November 17, 2010

Jeffrey Zients
Acting Director
725 17th Street, NW
Washington, DC 20503

Dear Mr. Zients:

On behalf of the undersigned organizations committed to increasing the federal government's response to viral hepatitis, we thank you for your leadership toward building a health care system that meets the needs of all Americans. **To that end we request the inclusion of increases in funding for programs that address viral hepatitis in the President's FY2012 budget**.

The most common viral hepatitis diseases, hepatitis B and C, affect nearly six million Americans; the vast majority of whom do not know they are infected. Viral hepatitis can lead to chronic liver disease, cirrhosis, liver cancer and liver failure. Each year, complications from these chronic infections claim 15,000 lives. To help ensure that those at higher risk of infection are protected and those currently infected are diagnosed and receive lifesaving medical care, we request increased federal resources for the prevention, medical management, treatment and research of viral hepatitis. With the release of the evidence-based recommendations in the Institute of Medicine's (IOM) viral hepatitis report, the pending HHS *Viral Hepatitis Action Plan* and the Division of Viral Hepatitis's professional judgment (PJ) budget, the government now has a comprehensive roadmap for its prioritization of hepatitis resources.

As you finalize the President's FY2012 budget, we ask that you consider the following critical funding needs to address the viral hepatitis epidemics. In addition to the typical discretionary process, we encourage you to leverage funding through the Affordable Care Act's (ACA) Prevention and Public Health Fund and through integration and eligibility of viral hepatitis into other health reform initiatives and funding mechanisms for activities not currently being funded at the Centers for Disease Control and Prevention (CDC).

Specific funding needs:

- Funding is needed for the HHS Office of the Assistant Secretary for Health (ASH) to support increased capacity for the implementation of the *HHS Viral Hepatitis Action Plan*;
- At least $40 million to CDC's Division of Viral Hepatitis (DVH) for the Division's program and resource priorities as outlined in its PJ to support:
    - $25 million for a national viral hepatitis testing and education initiative;
    - $15 million for a national surveillance initiative;
- At least $16 million to CDC's National Center for Immunization and Respiratory Diseases (NCIRD) for the continuation of the Adult Hepatitis B Vaccination Initiative through the Section 317 Vaccine Program;
- At least $10 million for the Substance Abuse and Mental Health Services Administration (SAMHSA) to fund a project within the Special Projects of Regional and National

Significance (SPRNS) to reach persons who use drugs with viral hepatitis prevention services;

General funding needs:

- We strongly encourage that funding to Community Health Centers (CHC) which provide a safety net for persons who may not benefit from increased access under the reforming health system go to increase their capacity to serve people at-risk or affected by viral hepatitis;
- Increase funding for the Ryan White Program to adequately cover persons co-infected with viral hepatitis through additional case management, provider education and coverage of viral hepatitis drug therapies;
- At least $35 billion to the National Institutes of Health to include support for their *Action Plan for Liver Disease Research*;

Please see the following attachment that provides in greater detail our FY2012 funding asks. The viral hepatitis community welcomes the opportunity to work with you and your staff on this important issue. Please contact Colin Schwartz with the Hepatitis Appropriations Partnership at 202.434.8005 or cschwartz@NASTAD.org if you have any questions or need additional information.

Attachment (1)

cc Jeff Crowley, ONAP
Greg Millett, ONAP
Howard Koh, HHS OASH
Ron Valdiserri, HHS OASH
Rosie Henson, HHS OASH
Marc Garufi, OMB
Aaron Lopata, OMB
Laurie Mignone, OMB
Tricia Schmitt, OMB
Thomas Frieden, CDC
Michael Craig, CDC
Kevin Fenton, CDC NCHHSTP
John Ward, CDC DVH
Dan Riedford, CDC DVH

Sincerely,

AIDS Community Research Initiative of America, New York, NY
AIDS Project Los Angeles, Los Angeles, CA
AIDS Treatment Activists Coalition, New York, NY
ALERT Health Inc, North Miami, FL
Alianza of New Mexico, Roswell, NM
American Association for the Study of Liver Diseases, Alexandria, VA
American Liver Foundation, New York, NY

American Social Health Association, Washington, DC
Asian Health Foundation, Parsippany, NJ
Asian Health Services, Oakland, CA
Association of Asian Pacific Community Health Organizations, Oakland, CA
Boulder County AIDS Project, Boulder, CO
C.O.R.E. Medical Clinic, Inc., Sacramento, CA
California Hepatitis Alliance, Sacramento, CA
California Prison Focus, Oakland, CA
Caring Ambassadors Program, Inc., Oregon City, OR
Center for Health Improvement, Sacramento, CA
Chicago Recovery Alliance, Chicago, IL
Chinatown Service Center, Los Angeles, CA
CitiWide Harm Reduction, Bronx, NY
City View Pharmacy, Astoria, NY
Community Access National Network, Jersey City, NJ
Community Health Action of Staten Island, Staten Island, NY
Community Wellness Program, New Mexico Department of Health, Santa Fe, NM
Downtown Manhattan Heptatitis C Support Group, NY, NY
Education for Healthy Choices, Sacramento, CA
Georgia AIDS Coalition, Snellville, GA
H.E.A.L.S. of the South (Hepatitis Education Awareness and Liver Support), Tallahassee, FL
Harlem United, New York, NY
Harm Reduction Coalition, New York, NY
Hep C Connection, Denver, CO
Hep C Meditations Project, San Francisco, CA & Seattle, WA
Hep Help of New Jersey Alliance, Inc., Lanoka Harbor, NJ
Hepatitis Appropriations Partnership, Washington, DC
Hepatitis B Coalition of WA (WithinReach), Seattle, WA
Hepatitis B Foundation, Doylestown, PA
Hepatitis B Initiative, Washington, DC
Hepatitis C Association, Scotch Plains, NJ
Hepatitis Education Project, Seattle, WA
Hepatitis Support Network of Hawaii, Honolulu, HI
HIVictorious, Inc., Madison, WI
International Association of Physicians in AIDS Care (IAPAC), Washington, DC
International Community Health Services, Seattle, WA
LiverHope, Minnetonka, MN
Malama Pono Health Services, Lihue, Kauai, HI
Metropolitan Community Churches, Washington, DC
Michigan AIDS Coalition, Ferndale, MI
Midwest Asian Health Association, Chicago, IL
Mo Hepatitis C Alliance, Columbia, MO
National Alliance of State and Territorial AIDS Directors, Washington, DC
National Coaltion of STD Directors, Washington, DC
National Latino AIDS Action Network (NLAAN), Washington, DC

National Task Force on Hepatitis B: Focus on Asian and Pacific Islander Americans, Palo Alto, CA
National Viral Hepatitis Roundtable, CA
New Mexico Hepatitis C Alliance, Santa Fe, NM
New York Harm Reduction Educators, Inc., Bronx, NY
North Carolina Harm Reduction Coalition, Winston-Salem, NC
North Shore Health Project, Gloucester, MA
NYU Medical Center Hepatitis C Support Group, New York, NY
O'Connor Hospital Hepatitis C & Hepatitis B Support Group, Delhi, NY
OraSure Technologies, Inc, Bethlehem, PA
Project Aware at Stanley Street Treatment and Resources, Fall River, MA
Project ECHO, Albuquerque, NM
Project Inform, San Francisco, CA
San Luis Obispo County AIDS Support Network, San Luis Obispo, CA
San Luis Obispo County Hepatitis C Project, San Luis Obispo, CA
Southeast Asian Assistance Center, Sacramento, CA
Southwest CARE Center, Santa Fe, NM
Spears Foundation For Hepatitis C, Franklin, TN
Status C Unknown, Medford, NY
SUNY Downstate College of Medicine Swan Project, Brooklyn, NY
Test Positive Aware Network, Chicago, IL
The AIDS Institute, Washington, DC
The Family Services Network Of New York, Inc, Brooklyn, NY
The Foundation for Research on Sexually Transmitted Diseases, Inc (FROST'D), NY, NY
The National Association of People with AIDS, Washington, DC
Total Health Awareness Team, Rockford, IL
Treatment Action Group, New York, NY
UHAP / Upstate New York Hepatitis C Awareness Project, Delancey, NY
Vertex Pharmaceuticals Inc., Cambridge, MA
Voices of Community Advocates and Leaders, Brooklyn, NY
VT Harm Reduction Coalition/ Opiate Dependence Resource Center, E. Dummerston, VT
Weill Medical College of Cornell University Center for the Study of Hepatitis C, New York, NY
Yvonne Frazier Consulting, San Francisco, CA

The Hepatitis Appropriations Partnership (HAP) is a national coalition based in Washington, DC and includes community-based organizations, public health and provider associations, national hepatitis and HIV organizations, and diagnostic, pharmaceutical and biotechnology companies from all over the country. HAP works with policy makers and public health officials to increase federal support for hepatitis prevention, testing, education, research and treatment. For more information, please contact Colin Schwartz at 202.434.8005 or cschwartz@NASTAD.org.

Detailed FY2012 Viral Hepatitis Funding Asks

It is absolutely essential that we respond aggressively to address the rising death rate caused by viral hepatitis in the United States. This is particularly urgent due to the rising incidence rate of viral hepatitis among disproportionately impacted populations. In 2007 alone, the CDC estimated that 43,000 Americans were newly infected with hepatitis B and 17,000 with hepatitis C. Unfortunately, it is believed that these estimates of hepatitis B and C infections are just the tip of the iceberg, since we lack sufficient data in the absence of an adequate surveillance system. Most people living with hepatitis B and over three-fourths of people living with hepatitis C are unaware that they are infected. Further, the baby boomer population currently accounts for two out of every three cases of chronic hepatitis C. As these Americans continue to age, they are likely to develop complications from hepatitis C and require expensive medical interventions. It is also estimated that this epidemic will increase costs by billions of dollars to private insurers and public systems of health such as Medicare and Medicaid, and account for additional billions lost due to decreased productivity from the millions of American workers suffering from chronic hepatitis B and C.

Viral hepatitis did not receive any of the $650 million in prevention and wellness funding authorized under the American Recovery and Reinvestment Act of 2009. Unlike other infectious diseases such as HIV, it also did not receive any of the $500 million of the Prevention and Public Health funding neither established in the Affordable Care Act in FY2010 nor is it slated to receive any of the $750 million in FY2011. Further, the CDC's Section 317 Vaccine Program's Adult Hepatitis B Vaccination Initiative, which helped expand hepatitis B vaccine to at-risk adults with a funding high of $20 million, has recently been discontinued. Finally, we believe health reform will not provide complete relief because there is scant investment in the public health infrastructure to provide core prevention and care services to these people. In addition, healthcare providers neither know nor screen for viral hepatitis and do not readily deliver hepatitis A and B vaccines to adults at highest risk. Similarly, much of the people impacted by viral hepatitis such as those incarcerated or who inject drugs are not covered and are difficult to reach under the reformed health system.

With the 2010 release of the Institute of Medicine (IOM) report, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*, the federal government has the opportunity to improve its response with the implementation of the IOM's evidence-based recommendations. The report attributes the profound ignorance among the American public and our health providers, the large health disparities and the current hepatitis morbidity and mortality, to the lack of adequate financial resources. On the heels of this report, the Assistant Secretary for Health, Dr. Howard Koh, has convened an interagency working group on viral hepatitis set to release a national action plan this fall. The implementation of the IOM recommendations must be given the financial resources to collaborate with key stakeholders, including state and local health departments, professional organizations, health care organizations, and community-based organizations to reduce the morbidity and mortality related to chronic viral hepatitis.

Increased Capacity Support for HHS Viral Hepatitis Action Plan
We ask for increased funding to support greater capacity for the implementation of the *HHS Viral Hepatitis Action Plan* in the HHS Office of the Assistant Secretary for Health (ASH).

The President's FY2012 budget must support increased capacity in order to realize the priority initiatives in Dr. Howard Koh's *HHS Action Plan on Viral Hepatitis*. Without adequately resourcing the staff needed to successfully implement the plan, we are concerned that the ASH will not be able to deliver on commitments to leverage new funding opportunities, integrate activities throughout HHS or strengthen partnerships with federal, professional, public health and patient organizations. Even goals of the plan that will not require dedicated funding such as harmonizing screening guidelines and creating new strategies for workforce development will not come to fruition without increased staff support. Increasing the federal response to the viral hepatitis epidemics require such a commitment.

National Testing, Education and Surveillance Initiative
We ask for an increase of at least $40 million for the Centers for Disease Control and Prevention's (CDC) Division of Viral Hepatitis (DVH) go to the development and implementation of a national testing, education and surveillance initiative.

According to DVH's professional judgment (PJ) budget requested by Congress, its top priority is to identify persons with viral hepatitis early and refer them to care with the first key strategy of wide access to testing. The Administration has shown great leadership to combat other infectious diseases like HIV/AIDS with a national strategy that anticipates increasing from 79 percent to 90 percent the percentage of people who know they are living with HIV. Compared to viral hepatitis, only 25-35 percent of people know they are living with chronic infection. It is unconscionable that there is an epidemic impacting nearly six million people in this country as the leading cause of liver disease and cancer, and an estimated four million do not know they are infected. The Administration must engage in comparable efforts as it has done with HIV to successfully decrease incidence and increase awareness with viral hepatitis through a national testing initiative that provides funding for testing and infrastructure, develops a national testing goal and supports a monitoring and evaluation component. Once identified, there are effective treatments and care that can delay or halt disease progression. According to the PJ, "identifying those who are infected and referring them to appropriate care can greatly reduce the public health and economic consequences of viral hepatitis."

With the increase in testing, the PJ's second priority is to improve the monitoring of viral hepatitis. We must modernize and begin to fund a national chronic viral hepatitis surveillance system that is on par with other infectious diseases like HIV. The federal government must provide funds to implement and integrate a national chronic surveillance system with all state and territorial health departments. This information is critical to understanding the impact of the hepatitis epidemics, identifying and averting outbreaks and to targeting limited resources for its greatest impact.

Vaccination of Adults At-Risk of Viral Hepatitis

We ask for at least $16 million for CDC's National Center for Immunization and Respiratory Diseases (NCIRD) go to continue the Adult Hepatitis B Vaccination Initiative through the Section 317 Vaccine Program.

The greatest remaining challenge for hepatitis A and B prevention is the vaccination of high-risk adults. High-risk adults account for more than 75 percent of all new cases of hepatitis B infection each year and annually result in an estimated $658 million in medical costs and lost wages. This is unacceptable as we have had a vaccine against hepatitis B for more than 25 years, yet there exists no funding for a national adult vaccination program.

In previous fiscal years, CDC had identified funds through program cost savings in the Section 317 Vaccine Program, allocating $20 million in FY2008 and $16 million in FY2009 and FY2010 for purchase of the hepatitis B vaccine for at-risk adults. While this initiative did not support any infrastructure or personnel for health departments to deliver the vaccine, and the funding was neither adequate nor consistent, it was an unprecedented expansion of the vaccine into our nation's public health system. The elimination of this funding will force immunization programs to rely on existing federal and/or other funds to continue adult hepatitis B vaccination activities in an already limited fiscal environment. Finally, health reform will not necessarily provide relief despite provisions of little to no cost of vaccine to the patient because health care providers are not always reimbursed adequately for their cost of the vaccine and therefore do will not deliver it. Similarly, much of this initiative's vaccine was delivered in prisons and jails; reaching at-risk adults who will not be covered under the reformed health system.

We believe that total discontinuation of this initiative is a step backwards in our efforts to eliminate hepatitis B in the U.S. Given the lack of fiscal resources dedicated to hepatitis B prevention among at-risk adults, this limited funding was a welcome change in the right direction is essential to elimination efforts.

Prevention for People who Use Drugs

We ask for at least $10 million for the Substance Abuse and Mental Health Services Administration (SAMHSA) to fund a project within the Special Projects of Regional and National Significance (SPRNS) to reach persons who use drugs with viral hepatitis prevention services.

Persons who use drugs are disproportionately impacted by hepatitis B and C. SAMHSA's Center for Substance Abuse Prevention (CSAP) and Center for Substance Abuse Treatment (CSAT) are uniquely positioned to reach populations at risk for hepatitis B and C. The existing infrastructure of substance abuse prevention and treatment programs in the United States provides an important opportunity to reach Americans at risk or living with viral hepatitis.

Medical Management and Treatment

Access to available treatments and treatment support services are critical to combat viral hepatitis mortality. While we are supportive of the President's efforts to modernize and expand access to health care, we also support increased funding for existing safety net programs. Low-

income patients who are uninsured or underinsured can and do seek services at Community Health Centers (CHCs). With the growing importance of CHCs as a safety net in providing frontline support for these individuals, we support increasing resources for CHCs to increase their capacity to serve people with chronic viral hepatitis.

We urge you to increase Ryan White funding so states can provide adequate coverage for co-infected clients. Many low-income individuals co-infected with viral hepatitis and HIV can obtain services through the Ryan White Program, however only half of the state AIDS Drug Assistance Programs (ADAPs) are able to provide viral hepatitis treatments to co-infected clients. Increased resources are also needed to improve provider education on viral hepatitis medical management and treatment, to cover additional case management for patients undergoing treatment and to allow more states to add viral hepatitis therapies and viral load tests to their ADAP formularies. While Ryan White providers offer lifesaving care to co-infected clients, they also have the expertise and infrastructure to provide limited services to viral hepatitis mono-infected clients.

Research

We ask at least $35 billion for the National Institutes of Health to increase support for their *Action Plan for Liver Disease Research.*

Finally, research is needed to advance understanding of prevention, pathogenesis, management and treatment of chronic viral hepatitis, and to develop strategies to delay liver disease progression, which too often ends in primary liver cancer. Hepatitis B antiviral drugs have overlapping resistance profiles; new drugs from different classes are needed to forestall and surmount resistance. There is no preventive HCV vaccine; more research is needed to identify and develop one. Dozens of new treatments for hepatitis C virus are in development, but there is no new clinical network to explore multi-drug treatment strategies with drugs from different classes and from different sponsors, or to study drug safety, efficacy and tolerability in understudied populations and those with the most urgent need, such as transplant candidates and recipients who usually lack access to these life-saving drugs until they have been approved. The Liver Disease Branch, located within the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), has developed a detailed *Action Plan for Liver Disease Research* that addresses these issues but lack of funding has hindered scientific progress. While several critical NIDDK biomedical research projects have already been supported by investments in NIH from the American Recovery and Reinvestment Act (ARRA), this one time funding is not a substitute for robust and sustainable growth and does not address long-term needs. A FY2012 funding level for NIH of at least $35 billion is necessary to support the recommendations and action steps outlined in this *Action Plan for Liver Disease Research* and to expand and leverage the current momentum of viral hepatitis biomedical research in NIDDK.