Oral Summary of 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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I am Catherine Hanssens, Executive Director of the Center for HIV Law and Policy, and I am pleased to offer testimony on behalf of The Center and on behalf of Dr. Jeffery Birnbaum, Director of the HEAT Program of SUNY Downstate Medical Center in Brooklyn.

The Center for HIV Law and Policy (CHLP) is the only national legal resource and support center for HIV advocates around the country addressing the needs of marginalized people living with HIV. Our multidisciplinary team is 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 is a comprehensive adolescent AIDS Clinic serving young people ages 13-24. HEAT is directed by Dr. Jeffrey Birnbaum, Assistant Professor of Pediatric Preventive Medicine with SUNY Downstate Medical Center. Dr. Birnbaum has been treating pediatric HIV patients for nearly 15 years.

As part of our written testimony, we are submitting two documents: CHLP's report addressing the evidence on the likely impact of opt-out testing on racial disparities in HIV care, and a copy of a slide presentation prepared by Dr. Michael Horberg, Dir. Of HIV/AIDS Policy, Quality Improvement and Research for Kaiser Permanente.

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.**

- 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. State and federal guidelines are not legally binding, but can be indicative of the standard of care. Changing Article 27 F will have no impact on these other laws, a number of which create special liability considerations.
- The provider-patient communications process is a legal and an ethical obligation spelled out in statutes and case law.8 General consent covers only those procedures whose risks and benefits are generally well-known. "Informed consent

is … a process of communication between a patient and physician that results in the patient's agreement to undergo a specific medical intervention."

- Either consent is general or it is specific informed consent. 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.

Potential Legal Pitfalls Posed By Pending Proposals

1. <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>

2. <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, such as adolescents or, people with language barriers, or emergency room patients dealing with health trauma.</u>

3. <u>A truncated pre-test counseling & consent process can reinforce a claim of medical malpractice, since one of the most common factors in decisions to file claims is inadequate physician communication.</u>

4. <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 domestic violence or loss of housing or employment.</u>

5. <u>The average physician's limited knowledge of state law on confidentiality issues specific to patients with HIV could lead to both individual and institutional liability for privacy violations.</u>

6. <u>People in correctional settings may have claims about inadequate medical care or privacy violations based on HIV testing without reliable access to medications during incarceration and prior to release.</u>

2) **All of 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;**

- There is substantial evidence of racial disparities in initiation and ongoing access to HIV care. M*ost of the evidence 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 behaviors underlying the problem is, to say the least, counterproductive.

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

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* and *remain in care for a sustained period*.

Retaining counseling before HIV testing, and for those who test negative -- to explain the meaning of test results and the importance of regular testing and care -- is crucial to the process, 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, when a person's viral load spikes and the person is probably the most infectious. 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. Focusing care and prevention efforts exclusively on those who test positive on a rapid test is effectively giving up on a significant cause of the further spread of HIV, as it is estimated that 40% of HIV-infected patients acquired HIV from someone who was in the primary infection stage.

Counseling and informed consent are most important with populations prone to mistrust, including those patients seen at Kings County Hospital and in the HEAT program, an adolescent HIV clinic recognized as a model of care. 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.

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 the state'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.

Finally, 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.

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, discuss risk behavior, sexuality, and STD testing; counseling and the frequency of testing 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

CONCLUSION

We submit that pending proposals to amend 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.