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THE COUNCIL

COMMITTEE REPORT OF THE HUMAN SERVICES DIVISION

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COMMITTEE ON HOSPITALS

Hon. Carlina Rivera, Chair

COMMITTEE ON HEALTH

Hon. Mark Levine, Chair

December 9, 2019

Oversight: The City's efforts to prevent and address HIV and Hepatitis

Int. No. 1808:

By Council Member Levine

Title:

A Local Law in relation to examining the causes and conditions surrounding HIV/AIDS-related deaths in New York City

Res. No. 0150:

By Council Member Dromm

Title:

Resolution calling upon United States Food and Drug Administration to remove any blood donation restrictions based on sexual orientation.

I. Introduction

On December 9, 2019, the Committee on Hospitals, chaired by Council Member Carlina Rivera, and the Committee on Health, chaired by Council Member Mark Levine, will hold a hearing on the City's efforts to prevent and address human immunodeficiency virus (HIV) and hepatitis. The Committees plan to discuss the City's efforts to eliminate hepatitis and to end the acquired immunodeficiency syndrome (AIDS) epidemic. Additionally, the Committees will hear Introduction Number 1808 (Int. No. 1808), a Local Law in relation to examining the causes and conditions surrounding HIV/AIDS-related deaths in New York City, as well as Resolution Number 0150 (Res. No. 0150), which calls upon the United States Food and Drug Administration (FDA) to remove any blood donation restrictions based on sexual orientation. Witnesses invited to testify include representatives from Health and Hospitals (H+H), the Department of Health and Mental Hygiene (DOHMH), community-based organizations, and advocates.

II. Background

Hepatitis

Overview

Hepatitis is an inflammation of the liver, and can lead to fibrosis, cirrhosis, or liver cancer.¹ Hepatitis viruses are the most common cause of hepatitis in the world, although other infections, toxic substances (e.g. alcohol, certain drugs), and autoimmune diseases can also cause hepatitis.² There are five main hepatitis viruses, including types A, B, C, D, and E.³ Hepatitis A and E are typically caused by ingestion of contaminated food or water, while hepatitis B, C, and

¹ World Health Organization, *What is hepatitis?*, September 2019, available at <https://www.who.int/features/qa/76/en/>

² *Id.*

³ *Id.*

D are usually the result of parenteral contact with infected body fluids, such as by receipt of contaminated blood or blood products and transmission from mother to baby at birth, from family member to child, and also by sexual contact.⁴

Millions of Americans are living with viral hepatitis and do not know they are infected.⁵ Although the most common types of hepatitis are hepatitis A, B, and C, hepatitis A is easily curable and preventable with a vaccine, while hepatitis B and C can result in life-long infection and can cause serious harm.⁶ Hepatitis C, like hepatitis A, is curable, yet requires access to costly medications.⁷ Hepatitis B and C are the most common cause of liver cirrhosis and cancer,⁸ and people may not learn they have hepatitis B or C until their liver starts to shut down.⁹ It is estimated that 230,000 people in New York City have chronic hepatitis B (including those who are diagnosed and undiagnosed), and an additional 116,000 have chronic hepatitis C (including those who are diagnosed and undiagnosed).¹⁰ In 2018, 6,075 people were newly reported with chronic hepatitis B and 4,682 were newly reported with chronic hepatitis C.¹¹

⁴ *Id.*

⁵ New York City Department of Health and Mental Hygiene, *Hepatitis*, 2019, available at <https://www1.nyc.gov/site/doh/health/health-topics/hepatitis.page>; and New York City Department of Health and Mental Hygiene, *Hepatitis A, B and C in New York City: 2018 Annual Report*, 2019, available at <https://www1.nyc.gov/assets/doh/downloads/pdf/cd/hepatitis-abc-annual-report-2018.pdf>

⁶ *Id.*

⁷ Young, K., *Utilization and Spending Trends in Medicaid Outpatient Prescription Drugs*, Kaiser Family Foundation, February 15, 2019, available at <https://www.kff.org/medicaid/issue-brief/utilization-and-spending-trends-in-medicaid-outpatient-prescription-drugs/>

⁸ World Health Organization, *What is hepatitis?*, September 2019, available at <https://www.who.int/features/qa/76/en/>

⁹ New York City Department of Health and Mental Hygiene, *Hepatitis*, 2019, available at <https://www1.nyc.gov/site/doh/health/health-topics/hepatitis.page>

¹⁰ New York City Department of Health and Mental Hygiene, *Hepatitis A, B and C in New York City: 2018 Annual Report*, 2019, available at <https://www1.nyc.gov/assets/doh/downloads/pdf/cd/hepatitis-abc-annual-report-2018.pdf>

¹¹ *Id.*

Hepatitis in New York City, and DOHMH's Response

In 2018, DOHMH developed a strategic plan to define priorities and goals to address viral hepatitis.¹² The goals include (1) identifying and sharing information about trends in viral hepatitis infections to promote citywide improvements in health care access and treatment, (2) supporting health care organizations in eliminating hepatitis C and managing hepatitis B, and (3) substantially reducing new viral hepatitis infections in NYC.¹³

DOHMH documents and shares information on hepatitis A, B, and C, their impact on New Yorkers, and initiatives to promote access to care and treatment.¹⁴ For example, DOHMH releases information regarding the geographic distribution of cases of hepatitis B and C, showing that hepatitis B disproportionately impacts individuals living in Sunset Park East, Flushing, and Queensboro Hill, while hepatitis C is extremely prevalent on Riker's Island.¹⁵ Furthermore, through enhanced surveillance interviews, data has shown that hepatitis C, which disproportionately impacts men, is associated with certain risk factors, with nearly 70 percent of interviewees reporting exposure to a risk factor.¹⁶ Common risk factors include injection drug use (nearly 40 percent of respondents), intranasal drug use (about 25 percent), a history of homelessness (about 23 percent), and a history of incarceration (nearly 18 percent).¹⁷

DOHMH's data points to severe equity concerns. Despite hepatitis C being curable, people who are Latinx or Black are more likely to die from hepatitis C than others.¹⁸ In fact, the rate of treatment initiation among people newly reported with a positive hepatitis C ribonucleic acid (RNA) test has been declining since 2015, with only 30 percent of people reporting that they

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

have initiated treatment in 2018.¹⁹ Only 50 percent of people reported with chronic hepatitis C in 2015 had started treatment by the end of 2018.²⁰ Inequities also persist in the rate of treatment amongst those who have both hepatitis C and HIV.²¹ People living with HIV who are Black and Latinx, living in high poverty areas, and/or with no history of incarceration were less likely than their counterparts to receive treatment for hepatitis C.²² Inequities also persist amongst the rate of hepatitis B infection among people who give birth in New York City.²³ Hepatitis B disproportionately impacts people born outside the United States, mainly individuals who are Asian or Pacific Islanders and/or who were born in China.²⁴

DOHMH has several initiatives aimed to treat and eliminate viral hepatitis while also reducing new exposures.²⁵ For example, DOHMH funds 14 syringe programs to provide health care services to people who use drugs, and these programs distributed over 4.5 million syringes in 2018 alone.²⁶ Additionally, DOHMH provides patient navigation and linkage to care services, with very high success rates for people with hepatitis B who gave birth, and established the Viral Hepatitis Initiative, which has helped 33 community health organizations hire and train hepatitis B and C patient and peer navigators.²⁷ DOHMH also provides technical assistance and support to community organizations, health facilities, and syringe service and harm reduction programs, produces educational materials, and works to increase the capacity of community health and clinical providers to provide high-quality viral hepatitis care.²⁸

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

HIV/AIDS

Overview

HIV is a virus that is spread through certain body fluids and attacks the body's immune system.²⁹ HIV is commonly spread through sexual contact and injection drug use.³⁰ If untreated, HIV can cause a person's body to be unable to fight off infections and disease, and can lead to acquired immunodeficiency syndrome or AIDS.³¹ AIDS is the most severe phase of HIV infection, and, without treatment, individuals with AIDS typically survive only three years.³²

HIV attacks the body's cluster of differentiation 4 (CD4) cells, or T cells, which help one's immune system fight off infections.³³ Although HIV is incurable, antiretroviral medications can stop the virus from multiplying within the body and the sooner a person begins treatment the better protected they are against the spread of the disease.³⁴ In fact, medicine can allow a person to reach an undetectable viral load, which means the virus is reduced to the point that it does not show up on tests and cannot be passed to a partner during sex.³⁵

Data from DOHMH's HIV Surveillance Annual Report, 2018

In 2018, the number of new HIV diagnoses fell below 2,000 for the first time in New York City.³⁶ Although there were declines in new HIV diagnoses among men and women, all "major" racial/ethnic groups, residents of all boroughs, and nearly all age groups, increases in

²⁹ The Centers for Disease Control and Prevention, *About HIV/AIDS*, December 2, 2019, available at <https://www.cdc.gov/hiv/basics/whatishiv.html>

³⁰ DOHMH, *HIV/AIDS*, 2019, available at <https://www1.nyc.gov/site/doh/health/health-topics/aids-hiv.page>

³¹ The Centers for Disease Control and Prevention, *About HIV/AIDS*, December 2, 2019, available at <https://www.cdc.gov/hiv/basics/whatishiv.html>

³² *Id.*

³³ *Id.*

³⁴ DOHMH, *HIV: Undetectable Equals Untransmittable (U=U)*, 2019, available at <https://www1.nyc.gov/site/doh/health/health-topics/hiv-u-u.page>

³⁵ *Id.*

³⁶ HIV Epidemiology Program, *HIV Surveillance Annual Report, 2018*, DOHMH, November 2019, available at <https://www1.nyc.gov/assets/doh/downloads/pdf/dires/hiv-surveillance-annualreport-2018.pdf>

diagnoses were seen among those who are transgender, people age 50 to 59, and men who report both having sex with men and a history of injection drug use.³⁷

Inequities persist among those who are virally suppressed as well as those who were newly diagnosed in 2018.³⁸ In 2018, Black men had a rate of new HIV diagnosis of 100.8 out of 100,000 people, which was 1.5 times higher than the rate among Latinx men (68.1), over three times higher than the rate among multiracial men (31.9), and over five times higher than the rates among White (20), Asian and Pacific Islander (20.7), and Native American men (15.6).³⁹ Rates among Black women were also disproportionately high, with Black women having a diagnosis rate 3.2 times higher than the rate among Latinx women and over 11 times higher than the rates among white, Asian and Pacific Islander, and Native American women.⁴⁰ In 2018, 59 people who were identified as transgender were newly diagnosed with HIV, including 56 transgender women.⁴¹ Of these individuals, nearly 60 percent were Black, nearly 31 percent were Latinx, and only 6.8 percent were White.⁴² Although people born in the United States and its territories made up 63.9 percent of new HIV diagnoses, followed by Central and South America, those born in sub-regions of Africa had, by far, the highest rate of HIV diagnosis.⁴³

Of those living with HIV, individuals who are Black are more likely to die sooner after receiving an HIV diagnosis than their peers.⁴⁴ Although the death rate among those living with HIV has decreased greatly, 2.6 per 1,000 people living with HIV still died from an HIV-related illness in 2017, accounting for 28 percent of deaths for those with HIV.⁴⁵

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

PrEP/PEP

PrEP, or pre-exposure prophylaxis, is a daily pill that significantly reduces the risk of contracting HIV,⁴⁶ and PEP, or post-exposure prophylaxis, is an emergency medication for people who may have been exposed to HIV.⁴⁷ PrEP and PEP are covered by Medicaid and many private health insurers, and a person without health insurance may still access one or both through patient assistance programs.⁴⁸ Although patient assistance programs exist, the cost of PrEP is prohibitive⁴⁹ and can act as a barrier to accessing potentially life-saving care. The manufacturer of PrEP, Gilead Sciences, has inflated the price of PrEP by more than 25,000 percent, despite the medication costing less than \$6 a month to make.⁵⁰ Patients can be charged more than \$1,600 for a 30-day supply.⁵¹

In May 2019, Gilead Sciences said it would donate enough medication to supply 200,000 patients with the drug for up to 11 years; however, of about 1 million Americans estimated to be at risk for infection, only about 270,000 people take PrEP.⁵² Additionally, inequities persist among those who take PrEP, with reports indicating low numbers among communities that could benefit the most from PrEP, such as people of color.⁵³ As a result, the federal government has

⁴⁶ DOHMH, *Daily PrEP to Prevent HIV*, 2019, available at <https://www1.nyc.gov/site/doh/health/health-topics/pre-exposure-prophylaxis-prep.page>

⁴⁷ DOHMH, *Post-Exposure Prophylaxis (PEP)*, 2019, available at <https://www1.nyc.gov/site/doh/health/health-topics/post-exposure-prophylaxis-pep.page>

⁴⁸ *Id.*; DOHMH, *Daily PrEP to Prevent HIV*, 2019, available at <https://www1.nyc.gov/site/doh/health/health-topics/pre-exposure-prophylaxis-prep.page>

⁴⁹ #BREAKTHEPATENT available at <https://breakthepatent.org/>

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² Victor, D., *Trump Administration Sues Gilead, Maker of H.I.V.-Prevention Drug*, The New York Times, November 7, 2019, available at https://www.nytimes.com/2019/11/07/business/gilead-truvada-hiv-lawsuit.html?utm_source=STAT+Newsletters&utm_campaign=806ad5ba2b-MR_COPY_02&utm_medium=email&utm_term=0_8cab1d7961-806ad5ba2b-151778981

⁵³ The Human Rights Campaign, *CDC Report Highlights Disparity in PrEP Usage Among Communities of Color in the U.S.*, March 7, 2018, available at <https://www.hrc.org/blog/cdc-report-highlights-disparity-in-prep-usage-among-communities-of-color-in>

sued Gilead Sciences because taxpayer money was used to fund the development of PrEP.⁵⁴ The federal government also recently announced that it will roll out a delivery program of donated PrEP to people who should be taking it yet cannot because they do not have prescription drug coverage.⁵⁵

The City's Actions

There are national, state, and city-level efforts to End the Epidemic (ETE).⁵⁶ In New York City, DOHMH is working to reduce the number of new infections to fewer than 600 in 2020.⁵⁷ DOHMH works to increase access to HIV prevention services, such as PEP and PrEP, and has marketing campaigns aims to expand awareness of care, such as #PlaySure.⁵⁸ DOHMH also promotes innovative and optimal treatment for HIV, and has successfully ensured that most individuals living with HIV are in treatment and living with undetectable viral loads.⁵⁹ A large majority (84 percent) of people newly diagnosed with HIV in 2018 were linked to care within one month of diagnosis, and over half (53 percent) were virally suppressed within three months.⁶⁰ Additionally, 77 percent of people with HIV were virally suppressed in 2018.⁶¹ In

⁵⁴ Victor, D., *Trump Administration Sues Gilead, Maker of H.I.V.-Prevention Drug*, The New York Times, November 7, 2019, available at https://www.nytimes.com/2019/11/07/business/gilead-truvada-hiv-lawsuit.html?utm_source=STAT+Newsletters&utm_campaign=806ad5ba2b-MR_COPY_02&utm_medium=email&utm_term=0_8cab1d7961-806ad5ba2b-151778981

⁵⁵ Branswell, H., *Trump administration will provide HIV prevention drug for free to uninsured in new program*, STAT News, December 3, 2019, available at <https://www.statnews.com/2019/12/03/trump-administration-will-provide-hiv-prevention-drug-for-free-to-uninsured-in-new-program/>

⁵⁶ DOH, *Ending the AIDS Epidemic in New York State*, October 2019, available at https://www.health.ny.gov/diseases/aids/ending_the_epidemic/; HIV.gov, *What is 'Ending the HIV Epidemic: A Plan for American'?*, September 3, 2019, available at <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>; and DOHMH, *Ending the Epidemic Overview*, January 31, 2017, available at <https://www1.nyc.gov/assets/doh/downloads/pdf/ah/ete-strategy.pdf>

⁵⁷ DOHMH, *Ending the Epidemic Overview*, January 31, 2017, available at <https://www1.nyc.gov/assets/doh/downloads/pdf/ah/ete-strategy.pdf>

⁵⁸ *Id.*

⁵⁹ *Id.*; HIV Epidemiology Program, *HIV Surveillance Annual Report, 2018*, DOHMH, November 2019, available at <https://www1.nyc.gov/assets/doh/downloads/pdf/dires/hiv-surveillance-annualreport-2018.pdf>

⁶⁰ HIV Epidemiology Program, *HIV Surveillance Annual Report, 2018*, DOHMH, November 2019, available at <https://www1.nyc.gov/assets/doh/downloads/pdf/dires/hiv-surveillance-annualreport-2018.pdf>

⁶¹ *Id.*

2018, no infants born to HIV-positive people tested positive for HIV.⁶² Additionally, 87 percent of people living with HIV who were connected to care were virally suppressed in 2018.⁶³ The ACE (Assess. Connect. Engage.) Team, after investigating approximately 1,000 people living with HIV and not engaged in care, was able to re-engage 679, or 64 percent, of respondents.⁶⁴

DOHMH is also enhancing methods for tracing HIV transmission, which allows the department to map possible transmission networks, identify New Yorkers who may be at risk or infected with HIV, and link people to care.⁶⁵ Also as a part of ETE efforts, DOHMH educates local providers about sexual health care for all individuals, and works to expand and develop community programs targeting populations specifically at risk for HIV/AIDS.⁶⁶

III. Bill Analysis

Int. No. 1808: A Local Law in relation to examining the causes and conditions surrounding HIV/AIDS-related deaths in New York City.

The proposed legislation would require DOHMH to conduct a study of all HIV/AIDS-related deaths in the city between 2017 and 2019 to assess the causes and circumstances that lead to each death. The department would submit a report to the Speaker of the Council no later than December 31, 2020, outlining the findings of such study. The goal of this legislation is to understand where existing gaps in HIV/AIDS services exist, and how the City can address these gaps.

IV. Conclusion

The Committees plan to discuss the City's efforts to treat, prevent, and eliminate viral hepatitis and HIV. The discussion will focus on the comprehensive work DOHMH is already

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ DOHMH, *Ending the Epidemic Overview*, January 31, 2017, available at <https://www1.nyc.gov/assets/doh/downloads/pdf/ah/ete-strategy.pdf>

⁶⁶ *Id.*

doing to tackle these issues, while also examining ways we can build upon this work to continue to reduce hepatitis and HIV in New York City.

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Int. No. 1808

By Council Member Levine

A Local Law in relation to examining the causes and conditions surrounding HIV/AIDS-related deaths in New York City

Be it enacted by the Council as follows:

- 1 Section 1. The department of health and mental hygiene shall conduct a study of all HIV/AIDS-
- 2 related deaths in the city between 2017 and 2019 to assess, where applicable, the causes and
- 3 circumstances that lead to each death. The department shall submit a report to the speaker of the
- 4 council no later than December 31, 2020, outlining the findings of such study.
- 5 § 2. This local law takes effect 60 days after it becomes law, and is deemed repealed after the
- 6 submission of the report required pursuant to this local law.

ZH
LS #10628
11/18/19

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Res. No. 150

Resolution calling upon United States Food and Drug Administration to remove any blood donation restrictions based on sexual orientation.

By Council Member Dromm

Whereas, A ban on men who have had sex with other men (MSM) donating blood was enacted in 1983 by the United States Food and Drug Administration (FDA), when there was very little information on HIV/AIDS and even less information on care and treatment; and

Whereas, There have been significant advancements in science, technology and medical developments relating to HIV and AIDS over the last 35 years; and

Whereas, Several advanced testing methods for HIV can detect the presence of HIV in a donor's blood sample in approximately 7-10 days after infection; and

Whereas, Numerous public health groups including the American Red Cross, the American Association of Blood Banks, America's Blood Centers, the American Medical Association (AMA) and leading LGBT and HIV/AIDS organizations had urged that the FDA's lifetime restriction be revised; and

Whereas, The AMA has called for individual testing assessments instead of a blanket policy based on sexual orientation and has condemned the lifetime ban as "discriminatory"; and

Whereas, The New York Blood Center (NYBC) has alerted the public of several emergency blood shortages in New York in recent years; and

Whereas, In December 2015, the FDA finalized guidance for the industry, shifting from a complete ban on MSM to donate blood to a one-year deferral period since last male-to-male sexual contact; and

Whereas, The new deferral period essentially requires gay and bisexual men to remain celibate for a minimum of one year in order to donate blood, which in practicality prevents about half the blood donor population of sexually active gay men from donating; and

Whereas, The new FDA guidelines also address gender for the first time, stating that gender will be "self-identified and self-reported"; and

Whereas, Transgender advocates have found that in practice, this policy change does not provide clarification for potential transgender donors; and

Whereas, While the majority of men's health groups hailed the amendments in the new revised policy, they assert that these changes do not align with the latest developments in science; and

Whereas, GMHC, a New York City provider of HIV/AIDS prevention, care and advocacy alleges that the policy is based not on the actual risk assessments, but on other factors such as stigma, gender identity and sexual orientation; and

Whereas, An article released in the Journal of the American Medical Association states that a twelve month deferral is "equally arbitrary" to a lifetime ban and that sexual orientation should not be a disqualifier, but a component of an individualized risk assessment; and

Whereas, The FDA does not provide sufficient reasoning or data for how a one-year deferral period for MSM has been decided; and

Whereas, HIV testing methods, such as nucleic testing and antibody testing, are already in use to test every single blood sample before transfusion in the United States; and

Whereas, According to the Williams Institute at the University of California, Los Angeles, with a one year deferral period, an estimated 185,800 additional men are likely to

donate, and this number would almost double to 360,600 in case of a complete lifting of the ban;
and

Whereas, The Williams Institute estimates that lifting the ban on MSM donors could help save the lives of more than a million people; and

Whereas, Countries like Chile, Mexico, Italy, Portugal, Russia, Spain, Uruguay and South Africa all have no deferral periods based on sexual orientation, though their potential donors could be screened for high-risk sexual practices; now, therefore, be it

Resolved, That the Council of the City of New York calls upon the United States Food and Drug Administration to remove any blood donation restrictions based on sexual orientation.

SR/CP
LS 5460/Res. 816/2015
LS 1130
12/28/17