hiv law project

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SOUTH BROOKLYN
LEGAL SERVICES

May 15, 2006

Donald P. Berens, Jr.
General Counsel
New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Mr. Berens:

We write to request that that the New York State Department of Health ("DOH") cease and desist its continuing violation of the law by the issuance of emergency regulations amending 10 N.Y.C.R.R. Part 63 and by authorizing the use of a legally defective form to obtain written informed consent prior to HIV testing. While we prefer to resolve this matter without a lawsuit, we are prepared to litigate this issue.

On April 25, 2005, DOH filed a notice of emergency regulations to amend 10 N.Y.C.R.R. Part 63, "HIV Laboratory Reporting" as necessary for the preservation of public health. These emergency regulations became effective on June 1, 2005 and expired on July 23, 2005. The emergency regulations were readopted on July 21, 2005 and expired on October 18, 2005. The emergency regulations were promulgated again on October 19, 2005 and expired on January 16, 2006. On January 17, 2006, the emergency regulations were renewed a third time and expired on April 16, 2006. The regulations were renewed for a fourth time on April 18, 2006 and will expire on July 16, 2006.

The regulations, *inter alia*, expand the HIV-related data laboratories are required to report under Public Health Law § 2130. Specifically, the emergency regulations mandate that, in addition to initial determinations or diagnosis of HIV infection, laboratories report the following pieces of data: (1) *all* viral loads; (2) *all* CD4 lymphocyte counts (unless the test was known to be performed for reasons other than HIV-infection or HIV-related illness); (3) HIV subtype; and (4) antiviral drug resistance testing. Moreover, the emergency regulations eliminate any guidance with respect to the content of the form to be used to obtain informed written consent prior to HIV testing, and the consent form that has been developed since the passage of the emergency regulation falls short of the requirements delineated in the Public Health Law.

For the three reasons set forth below, we believe that the Department is violating the Public Health Law, and request that the Department cease its illegal conduct and take steps to remedy its impact to date. First, DOH's emergency regulations are legally deficient because

they eliminate informed consent for the reporting of an individual's HIV information. Second, DOH's repeated renewal of these emergency regulations outside of the normal rule-making process violates the State Administrative Procedures Act, as well as the due process guarantees of the state and federal constitutions. Third, after eliminating the regulatory guidance regarding the contents of the written informed consent form for HIV testing, DOH impermissibly authorized the use of a form that fails to comply with the Public Health Law § 2786. Each of these violations is discussed in greater detail below.

1. The Emergency Regulations Violate the Public Health Law by Eliminating Informed Consent for the Reporting of an Individual's HIV Information

The emergency regulations violate Public Health Law § 2130(1), which permits physicians and diagnostic laboratories to report only: (1) an *initial determination* that a person is infected with HIV; or (2) an *initial diagnosis* that a person is afflicted with AIDS; or (3) an *initial diagnosis* that a person is afflicted with HIV-related illness. The statute does not authorize mandatory reporting of HIV-related tests beyond the initial determination or diagnosis, nor does it authorize the reporting of HIV subtype data or antiviral resistance testing data.

The additional data reporting mandated by DOH Commissioner is outside the scope of the authority of the statute. In short, the DOH has usurped the role of the legislature by adopting *ultra vires* emergency regulations that mandate the reporting of far more data than is currently permitted by state law.

2. The Emergency Regulations Violate the State Administrative Procedure Act

DOH violated the State Administrative Procedure Act ("SAPA") §202 (6)(d)(iv) by failing to provide a statement why compliance with the notice and rule making procedures was contrary to the public good and why current circumstances necessitated that the public and interested parties be given less than the minimum period for notice and comment on the rule making. Moreover, in readopting the emergency regulations on July 21, 2005, DOH failed to comply with SAPA procedures mandating that no readoption shall be filed unless the agency has submitted a notice of proposed rule making, and that no subsequent readoption shall be filed unless the agency submits an assessment of public comment. Additionally, SAPA provides that a readopted emergency rule shall remain in effect for no more than 60 days, not the 90 days set forth by DOH in the readopted regulations of July 21, 2005.

Apparently, to avoid complying with SAPA regulations governing the readoption of emergency rules, DOH re-promulgated the exact text of the original emergency regulations thereafter. Such attempts to bypass the rulemaking process deprive citizens of New York State of their due process right to be heard on the wisdom of these substantive rule changes. The emergency rules have been in effect for over 10 months, and DOH has failed to provide any mechanism for any public input into the rulemaking process.

Additionally, the "emergency" offered by DOH for the necessity of promulgating regulations on an emergency basis—the identification of a single case of a fast progressing, multi-drug resistant strain of HIV--has long since passed, particularly since that isolated case has

since been recognized as a statistical outlier, or anomaly, rather than a widespread public health threat.

DOH's continued reliance on this one isolated case, diagnosed over a year ago; to justify the ongoing exclusion of the public from the normal rule-making process is legally insufficient. DOH's ongoing use of the emergency rule-making process violates the procedural due process guarantees codified in SAPA and protected by the federal and State constitutions.

3. The New HIV Testing Consent Form Fails to Comply with the Public Health Law

The amendments to the regulations also provide for the repeal of the regulatory promulgation of the previous HIV consent form, which was compliant with the statutory requirements for informed consent. *See* Public Health Law § 2781. While the undersigned do not dispute the Commissioner's authority to change administrative forms, the revised consent form fails to comply with those statutory requirements. The form neither specifies the HIV tests to which a person is consenting, nor makes clear to whom the consent has been given. In addition, the form purports to serve as consent for all tests that may be conducted in the future. A "one time for all time" consent form violates both the letter and the spirit of the Public Health Law.

While obtaining information to help guide HIV prevention programs is an important component of HIV public health, patients have a right to be specifically informed as to whom their identifiable personal health information will be provided, and the right to decline to provide a specimen to be used for targeted prevention efforts or other research. By linking testing for treatment and targeted prevention efforts, patients are unable to "opt out" of one component.

The revised consent form is also problematic to the extent that it does not make clear specifically to whom consent is being granted. This form provides authorization to anyone who comes into possession of this document. Moreover, the revised consent forms does not contain a certification that informed consent has been obtained as required by Public Health Law § 2781. All of these important safeguards are essential elements of any informed consent form.

Steps the Department Must Take to Avoid Litigation

In order to avoid costly litigation, we propose that your client take the following steps:

1) File emergency regulations by June 1, 2006 that return 10 N.Y.C.R.R. Part 63 to the regulatory status quo prior to the filing of the emergency regulations on April 25, 2005;

2) Revise the consent form to address the infirmities discussed above to enable patients to provide fully informed consent;

3) Destroy all illegally acquired data from New York State and City data bases and, in the event that this data has been redisclosed to any third parties or agencies, ascertain that such redisclosed data has been destroyed by these entities.

We wish to resolve these issues constructively without litigation. We would like to work closely with the State to ensure that any HIV Reporting System regulations promulgated are procedurally consistent with applicable law and provide individuals testing for HIV with the panoply of civil rights to which they are entitled while addressing critical public health issues in an effective, efficient way. If you have any questions or wish to discuss the contents of this letter, please feel free to contact Cynthia B. Knox, Deputy Executive Director, HIV Law Project at: (212) 577-3001 or Elisabeth Benjamin, Reproductive Rights Project Director, NYCLU at: (212) 607-3327.

Sincerely,

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