September 12, 2016

Hillary for America
Post Office Box 5256
New York, NY 10185-5256

Re: Importance of Addressing Hepatitis C in the United States

Dear Secretary Clinton,

The AIDS Institute, a national non-partisan non-profit dedicated to supporting and protecting health care access for people living with HIV/AIDS, Hepatitis, and others with chronic and serious health conditions, applauds you for your long time commitment to expanding health care in the United States. Because of your leadership, more people, including many low-income individuals and children, now have access to high-quality and affordable health care. We are especially appreciative for your work over the years combating HIV both domestically and globally. You truly have been a champion for people with HIV/AIDS, and we appreciate the attention you have given the issue during your campaign.

Given your extensive history in fighting for health care for the underserved, we were disappointed in several inaccuracies in your comments regarding Hepatitis C (HCV) and drug pricing at your August 17th event in Cleveland, Ohio.

HCV is a serious deadly infectious disease. Every year, approximately 20,000 people in the United States die from HCV and its complications. According to the Centers for Disease Control and Prevention (CDC), more than one third of the estimated 3.5 million persons living with HCV are expected to die from HCV-related complications that could be averted with care and treatment. The CDC additionally reports the annual number of HCV-associated deaths now exceed the number of deaths from 60 other nationally notifiable diseases (including HIV) combined. The number of deaths is on the rise, with a nearly 20 percent increase in annual deaths since 2010.  

Due to the significant investment by life sciences companies into research and development, new therapies for the treatment of HCV have been discovered and approved. After years of treatment...

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1 Centers for Disease Control and Prevention, Viral Hepatitis - Hepatitis C Information, Updated May 2016, http://www.cdc.gov/hepatitis/hcv/statisticshcv.htm
therapies that were very difficult to administer and tolerate, and had lower cure rates, the new drugs are easy to take, have little to no side-effects, and almost always lead to a cure. This is something that should be celebrated.

The issue of drug pricing is extremely complex and cannot be told easily in sound bites. While headlines may continue to claim that HCV curative drugs cost $1,000 a pill or $84,000 for the entire multi-week treatment regimen, that was the initial list price and never the actual price paid by Medicaid, Medicare, or private insurers. As you know, public payers such as Medicaid, Medicare, and Tricare, receive substantial rebates and discounts from the list price. For example, state Medicaid programs automatically receive a 23 percent rebate and negotiate additional discounts. Drug companies also participate in the 340B drug pricing program which requires drug manufacturers to provide outpatient drugs to eligible health care organizations, also at a minimum 23 percent discount. Private insurance companies, who often work with pharmacy benefit managers, also negotiate discounted prices and enter into rebate agreements with drug manufacturers to acquire drugs at a much lower cost than the list price. According to the Senate Committee on Finance’s bipartisan report on drug prices, issued prior to the approval of some of the now available HCV curative drugs, industry experts believe discounts to the new HCV drugs are upwards of 40 percent off the list price.2

Competition is driving down HCV drug prices. The first of the new curative HCV drugs was approved just over two years ago. Since then, several new therapies by different manufacturers have been approved with lower list prices. This has created a very competitive market allowing purchasers to demand additional substantial discounts. Due to our drug patent laws, manufacturers have a limited time before their patents expire and their drugs can become generic. At that time, it is expected that prices will continue to drop.

The cost effectiveness of these new drugs is undisputed. Patients with HCV frequently progress to severe liver disease and liver cancer, and some patients require liver transplants. By curing HCV, especially early, the costly treatments for liver disease, liver cancer and liver transplants can be reduced or avoided altogether. The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America released a joint report examining six cost-effectiveness studies of the new HCV drugs. The report found the HCV drugs were cost-effective 80 percent of the time because money spent on the HCV cure today is more than recouped by the prevention of costly treatments down the road.3 The International Society for Pharmacoeconomics and Outcomes Research released a study in June that stated, “current Medicaid policies restricting HCV treatment to patients

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with advanced disease are more costly and less effective than unrestricted, full-access strategies.”

And, a review in *Infectious Agents & Cancer* examined the findings of more than 30 different cost-effectiveness studies on HCV medications and found the newer HCV drugs are more cost-effective than the previous treatment options, even at the current prices. As the prices continue to go down, the cost effectiveness will continue to go up.

The greatest concern for The AIDS Institute at this time is the barriers several payers have discriminatorily enacted that prohibit patients from accessing curative treatments.

Currently, numerous state Medicaid programs are restricting access by allowing only patients with severe liver disease or who pass sobriety tests to receive curative treatments. States are preventing access to these drugs despite their legal requirements to provide them. While they may be doing this for short-term cost savings, requiring patients to progress to severe liver disease will require more long-term care and higher costs. Fortunately, the Centers for Medicare and Medicaid Services (CMS) sent a State Notice in November 2015 warning states that they cannot restrict access to approved HCV drugs for non-medical reasons. Since that Notice, some states have expanded access to the medications, but this has mostly come about as a result of litigation or the threat of litigation, which is a long, arduous, and costly process. If you are elected President, The AIDS Institute hopes your administration will continue to enforce the Medicaid statute and ensure that states are complying with the law. Patients should not have to rely on state-by-state litigation to ensure access to FDA approved drugs that can cure them.

The AIDS Institute is also very concerned with the access restrictions several private insurance companies are instituting that prevent beneficiaries with HCV from accessing curative medications. While some insurers cover the drugs with reasonable co-pays, others do not put the HCV drugs on their formularies, and if they do, are placing them on the highest cost-sharing tier, frequently with coinsurance of 30, 40 or 50 percent. This makes the drugs cost prohibitive to the beneficiary and can lead to the detriment of their health. We believe practices such as these run contrary to the strong patient protections and nondiscrimination provisions included in the Affordable Care Act (ACA). We applaud your proposal to limit patient co-pays on private insurance plans and look forward to working with you to ensure the ACA patient protections and nondiscrimination provisions are enforced if you are elected President.

The next administration must make it a priority to eliminate HCV as a public health threat in the United States. The 3.5 million Americans living with HCV are looking forward to the day that once diagnosed, they can be linked to care and treatment and be cured of their virus.

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Eliminating HCV as a public health threat is not a pipe dream. Several studies by leading national and international health organizations have recently detailed exactly how elimination can happen. In March of this year, the Division of Viral Hepatitis at CDC released their report “Strategic Plan, 2016–2020: Bringing Together Science and Public-Health Practice for the Elimination of Viral Hepatitis.” In it the CDC outlined the steps the United States can take over the next five years to start to eliminate HCV and Hepatitis B (HBV) in the United States. The following month, the National Academies of Sciences released phase one of their report “Eliminating The Public Health Problem of Hepatitis B and C in The United States,” which discusses the feasibility of eliminating HBV and HCV from the United States. The month after, the World Health Organization released their report “Combating Hepatitis B and C to Reach Elimination by 2030,” which laid out how to eliminate HBV and HCV globally. In a span of several months, three highly respected health organizations laid out similar blueprints on how HCV can be stopped both nationally and globally.

In order to achieve these goals, a strong commitment and necessary resources will be required. Soon, the Obama Administration will be releasing its Updated National Viral Hepatitis Action Plan, which will describe goals, strategies, and efforts to be undertaken from 2017 to 2020. The AIDS Institute urges you, if you are elected President, to continue to implement this Action Plan. Additionally, we urge you to dramatically increase in your first proposed budget, funding for CDC’s Division of Viral Hepatitis to scale up testing, surveillance and education programs. Current funding for the Division is woefully inadequate.

Again, we thank you for your long time commitment to improving health care in our Nation. The issue of HCV is extremely critical to the public health of our country. In order to further discuss this issue, The AIDS Institute would very much like to meet with representatives of your campaign at their earliest convenience. To arrange such a meeting, please contact Carl Schmid, Deputy Executive Director, The AIDS Institute at cschmid@theaidsinstitute.org.

Thank you very much. We look forward to hearing from your representatives.

Sincerely,

Michael Ruppal
Executive Director

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