October 13, 2014

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

Dr. Howard A. Zucker
New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Governor Cuomo and Dr. Zucker,

As people living with or at risk for hepatitis C, their advocates, and care providers – and as New York State voters and taxpayers – we write to express our serious concerns about proposed Medicaid criteria that will limit access to sofosbuvir and other lifesaving hepatitis C medications. We urge you to reject these restrictive criteria and to support a comprehensive plan to end New York's hepatitis C epidemic, as you have with HIV/AIDS.

On September 18, 2014, state officials made recommendations to the New York State Medicaid Drug Utilization Review Board (DURB) about several drugs, including dangerous restrictions on access to sofosbuvir (Sovaldi), a game-changing new treatment for hepatitis C virus (HCV). Unfortunately, DURB allowed an extremely short public comment period of only five days, and information about it was not properly publicized.

These restrictions will allow the HCV epidemic to continue to spread, since treatment will largely be withheld from the highest-prevalence population. They will also force people to live with a curable but highly infectious virus that will compromise their overall health, quality of life, and which can eventually cause serious organ damage.

New York State epidemiologists estimate that 200,000 people are infected with HCV in New York State. This is widely recognized as an underestimate, due to poor surveillance. If untreated, HCV can lead to cirrhosis, liver transplantation, and hepatocellular carcinoma. It can also cause autoimmune, dermatological, and other conditions outside of the liver. But hepatitis C is curable, and being cured reduces rates of liver-related illness and death by as much as 90%.

This is the first time in history we can cure hepatitis C without the use of interferon-based regimens, which cause significant side effects and have much lower cure rates. We have been waiting for these breakthrough treatments for decades. Treating and curing patients will result in the long-term savings of billions of dollars incurred by our health care system.

People who are cured of hepatitis C cannot pass the virus to others. As with HIV treatment, researchers have developed models that demonstrate the effect of HCV treatment on the rate of new infections. We could eradicate hepatitis C in New York with unrestricted access to treatment.

Hepatitis C can be easily cured with 12 weeks of oral medication, instead of 24 to 48 weekly injections of pegylated interferon and twice-daily ribavirin pills. Both these drugs have debilitating side effects and cure only about 55% of patients overall. In clinical trials, sofosbuvir-based regimens have been safe, tolerable and highly effective; cure rates have topped 95%.

The proposed clinical criteria for New York State Medicaid will limit access to sofosbuvir to certain patient populations. Restricting access to sofosbuvir will have disastrous consequences for individuals and for overall public health in New York. Private payers are likely to institute similar criteria, further limiting HCV treatment access.

Key restrictions:
Patients with HCV monoinfection must have advanced liver damage (pre-cirrhosis or cirrhosis) to become eligible for hepatitis C treatment.

- New York has been a national leader in the fight against AIDS and is already taking steps to address hepatitis C. But efforts to tackle our HCV epidemic will hit a dead end if access to curative treatment is restricted.
- New York has already passed a law requiring one-time HCV screening be offered to all persons born between 1945 and 1965, and allowing registered nurses to perform it. But once New Yorkers are screened and have been diagnosed with hepatitis C, they may be forced to develop serious liver damage before they can be treated and cured.
- The restriction in the proposed criteria to only treat patients with advanced disease (stages F3 and F4) unnecessarily puts many patients at risk for developing liver cancer. Hepatocellular carcinoma can develop before F3/F4, often starting in F2.
- Withholding treatment takes a toll on people living with hepatitis C, their families, and communities. Studies have reported that people with hepatitis C die decades earlier than their non-infected peers from heart disease, respiratory failure and other non-liver related illnesses. In people with cirrhosis, hospitalization and absenteeism rates are higher and quality of life is lower. Cure rates are lower in people with cirrhosis than in people with less liver damage, and they remain at higher risk for hepatocellular carcinoma, even after being cured.
- It does not make sense, clinically or ethically, to withhold treatment; especially in the context of laws that increase screening and diagnosis rates. It would be unacceptable to withhold antiretroviral therapy from HIV-positive people until they develop AIDS, and it is equally unacceptable to deny HCV treatment access until people develop pre-cirrhosis or cirrhosis.

People who are HIV/HCV coinfected must have undetectable HIV RNA to be eligible for HCV treatment

- End-stage liver disease from hepatitis C coinfection is a leading cause of death among HIV-positive people in the U.S. HIV increases the likelihood and rate of liver disease progression from hepatitis C, and worsens survival in people with advanced liver disease.
- Curing HCV in HIV-positive people reduces their risk of liver-related, AIDS-related and all-cause morbidity and mortality – and is therefore a life-saving intervention.
- Clinicians should use this opportunity to work together with patients to optimize HIV and HCV treatment outcomes.

“High-risk” patients – people with a history of, or current drug and alcohol use – should be treated on a case-by-case basis

- In the U.S., hepatitis C is most prevalent among people who inject drugs. According to the CDC, around 50% of HCV+ people in the U.S. are either current or former IDUs. There is no evidence base to support withholding HCV treatment from people who need and are willing to undergo it, regardless of current or past substance use.

- Treating and curing hepatitis C in people who use and inject drugs is the surest way to end the epidemic. The benefits to individual and public health should inform access to hepatitis C treatment, as they have with HIV treatment. No one accepts refusing antiretroviral therapy to people who use and inject drugs, especially in the absence of evidence to support such criteria.

The predictions that treating hepatitis C will bankrupt New York Medicaid are not based on facts.

- Although HCV treatment is overpriced, Medicaid programs receive a 23% rebate, and can negotiate deeper price reductions.
- In the first seven months since approval, sofosbuvir has been prescribed to 2,489 patients. This suggests an initial pace of treating around 5,000 patients per year, presumably increasing as more capacity is developed.
- Most New Yorkers who have hepatitis C have not been diagnosed, and it will take time before everyone can be treated and cured. If anything, lack of workforce capacity will curb spending on treatment, and once we develop a greater capacity we can negotiate larger discounts.

<u>We need a plan to end HCV in New York State—not treatment rationing!</u>

Since 2007, hepatitis C has killed more people in the U.S. than AIDS.

New York has been a trailblazer in the fight against HIV/AIDS, due to strong leadership and political will. We fully support, and are proud of New York’s plan to dramatically reduce new HIV infections and bring an end to the AIDS epidemic by 2020, which is seen as possible in part through serious pricing negotiations with drug companies. We can do the same for hepatitis C.

New York has taken groundbreaking steps to tackle the HCV epidemic, through legislation to increase access to HCV screening. But without access to treatment, people will have no reason to be screened and tested, and the epidemic will continue to spread.

Governor Cuomo, your leadership will lead to the end of AIDS in New York. You can do the same for hepatitis C, by convening an expert panel to develop a plan and timeline for ending the HCV epidemic in New York State, and allocating the resources to implement it. The plan must include steps to:

1) Improve surveillance, to identify routes of transmission, target prevention, care and treatment services, and forecast the need for HCV treatment;
2) Improve access to screening and diagnosis;
3) Scale up prevention – in partnership with the communities most impacted – to provide widespread access to sterile injection equipment and medication-assisted treatment for opioid dependence, in an environment free of stigma, following a risk-reduction model;
4) Provide unrestricted access to, and provision of HCV treatment, keeping the concept of Cure as Prevention (CasP) in the forefront;
5) Negotiate with industry and payors to make reimbursement for HCV prevention, care and treatment feasible.

Sadly, Medicaid's treatment criteria are based on budgetary considerations, not on a clinically sound, evidence-based, ethical, public health, and rights-based framework. They will allow the epidemic to continue spreading even though we now have what we need to eradicate it.

We call on you, Governor Cuomo, to demonstrate leadership in the fight to end HCV in New York, as you have with HIV.

We call upon you, Dr. Zucker, as acting New York State Health Commissioner, to reject the proposed Medicaid criteria and work to ensure access to sofosbuvir and other critical medications for all people with HCV.

We look forward to your response,

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