

The Honorable Andrew M. Cuomo
Governor of New York State
NYS State Capitol Building
Albany, NY 12224

The Honorable Dean G. Skelos
President, New York State Senate
Legislative Office Building, Room 909
Albany, NY 12247

The Honorable Sheldon Silver
Speaker, New York State Assembly
Legislative Office Building, Room 932
Albany, NY 12248

DATE

Subject: Invest in Ending New York’s Hepatitis C Epidemic

Dear Governor Cuomo, Senate President Skelos, and Assembly Speaker Silver,

On behalf of people living with hepatitis C, healthcare providers, and advocates committed to ending the hepatitis C epidemic in New York, the undersigned groups ask that New York State make a substantial new investment to address the hepatitis C virus (HCV) epidemic by providing \$20 million of annual funding to the Department of Health (DOH). We propose that new funding equally support scale-up of prevention – including harm reduction and drug treatment – and treatment services. Currently the State appropriates less than \$1.2 million annually for HCV programs, despite the epidemic affecting many more New Yorkers than HIV/AIDS.

With new medications that can cure HCV quickly and safely, and scientific evidence pointing the way toward combination prevention strategies that include wider testing, injection equipment access, drug treatment, sexual health services, and treatment, we finally have the opportunity to reverse the epidemic. This effort would build on the pioneering work of the State’s Plan to End the AIDS Epidemic by 2020, making New York an international model for addressing two of the world’s most challenging public health problems.

DOH and SUNY researchers have estimated that at least 215,000 New Yorkers have chronic HCV infection, with half unaware of their status.¹ Injection drug use is the leading risk factor for infection, and indeed new local outbreaks among young people

¹ Hart-Malloy R, Carrascal A, DiRienzo AG, Flanigan C, et. al. (August 2013). Estimating HCV Prevalence at the State Level: A Call to Increase and Strengthen Current Surveillance Systems. *American Journal of Public Health*, Vol. 103, No. 8.

have been identified alongside an increase in heroin use both Upstate New York² and nationally.³ Transmission among young injectors is a particular concern, with studies showing incidence of 10-35% per year.⁴ HCV is the leading cause of serious liver disease, which may lead to disability or death related to fibrosis, cirrhosis, liver cancer, and the need for transplantation. As many as 30% of people living with HIV (PLWH) in New York are HCV co-infected⁵, and HCV is a leading cause of death among PLWH.⁶ Nationally, an estimated 3.2 million Americans are living with chronic HCV, and the disease kills more Americans each year than AIDS.⁷ Both in New York and the rest of the country, HCV-related mortality has risen steadily during the past decade.⁸

With the recent FDA approval of a game changing new generation of all-oral, highly effective, and easy to tolerate anti-HCV drugs, we are finally at a moment where the epidemic can be reversed – and eventually eradicated – with the tools we have available. We recognize the serious challenge currently posed by Gilead’s excessive pricing for Sovaldi and Harvoni, the core drugs in the new anti-HCV treatment regimens. State Medicaid programs and other payers have begun to impose a variety of restrictions on access to treatment in order to contain costs. But this challenge can be overcome, just as has been done for HIV treatment, most recently in the case of New York’s successful negotiations to reduce drug prices as part of the Plan to End the AIDS Epidemic.

Reducing the price of treatment may be a necessary condition for ending the HCV epidemic, but it is not the only necessary condition. With targeted funding, New York can take steps to eliminate barriers to prevention, screening, care, and treatment, and maximize the impact of such services on the epidemic. For now, although New York has been a leader on HCV relative to other states, we still lack important components of HCV infrastructure after years of underinvestment.

New York has nonetheless made important progress in building the response to the epidemic. In 2013, you provided leadership to pass the first 1945-1965 birth cohort HCV testing law in the nation, a strategy that CDC scientists have recently found identifies five times as many cases as previously used strategies.⁹ DOH’s innovative Hepatitis C

² Zibbell JE, Hart-Malloy R, Barry J, Fan L, Flanagan C. (2014). Risk Factors for HCV Infection Among Young Adults in Rural New York Who Inject Prescription Opioid Analgesics. *American Journal of Public Health*, Vol. 104, No. 11.

³ Page K, Hahn JA, Evans J, Shiboski S, Lum P, Delwart E, et al. (2009). Acute hepatitis C virus infection in young adult injection drug users: a prospective study of incident infection, resolution, and reinfection. *J Infect Dis* Vol. 200, No. 8.

⁴ Hahn JA, Page-Shafer K, Lum PJ, Bourgois P, Stein E, Evans JL, et al. (2002). Hepatitis C virus seroconversion among young injection drug users: relationships and risks. *J Infect Dis*, Vol. 186, No. 11.

⁵ Taylor LE, Swan T, Mayer KH. (2012). HIV Coinfection With Hepatitis C Virus: Evolving Epidemiology and Treatment Paradigms. *Clinical Infectious Diseases*, Vol. 55 (suppl. 1).

⁶ Pinchoff J, Drobnik A, Bornschlegel K, Braunstein S, Chan C, Varma JK, Fuld J. Deaths Among People With Hepatitis C in New York City, 2000–2011. (2014). *Clinical Infectious Diseases*, Vol. 58, No. 8.

⁷ Ly KN, Jian X, Klevens RM, Jiles RB, et al. (2012). The Increasing Burden of Mortality From Viral Hepatitis in the United States Between 1999 and 2007. *Annals of Internal Medicine*, Vol. 156, No. 4.

⁸ NYC Department of Health & Mental Hygiene. (2013). Hepatitis C in New York City: State of the Epidemic and Action Plan. New York, NY.

⁹ Smith BD, Yartel AK, Brown KA, Krauskopf K, Massoud OI, et al. Effectiveness of Hepatitis C Virus (HCV) Testing for Persons Born during 1945-1965 - Summary Results from Three Randomized Controlled Trials. Presentation at the American Association for the Study of Liver Diseases conference, Nov. 11, 2014.

Care and Treatment Initiative has offered modest funding to 13 programs statewide to build capacity at hospitals and clinics. New York's more than 20 year history of support for syringe exchange and related harm reduction services, and its role in originating and expanding opioid agonist therapy for the treatment of opioid dependence, have influenced HIV, hepatitis, and drug services worldwide. Meanwhile, alongside the largest state-level HCV epidemic, New York has some of the most skilled medical providers, prevention specialists, researchers, and public health officials in the nation.

In short, most of the pieces are in place, but they need to be brought to scale.

New funding should be programmed by the DOH in consultation with the broader public health and medical communities. We would, however, prioritize new funding to be evenly apportioned for prevention and treatment activities (roughly \$10 million in each category), which would allow the following critical investments.

Prevention: High Coverage and Easy Access

Just as with HIV/AIDS, we cannot turn back the HCV epidemic without utilizing both new advances in treatment *and* full-scale prevention services. Evidence gathered over the past decades points to the need for a combination approach to prevention that prioritizes harm reduction, drug treatment, and access to other supportive services. In addition, prevention activities should pay due attention to sexual transmission, particularly among HIV-positive men who have sex with men, since HCV infection appears to be increasing among HIV-positive MSM, and may be more than twice as prevalent among this population than general adult population.¹⁰

Access to sterile syringes and other injection equipment, in combination with other harm reduction services, has been lauded for reducing HIV transmission among New York PWID from roughly 50% of new infections in the 1980s to less than 5% today.¹¹ But harm reduction programs have sometimes been criticized for not reducing HCV transmission to the same extent, an interpretation that ignores both the biology of HCV and epidemiological evidence in favor of harm reduction as an HCV prevention intervention. HCV is 10 times more transmissible than HIV,¹² unlike HIV it survives for weeks on non-syringe injection equipment,¹³ and HCV prevalence has historically been far higher than HIV among PWID (which means a greater chance of exposure).

¹⁰ Seaberg EC, Witt MD, Jacobson LP, Detels R, Rinaldo CR, Young S, Phair JP, Thio CL. (2014). Differences in hepatitis C virus prevalence and clearance by mode of acquisition among men who have sex with men. *J Viral Hepatitis*, Vol. 21, No. 10.

¹¹ NYS Department of Health. (2014). Comprehensive Harm Reduction Reverses the Trend in New HIV Infections. Albany, NY.

¹² Kwon JA, Iversen J, Maher L, Law MG, Wilson DP. (2009). The impact of needle and syringe programs on HIV and HCV transmissions in injecting drug users in Australia: a model-based analysis. *J. Acquir. Immune Defic. Syndr*, Vol. 51, No. 4.

¹³ Paintsil E, Binka M, Patel A, Lindenbach BD, Heimer R. (2014). Hepatitis C virus maintains infectivity for weeks after drying on inanimate surfaces at room temperature: implications for risks of transmission. *J Infect Dis*, Vol. 209, No. 8.

Historical data, however, document a sharp decrease in HCV transmission among New York PWID after the introduction of syringe exchange in the early 1990s, when incidence fell from an estimated 15-20% per month¹⁴ to 10-25% per year more recently.¹⁵ While this rate of transmission remains unacceptably high, a number of other studies point to reductions in HCV transmission ranging from 2% to more than 45% in locations with syringe access and other harm reduction services.¹⁶

Harm reduction in New York is deeply underfunded, and completely unavailable in much of the state, including in large sections of New York City, most of Long Island, and many Upstate communities. As the foundation of HCV prevention efforts, we call on the State to double the amount of funding from the current amount of just over \$8 million to approximately \$16 million per year total. New funding should be targeted using available data on HCV incidence and drug use (overdose mortality, drug-related hospitalizations, etc.) and directed toward serving young and other new injectors, filling geographic gaps in coverage, and enhancing HCV-specific programming. Doing so will safeguard against a new wave of HCV infections among young people and allow earlier linkage to healthcare and drug treatment.

New harm reduction funding will have the added benefit addressing a range of other drug-related issues for a high need population, including further reductions in HIV infection, care coordination as part of NYS Medicaid Redesign efforts, and improving uptake of drug treatment and primary healthcare.

To optimize HCV prevention, scientific studies strongly support increasing access to evidence-based drug treatment in combination with harm reduction services. When used together and instituted at sufficient scale, research has found as much as a 75% decrease in HCV incidence, significantly greater than either drug treatment or syringe access alone.¹⁷ A number of reforms to drug treatment systems are needed in order to improve quality, ensure that providers are offering evidence-based treatment, and to improve access. We would start by prioritizing expanded access to buprenorphine, a medication that is highly effective for opioid treating dependence and that, unlike methadone, may be prescribed by general practice physicians. But buprenorphine has been grossly underutilized, missing a key opportunity to support people with opioid dependence and consequently reduce injection drug use and the risk of HCV transmission and other harms. Aside from its role in HCV prevention, expanding buprenorphine access would carry all the additional benefits of medication-assisted

¹⁴ Garfein RS, Vlahov D, Galai N, Doherty MC, Nelson KE. (1996). Viral infections in short-term injection drug users: the prevalence of the hepatitis C, hepatitis B, human immunodeficiency, and human T-lymphotropic viruses. *Am. J. Public Health*, Vol. 86, No. 5.

¹⁵ Thorpe LE, Ouellet LJ, Hershov R, Bailey SL, Williams IT, et. al. (2002). Risk of hepatitis C virus infection among young adult injection drug users who share injection equipment. *Am. J. Epidemiol*, Vol. 155, No. 7.

¹⁶ Abdul-Quader AS, Feelemyer J, Modi S, Stein ES, et. al. (2013). Effectiveness of Structural-Level Needle/Syringe Programs to Reduce HCV and HIV Infection Among People Who Inject Drugs: A Systematic Review. *AIDS Behav*, Vol. 17, No. 9.

¹⁷ Hagan H, Pouget ER, Des Jarlais DC. (2011). A Systematic Review and Meta-Analysis of Interventions to Prevent Hepatitis C Virus Infection in People Who Inject Drugs. *J Infect Dis*, Vol. 204, No. 1.

opioid treatment, including reducing overdose deaths, reducing injection drug use, and more.¹⁸

The NYC Department of Health and Mental Hygiene recently announced a request for proposals, modeled on a successful statewide program in Massachusetts, to support expanded access to buprenorphine through Federally Qualified Health Centers and Opioid Treatment Programs. We support a parallel effort at the NYS level to ensure that Upstate and Long Island communities experiencing increased opioid and heroin use have the best available drug treatment resources.

Capacity to Provide Testing, Care, and Treatment, and Local Surveillance

It is thought that between 45-85% of people with chronic HCV infection are unaware of their status.¹⁹ Though New York's new birth cohort testing law is expected to increase access to testing, the law was not accompanied by funding for implementation. Many frontline community-based healthcare providers serving those at high risk of infection, for example, have few or no resources to provide testing and linkage to care activities. Furthermore, while New York has developed a high quality HCV surveillance program situated in the DOH, local surveillance efforts – the backbone of a functional system – have been chronically under-resourced. While NYS receives limited CDC funds for HCV surveillance efforts, but none are designated for local activity.

Even more important, new HCV treatments are easier to administer and require significantly less patient monitoring, meaning that trained primary care or other physicians can take a leading role in treatment delivery. This has the potential for greatly increasing treatment access by reducing the need for constant involvement by specialist hepatology clinicians, who are few in number and unevenly distributed around the state. It will, however, take years to develop the workforce to deliver treatment to a meaningful number of people in need.

New York should speed the development of expanded testing, linkage to care, and treatment services by increasing funding from less than \$1.2 million to \$10 million per year. New funding should primarily support expansion of DOH's successful Hepatitis C Care and Treatment Initiative, as well as additional programming around testing and surveillance.

This investment would lead to:

- A substantial decrease in the number of individuals with undiagnosed infection, therefore allowing them to take steps to avoid transmitting the virus to others, and to enter care to prevent debilitating and costly disease progression.

¹⁸ World Health Organization. (2009). Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence. WHO Press, Geneva.

¹⁹ Smith BD, Jorgensen C, Zibbell JE, Beckett GA. (2012). Centers for Disease Control and Prevention Initiatives to Prevent Hepatitis C Virus Infection: A Selective Update. *Clinical Infectious Diseases*, Vol 55, Suppl 1.

- New testing resources to support implementation of the 2013 birth cohort testing law, and increase testing opportunities for other people at elevated risk, including young injection drug users, people with criminal justice involvement, foreign-born individuals, and men who have sex with men, especially those who are HIV-positive.
- Enhanced linkage to care and other patient support services to ensure that patients are informed, connected, and retained in care.
- An expanded provider base within primary care and other non-hepatology disciplines so that treatment may reach all those in need, and do so more cost-effectively.
- Capacity for local surveillance activities in order to systematically collect and analyze HCV data for the purpose of informing programming and public funding.

Alongside funding care and treatment workforce and related activities, there is an urgent need for New York to negotiate significant price rebates for current and future anti-HCV medications. We encourage the State to begin such efforts now, with the backing of people affected by HCV and the organizations of which they are a part.

Regardless, there are potentially major cost savings associated with preventing new HCV infections and identifying and curing those who are already infected. Researchers have estimated HCV-related liver disease costs New York State between \$1.36 and \$2.43 billion per year in direct healthcare costs, lost productivity, and deaths.²⁰ Costs associated with HCV disease have been increasing sharply in recent years as more ‘baby boomers’ – the age cohort with the highest rate of infection – progress to cirrhosis and end-stage liver disease.²¹

Although cost-effectiveness studies on new HCV treatments are limited given the recent approvals of these medications, recent studies by the Veterans Administration and others have found expanded treatment access to be cost effective by usual standards,²²⁻²³ including for current injection drug users.²⁴ Moreover, newly approved medications have been estimated to require 30% fewer treatment courses to achieve cure in the same number of people, because they offer cure rates well above 90%, compared to the 40-60% range typically seen from the previous standard of treatment.²⁵ Similarly, while the cost effectiveness of harm reduction services for preventing HIV infection is well

²⁰ Hart-Malloy R, Flanigan C, Laufer F. (2013) Costs associated with hepatitis C: A model for estimating cost burden at the state level. Unpublished manuscript.

²¹ Wong J, McQuillan GM, McHutchison JG, Poynard T. (2000). Estimating future hepatitis C morbidity, mortality and costs in the United States. *Am J Public Health*, Vol. 90, No. 10.

²² Chan K, Lai MN, Groessl EJ, Hanchate AD, Wong JB, Clark JA, Asch SM, Gifford AL, Ho SB. (2013). Cost Effectiveness of Direct-Acting Antiviral Therapy for Treatment-Naive Patients With Chronic HCV Genotype 1 Infection in the Veterans Health Administration. *Clinical Gastroenterology and Hepatology*, Vol. 11, No. 11.

²³ Younossi ZM, Singer ME, Mir HM, Henry L, Hunt S. (2014). Impact of interferon free regimens on clinical and cost outcomes for chronic hepatitis C genotype 1 patients. *J Hepatology*, Vol. 60, No. 3.

²⁴ Martin NK, Vickerman P, Miners A, Hickman M. (2013). How cost-effective is hepatitis C virus treatment for people who inject drugs? *J Gastroenterology and Hepatology*, Vol. 28, No. 4.

²⁵ Martin NK, Hickman M, Hutchinson SJ, Goldberg DJ, Vickerman P. (2013). Combination interventions to prevent HCV transmission among people who inject drugs: modeling the impact of antiviral treatment, needle and syringe programs, and opiate substitution therapy. *Clinical Infectious Diseases*, Vol. 57, Suppl. 2.

established, few studies have specifically examined HCV; however, a major 10 year review by Australia found a more than \$1 billion return on investment from HCV prevention related to large scale syringe access programming.²⁶

In conclusion, New York has already made important advances in HCV policy, and prevention, care, and treatment services, but we lag far behind the scale of the epidemic. Now is the time to invest in programs that will reduce the pace of new infections, identify people in need of care and treatment, and ultimately both reduce the burden of death and disability and save the State millions of dollars. We thank you for your commitment to date to addressing the epidemic, and for your consideration of this budget proposal.

Sincerely,

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Organizations

1199SEIU Healthcare Workers East
ACT UP New York
Harm Reduction Coalition
Health GAP
Housing Works
National AIDS Treatment Advocacy Group (NATAP)
Treatment Action Group
VOCAL New York

Individuals

²⁶ National Centre in HIV Epidemiology and Clinical Research. (2009). *Return on investment 2: Evaluating the cost-effectiveness of needle and syringe programs in Australia*. Darlinghurst, NSW: Australian Government, Department of Health and Ageing.