *The Vagaries of Informed Consent*, 1 Ind. Health L. Rev. 109 (2004); *See also Salgo v. Leland Stanford Jr. University Board of Trustees* (patient had cause of action for physician's failure to discuss known risks of a medical procedure prior to securing patient's consent), 154 Cal. App. 2d 560 (Oct 1957).
12. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.).
13. Coughlin, S., *Ethical Issues in Epidemiological Research and Public Health* Practice, 3 Emerg. Themes Epidemiol. (Oct. 2006); *see also* Melissa Weddle & Patricia Kokotailo, *Adolescent Substance Abuse Confidentiality and Consent, 49* Pediatric Clinicians N. Am. 301, 310 (2002)(psychological risks of screening warrant close attention to informed consent requirements).
14. E.g., *Leonel v. Amer. Airlines*, 400 F.3d 702 (9th Cir. 2005).(Airlines' testing of flight attendant applicants for HIV without their consent stated claim for privacy violation under CA constitution.); *Doe v. High-Tech Institute, Inc.*, 972 P.2d 1060 (Colo Ct. App. 1998).
15. ACLU AIDS Project, HIV & Civil Rights, A Report from the Frontlines of the HIV/AIDS Epidemic, November 2003 (hereinafter "ACLU, Report from the Frontlines"). The report, which surveyed 43 community-based AIDS service organizations from across the country states, for example, that even today and even in Los Angeles, many nursing homes and psychiatric facilities will not take clients with HIV, some claiming a lack of experience in caring for patients with HIV as the basis for refusing admission.
16. E.g., Smith and U.S.A. v. City of Philadelphia, No. 03-6494, E.D. Pa. (Nov. 2006) When the emergency response personnel learned that Smith, who called 911 with severe chest pains, was HIV-positive, one EMT left the house and another told Smith, "Cover your face or I'm not going to help you." The suit also alleged that the EMTs would not help Smith to the ambulance.
17. *E.g.*, G.M. Herek, J.P Capitanio, K.F Widaman, *Stigma, Social Risk, and Health Policy: Public Attitudes Toward HIV Surveillance Policies and the Social Construction of Illness*, 22 Health Psychology 533-540 (Sept. 2002), http://psychology.ucdavis.edu/rainbow/html/healthpsych2003_pre.PDF, (More

than one-third of those surveyed reported that concerns about AIDS stigma would affect their own decision to be tested for HIV); Centers for Disease Control and Prevention, *HIV-Related Knowledge and Stigma – United States, 1999-2000,* 49 MMWR 1062-4 (Dec. 1, 2001); Herek, G.M., *Thinking About AIDS and Stigma: A Psychologist's Perspective*, 30 J. of Law, Medicine and Ethics 594-607 (2002).

18. Huebner, David M. et al., *Experiences of Harassment, Discrimination, and Physical Violence Among Young Gay and Bisexual Men,* 94 Am. J. Pub. Health 1200 (July, 2004).
19. Centers for Disease Control and Prevention, *Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures*, MMWR 1991: 40 (RR-8): 1-9. As the title indicates, the recommendations addressed infection with Hepatitis B virus (HBV) as well; they noted that hepatitis is approximately 100 times as infectious as HIV, and developed a partial definition for "exposure-prone procedures" by referring to those procedures implicated in the transmission of HBV, not HIV. *Id.* at 3-4.
20. The State Department/Foreign Service, Job Corps, Peace Corps, Federal Aviation Administration (FAA) and all branches of the military continue to exclude or significantly restrict the employment or licensing of individuals with HIV.
21. See HIV Criminal Law and Policy Project, HIV-Specific Criminal Transmission Laws, http://www.hivcriminallaw.org/laws/ hivspec.cfm.; Iowa Code §§ 139.1, 139.31 (1997); for examples of states that forbid sex regardless of consent, see Md. Health Code Ann. § 18-601.1(a) (1994); Mont.Code Ann. §§ 50-18-101, 50-18-112 (1997); Utah Code Ann. § 26-6-3.5(3) (Supp.1997); *id.*, § 26-6-5 (1995); Wash. Rev.Code § 9A.36.011(1)(b) (Supp.1998); see also N.D. Cent.Code § 12.1-20-17 (1997).
22. A.B. Hutchinson, G. Corbie-Smith, S.B. Thomas, S. Mohanon, C. del Rio, *Understanding the Patient's Perspective on Rapid HIV Testing in an Inner-City Urgent Care Center*, 16 AIDS Educ. Prev. 101-114 (April 2004).
23. Schuster, et al., *Perceived Discrimination in Clinical Care in a Nationally Represenative Sample of HIV-Infected Adults Receiving Health Care*, 20 UJ. Gen. Intern. Med. 807-813 (2005). In this study of 2,466 HIV infected adults receiving health care in the U.S., 26% reported experiencing some form of discrimination by a health care provider since becoming infected.

24 Levinson, W., Roter, DL, Mulloly, J.P et al., *Physician-patient communication: the relationship with malpractice claims among primary care physicians and surgeons,* 227 JAMA 553-559 (1997); Raab, E.L, *The Parameters of Informed Consent*, 1`02 Trans. Am Ophthalmol. Soc. 225 (2004).

25 Mckinley, Thomas. et al., *Physician Perceptions and Knowledge of the Legal and Ethical Issues Regarding HIV/AIDS Confidential Disclosure in Managing Persons With*

HIV/AIDS at an Academic Medical Center, 1 the Internet J. of Law, Healthcare and Ethics (2003), www.ispub.com/ostia/index.php?xmlPrinter=true&xmlFilePath=journals/ijlhe/vol1n2hiv.xml.

26 T. Wilkin, MD, MPH, The Body Covers: The 13th Conference on Retroviruses and Opportunistic Infections Detecting Primary HIV Infection: Important for Prevention and, Extremely Rarely, Treatment as Well, http://www.thebody.com/confs/retro2006/wilkin1.html, discussing H Truong, W McFarland, T Kellogg, B Louie, E Wong, R Grant, and J Klausner , *Detection of acute HIV infection among STD clinic patients in San Francisco* (Poster 914), 2006; S Morpeth, N Thielman, J Giner, P Menezes, S Fiscus, G Tomaras, C Pilcher, J Lennox, J Eron, and C Hicks, *Time to HIV-1 seroconversion is similar among patients with acute HIV-1 infection, but there are exceptions* (Poster 389), 2006.

27 CDC, *Late Versus Early Testing of HIV --- 16 Sites, United States, 2000—2003,* MMWR June 27, 2003 / 52(25);581-586.

28 Kaiser Permanente combines a health plan, hospitals and medical groups located in multiple communities throughout California, Colorado, Georgia, Hawaii, Washington, DC, Maryland, Virginia, Ohio, Oregon and Washington State.

29 Dr. Holtgrave noted KP believes that increased testing is needed, although following the CDC's recommendations would require testing considerably more than 5 million more of their health plan members, with anticipated identification of 1773 new cases at a cost of nearly $27,000,000 a year, or about $15,000 per patient. Dr. Holtgrave also noted that most managed care organizations traditionally follow the recommendations of the U.S. Preventive Services Task Force (USPTF), the nation's leading independent panel of private-sector experts on prevention and primary care, whose 2005 findings on HIV testing are at odds with the CDC recommendations. USPTF, sponsored by the U.S. Agency for Healthcare Research and Quality, concluded there wasn't enough evidence to recommend for or against routine HIV screening. The USPTF's recommendations are in fact what all of the nation's health insurers generally look to when deciding coverage issues.

APPENDIX

1. ***HIV Testing Policies & Racial Disparities In HIV Care: A Call For An Evidence-Based Response***, prepared by The Center for HIV Law and Policy, May, 2006.

2. ***Delivering on the Promise: The Managed Care View***, a slide presentation prepared by Dr. Michael Horberg, MD, MAS, FACP, Director, HIV/AIDS Policy, Quality Improvement, Research, Kaiser Permanente/The Permanente Federation, and November, 2006.