

Raising the Profile, Raising Your Voice:

A Primer on Viral Hepatitis Policymaking
and Programs at the Federal Level



Raising the Profile, Raising Your Voice:

The National Alliance of State and Territorial AIDS Directors (NASTAD) represents the nation's chief state health agency staff who have programmatic responsibility for administering HIV/AIDS and viral hepatitis health care, prevention, education and supportive services programs funded by state and federal governments. More than one half of state adult viral hepatitis programs fall under the purview of the state AIDS director. State HIV/AIDS programs are increasing collaboration with adult viral hepatitis programs and are more formally integrating viral hepatitis into their HIV/AIDS and STD portfolios.

This *Primer* was prepared by Laura Hanen, Director of Government Relations; Terrance Moore, Senior Manager, Government Relations; Chris Taylor, Manager, Viral Hepatitis Program; Britten Ginsburg, Associate, Care and Treatment Program; Rebecca Sullivan, Intern; and Shawn Magnuson, Intern.

For more information on NASTAD's work on viral hepatitis policy and programs, go to www.NASTAD.org

Julie M. Scofield, Executive Director

Andre Rawls, *Illinois*, Chair

May 2007

Introduction

Since the identification of the hepatitis B virus (HBV) in 1963, multiple forms of the hepatitis virus have been identified and progress towards fighting the viruses has been made. In 1981, a vaccine was introduced to prevent HBV and in 1995, hepatitis A virus (HAV) also became a vaccine preventable disease. Infants have routinely been vaccinated against HBV since 1991 and HAV since 1995, dramatically reducing the incidence of HAV and HBV in children. Higher rates of hepatitis B continue among adults, particularly males aged 25–44 years, which points to the need to vaccinate adults at risk for HAV and HBV infection.¹

Hepatitis C virus (HCV) was first identified in 1988 and was responsible for many of the non-A and non-B hepatitis infections that were occurring in blood transfusion patients.² No vaccine has been found for HCV and it continues to be the most common blood-borne, chronic viral disease in the United States. Viral hepatitis is one of the leading indications for liver transplants. In addition, approximately 33 percent of individuals infected with HIV are co-infected with hepatitis C and ten percent are co-infected with hepatitis B.

Continued declines in revenue and increased resources being allocated to other spending priorities have led to the erosion of funding for public health. These funding cuts impede public health from offering the most basic services to address viral hepatitis, including counseling, testing, and referral; hepatitis A and B vaccination for high-risk adults; medical management; and drug therapy. Each year since FY2003, there has been a decline in funding at the Centers for Disease Control and Prevention (CDC) for viral hepatitis, which is the only dedicated funding stream to address hepatitis. Due to the inadequate funding to prevent viral hepatitis infection and the lack of a federal response to treating infected Americans, thousands of preventable infections and deaths will occur.

Understanding the process through which federal viral hepatitis funding and program decisions are made is critical to impacting policies affecting state adult hepatitis programs and persons living with hepatitis. This document provides a basic overview of legislative and regulatory processes to aid in effective participation in these systems.

Table of Contents

Federal Budget Process..... 1

Congressional Leadership 3

Congressional Authorizing Committees 4

Executive Office of the White House..... 5

Federal Regulations..... 6

Administrative Agencies 7

Department of Health and Human Services (HHS) 7

Assistant Secretary for Health (ASH) 7

Agency for Healthcare Research and Quality (AHRQ)..... 7

Centers for Disease Control and Prevention (CDC)..... 8

 Coordinating Center for Infectious Diseases (CCID) 8

 National Center for HIV, Hepatitis, STD and TB Prevention (NCHHSTP) 8

 National Center for Immunization and Respiratory Diseases (NCIRD) 9

Center for Medicare and Medicaid Services (CMS) 9

Health Resources and Services Administration (HRSA) 10

Bureau of Primary Health Care (BPHC)..... 10

 HIV/AIDS Bureau (HAB)..... 10

National Institutes of Health (NIH) 11

 National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK) 11

 National Institute of Drug Abuse (NIDA)..... 11

 National Institute of Allergy and Infectious Diseases (NIAID) 11

 National Center for Complimentary and Alternative Medicine (NCCAM) 11

Substance Abuse and Mental Health Services Administration (SAMHSA) 11

Department of Veterans Affairs (VA) 12

Legislation..... 12

Useful Links and Resources..... 13

Addendum 16

Federal Budget Process

The term “budget process,” when applied to the federal government, actually refers to a number of processes that have evolved separately and that occur with varying degrees of coordination. They include: the President’s budget, the budget resolution, reconciliation, authorizations, and appropriations. For more information on this process, the House and Senate Budget Committees provide informative primers on the budget process (see links section). The federal budget contains two types of program funding: mandatory spending for entitlement programs (the largest are Medicare, Medicaid, and Social Security) and discretionary spending for defense and most other programs.

President’s Budget

The release of the President’s budget, which outlines the funding priorities of the Administration, is the starting point for deliberations on federal funding for a given fiscal year. The President is required to submit to Congress a proposed budget by the first Monday in February. Although this budget does not have the force of law, it is a comprehensive examination of federal revenues and spending, including any initiatives recommended by the President, and is the start of extensive interaction with Congress.

Budget Resolution

The House and Senate Budget Committees then prepare a budget resolution to determine the spending amounts for the fiscal year, which includes funding for priority policy initiatives by the President. Although it does not have the force of law, the budget resolution is a central part of the budget process in Congress and is targeted

for completion by mid-April. The budget resolution is the blueprint for broad spending and tax decisions that will be made during the balance of the year. The budget resolution’s spending distribution is primarily implemented through two processes: reconciliation and appropriations.

Reconciliation

Once the House and Senate agree on a budget resolution, the budget reconciliation process begins. Budget reconciliation (sometimes called OBRA – Omnibus Budget Reconciliation Act) is the process by which the authorizing and appropriations committees change programs in their jurisdictions to meet budget targets and implement initiatives contained in the budget resolution. The authorizing and appropriations committees must provide the Budget Committee with legislative language that rewrites parts of their programs to reconcile the actual outcome in spending with what is called for in the budget resolution. The Budget Committees combine the legislative language, which is then brought before the full House and Senate for a vote.

Authorizations

Congress may pass freestanding authorization bills, outside the reconciliation process, that may change tax or entitlement law. Although such measures are not part of reconciliation, they remain subject to the spending and revenue levels established in the budget resolution. Authorizations are legislation that establish, continue, or modify an agency or program, and authorize the enactment of appropriations for that purpose. Authorizations may be temporary or permanent, and

their provisions may be general or specific, but they do not themselves provide funding in the absence of appropriations committee action. Although House and Senate rules generally prohibit unauthorized appropriations, both provide exceptions in their respective rules and the prohibition itself may be waived.

Appropriations

The spending amounts in the budget resolution are translated into several sets of allocations. One allocation goes to the appropriations committees, which then subdivide the amount among their 12 subcommittees. This second-level distribution is provided for under Section 302(b) of the Budget Act, so the sub-allocations are known as the “302(b)s.” The subcommittee allocations will determine the overall spending levels for the Labor-Health and Human Services-Education Appropriations bill and the Veterans Affairs-Housing and Urban Development Appropriations bill, which contain funding for viral hepatitis programs. The House and Senate can, and often have, different 302(b)s for the individual appropriations bills which must be reconciled later in the appropriations process. Once the appropriations subcommittees have their 302(b) allocations, the appropriations bills can be drafted for consideration by the subcommittees.

In anticipation of the drafting of the appropriations bills, each Member of Congress (MOC) submits to the appropriations subcommittees appropriations request letters that prioritize their funding requests. There is a project and a programmatic letter. The project letter is specific to requests within a Member’s state. The programmatic letter is specific to authorized federal funding streams. Hepatitis constituent groups often

contact their MOCs to request they include specific hepatitis funding requests or “asks” in their programmatic request letters. The subcommittee staff often prioritize spending based on the amount of Member requests they receive for a particular federal program.

When the 12 appropriations bills are taken up in regular order they are first considered and passed by their respective subcommittee, passed individually in full committee, and then brought to the full House and Senate for floor consideration. Although the House and Senate draft separate appropriations bills, the bills originate in the House. After an appropriations bill has been passed in both the House and Senate, the bill is then referred to a conference committee where the differences between the two bills can be reconciled. The conferenced bill is then passed in both chambers and sent to the President for signature.

Although Congress is required to complete action on all 12 appropriations bills by September 30, it rarely meets its deadline. In recent years, the appropriations process has finished well into the new fiscal year often due to the intense political nature of spending legislation. Since most government programs must continue to operate even if funds have not been appropriated, Congress will usually pass a continuing resolution (referred to as a “CR”) to temporarily fund government programs at the prior year’s levels or some other agreed-upon rate until appropriations measures are passed and signed into law. Congress often enacts a number of short-term resolutions to prevent the government from shutting down at the beginning of a new fiscal year (October 1st). Due to the press of time at the end of a legislative session or intense political pressure to finish the process, several appropriations bills can be combined in an “omnibus” bill to fund the remainder of the fiscal year.

Congressional Leadership

The House and Senate leadership are critical to the legislative functioning of the House and Senate. The leaders of the majority party in each chamber have enormous discretion over whether and when to allow a bill to be brought before the chamber. The leadership also decides who chairs congressional committees and approves of new Members to committees. In choosing these positions, party loyalty can often take precedence over seniority.

The House leadership consists of the Speaker of the House who presides over the entire chamber. The next in line to the Speaker is the Majority Leader whose role is to work with the Speaker to advance the majority party's agenda. The Minority Leader presides over the minority party. Both the Majority and Minority Leaders have deputies called "whips," whose job it is to try to maintain party unity on important votes. The Members from each party meet to discuss issues of concern and for informational briefings via the Republican Conference and the Democratic Caucus. The Conference Chairs for each party preside over their respective conference's meetings.

In the Senate, there are also Majority and Minority Leaders who are the "floor managers." The Majority and Minority Leaders are the elected spokesperson on the Senate floor for their respective political parties, having been elected by their fellow Senators of the same party. The purely ceremonial presiding officer of the Senate is the Vice President of the United States, who cannot introduce legislation or participate in debates and who votes only in the rare occasion of a tie vote.

Congressional Authorizing Committees

Standing committees are generally organized to parallel the major departments and agencies of the executive branch. Because viral hepatitis programs are heavily concentrated across agencies within the Department of Health and Human Services (HHS), the most significant congressional committees of jurisdiction are those that oversee this Department.

When a committee or subcommittee favors a legislative measure, it usually takes four actions. First, it asks relevant executive agencies for written comments on the legislation. Second, it holds hearings to gather information and views from non-committee experts. Before the committee, these witnesses summarize submitted statements and respond to questions from Members. Third, a committee meets to perfect the bill through amendments, and non-committee Members sometimes attempt to influence the language. Fourth, when language is agreed upon, the committee sends the measure back to the chamber, usually along with a written report describing its purposes and provisions and the work of the committee thereon. The influence of committees over legislation extends to the enactment into law. A committee that considers a bill will manage the full chamber's deliberation on it. Also, its Members will be appointed to any conference committee created to reconcile the two chambers' differing versions of the legislation.

In the House, the Energy and Commerce Committee has jurisdiction over Medicaid, Medicare Part B and D, the Food and Drug Administration's (FDA) drug approval process, and discretionary public health programs, including CDC programs and the Ryan White Program. The House Ways and Means Committee has jurisdiction over the entire Medicare program, Part A, B, C and D, which provides hepatitis B vaccines and medications to treat hepatitis for the elderly and the disabled. The House Veterans' Affairs Committee has jurisdiction over the Veterans Health Administration (VA) and the VA health care system, which is the largest federal provider of hepatitis C treatment services.

In the Senate, the Health, Education, Labor and Pensions Committee (HELP) has jurisdiction over the FDA's drug approval process, biomedical research and development, and public health, including CDC programs and the Ryan White Program. The Senate Finance Committee has jurisdiction over the Medicaid and Medicare programs. The Senate Veterans' Affairs Committee has jurisdiction over the Veterans Health Administration and the VA health care system.

Both the House and Senate websites (see links section) contain a variety of information that is useful in learning about individual Members of Congress, committees, status of legislation, House and Senate calendars, floor procedure, "how a bill becomes a law," and "how to write your representatives."

Executive Office of the White House

The power of the executive branch is vested in the President who also serves as Commander in Chief of the Armed Forces. The President appoints the Cabinet and oversees the various agencies and departments of the federal government. The Cabinet includes the Vice President and, by law, the heads of 15 executive departments -- the Secretaries of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, Housing and Urban Development, Interior, Labor, State, Transportation, Treasury, Veterans Affairs, and the Attorney General. Under President George W. Bush, Cabinet level rank also has been accorded to the Administrator of the Environmental Protection Agency, the Director of the Office of Management and Budget, the Director of the National Drug Control Policy, and the U.S. Trade Representative.

The Office of Management and Budget (OMB), as part of the executive office of the President, plays an integral role in the Administration's funding decisions for viral hepatitis programs. OMB's predominant mission is to assist the President in overseeing the preparation of the federal budget and to supervise its administration in executive branch agencies. In helping to formulate the President's spending plans, OMB evaluates the effectiveness of agency programs, policies, and procedures, assesses competing funding demands among agencies, and sets funding priorities.

OMB has undertaken performance evaluations of select HHS programs as part of the President's agenda for reforming the management of the government and improving the performance of federal programs. Each agency is evaluated quarterly by the OMB on five initiatives. These initiatives are: Strategic Management of Human Capital; Competitive Sourcing; Improved Financial Performance; Expanded Electronic Government; and Budget and Performance Integration (see links section).

Three councils – the Domestic Policy Council, the National Economic Council, and the National Security Council, make policy at the White House. Viral hepatitis issues are not directly addressed by any of the White House councils.

Federal Regulations

While laws provide the framework, federal agencies develop rules to spell out the details of the law. Since federal regulations implement laws and are legally binding, the Administrative Procedures Act requires federal agencies to allow the public to participate in the development of federal rules and regulations. The most common way for the public to participate is through commenting on proposed regulations. The agencies within HHS write nearly all of the regulations that impact state viral hepatitis programs.

Regulations can be found in the Federal Register, which is published every working day and serves to notify the public of all government rules, notices, Presidential documents, grant applications, meetings and hearings. The Federal Register is available on-line (see links section). This open access to information enables one to participate in the decision-making process by submitting written comments. Any person, organization, or health department may submit written comments on a proposed rule or an interim final rule with comment period. All federal grant information is also available at a separate web site (see links section).

Despite its relatively straightforward format the rulemaking process can drag on for years and is often subject to political pressures from a variety of sources. Agency administrators, who are political appointees of the President, often strive to fulfill the Administration's policy objectives as they develop regulations to implement federal laws. Interested parties can meet with agency officials to discuss their concerns prior to submitting written comments, and can petition agencies to develop or withdraw regulations. Stakeholders can also ask Congress to intervene to change regulations, since federal agencies are generally responsive to Congress. Members of Congress are not always aware of problems with agency rules and regulations, and are often willing to intervene if a regulation is contrary to Congressional intent in passing the legislation or contrary to the mission of the agency.

Administrative Agencies

Programs addressing viral hepatitis reside in several agencies of the federal government. The greatest concentration of federal viral hepatitis programs is housed within HHS. The Department of Veterans Affairs, through the Veterans Health Administration and the VA health care system, provide a significant amount of care and treatment to eligible veterans living with hepatitis C through their VA National Hepatitis C Program. Hepatitis advocates have long called for an inter-agency committee within HHS or across all federal agencies to address hepatitis, with no result.

Below are profiles of the administrative agencies with the most significant portions of the federal viral hepatitis portfolio.

Department of Health and Human Services (HHS)

Assistant Secretary for Health (ASH)

The Assistant Secretary for Health (ASH) is the senior advisor on public health and science issues to the Secretary of Health and Human Services. The ASH oversees the Office of Public Health and Science (OPHS) and the U.S. Public Health Service (PHS). OPHS includes eleven offices including the Office of the Surgeon General, the Office of Minority Health (OMH), and the National Vaccine Program Office (NVPO).

The Surgeon General is our nation's chief spokesperson on matters of public health and medicine, and serves as special advisor to the President, HHS Secretary, the Congress and the general population on hazards to health, disease prevention and health promotion, based on the best available scientific evidence. The Office of the Surgeon General focuses on seven public health priority areas. These include disease prevention, eliminating

health disparities, public health preparedness, improving health literacy, organ donation, children and healthy choices, and bone health and osteoporosis. Viral hepatitis is not addressed in any of these priority areas.

The Deputy Assistant Secretary for Minority Health heads the Office of Minority Health with the mission to improve the health of racial and ethnic populations through the development of effective health policies and programs that help to eliminate disparities in health. OMH works closely with sister agencies within HHS and their minority health representatives. Hepatitis B disproportionately impacts Asian Americans and hepatitis C disproportionately affects people of color: 3.2 percent of African Americans and 2.1 percent of Mexican Americans are infected with HCV, compared to 1.5 percent of non-Hispanic whites. These numbers underestimate the actual impact because they do not include infections in prisoners or the homeless.³

The National Vaccine Program Office (NVPO) has the responsibility for ensuring the collaboration among agencies of national vaccine and immunization initiatives. Using the National Vaccine Plan, NVPO works to prevent infectious diseases through immunization. NVPO seeks to limit adverse reactions to vaccines and ensure that minimal gaps in federal planning for vaccines and immunizations occur.

Agency for Healthcare Research and Quality (AHRQ)

AHRQ is the health services research arm of HHS. AHRQ is the lead agency charged with supporting research designed to improve the quality of health care, reduce its cost, and broaden access to essential services. AHRQ's programs seek to bring science-based information to medical practitioners and to consumers and other health care purchasers. AHRQ supports improvements in health outcomes; develops strategies to strengthen quality

measurement and improvement; identifies strategies to improve health care access, foster appropriate use, and reduce unnecessary expenditures; improve the quality of health care; promote patient safety and reduce medical errors; and advance the use of information technology for coordinating patient care and conducting quality and outcomes research. AHRQ is comprised of four offices and five centers. AHRQ has some work dedicated to HCV through co-funded grants, however this portfolio is very limited.

Centers for Disease Control and Prevention (CDC)

The CDC, as an agency of HHS, is recognized as the lead federal agency for protecting the public health and safety of people, providing credible information to enhance health decisions and promoting health through strong partnerships. CDC is tasked with national-level disease surveillance, first-response, and other prevention-related activities. CDC's top level organizational components include the Office of the Director, the National Institute for Occupational Safety and Health, and six Coordinating Centers/Offices.

Coordinating Center for Infectious Diseases (CCID)

CCID has been reorganized into four Centers and Budget Activities: Immunization and Respiratory Diseases; HIV/AIDS, Viral Hepatitis, STD and TB Prevention; Zoonotic, Vector-Borne, and Enteric Diseases; and Preparedness, Detection and Control of Infectious Diseases.

National Center for HIV, Viral Hepatitis, STD and TB Prevention (NCHHSTP)

NCHHSTP provides national leadership in preventing and controlling HIV, viral hepatitis, sexually transmitted diseases, and tuberculosis. Center staff work in collaboration with governmental and non-governmental

partners at community, state, national, and international levels, applying integrated multidisciplinary programs of research, surveillance, technical assistance, and evaluation.

Division of Viral Hepatitis (DVH)

The central focus of DVH is the prevention, control, and elimination of viral hepatitis infections in the U.S. and assists the international public health community in these activities. DVH provides funding to promote the integration of viral hepatitis, HIV/AIDS and STD programs and services to address the prevention needs of individuals at high risk for HIV, hepatitis C and hepatitis B infection. DVH funds adult hepatitis coordinators in 48 states and three large metropolitan areas to provide management, networking, and technical expertise for successful integration of hepatitis prevention and control activities into existing public health programs. DVH also supports limited viral hepatitis surveillance, which includes responding to hepatitis A, B and C outbreaks and monitoring chronic viral hepatitis infection and chronic liver disease.

In 2001, CDC created the *National Hepatitis C Prevention Strategy* in response to the Secretary of the Department of Health and Human Services request for a comprehensive plan for the prevention and control of hepatitis C. The central components of the National Hepatitis C Prevention Strategy are to educate health professionals and the public about persons at risk for hepatitis C virus (HCV) infection and about risk for HCV transmission. The strategy seeks to identify, counsel, and test persons at risk for and infected with HCV. Guidelines for identifying, counseling, and testing persons at risk for HCV infection have been developed and chronic HCV has been classified as a nationally notifiable disease. Funds to fully implement the *Prevention Strategy* have not been provided by Congress up to this point.

Viral Hepatitis Policymaking and Programs at the Federal Level

National Center for Immunization and Respiratory Diseases (NCIRD)

The Immunization Services Division (ISD) under NCIRD awards grants through Section 317 of the Public Health Service Act and the Vaccines for Children (VFC) program to assist state and local health departments in purchasing vaccines and in planning, developing, and conducting immunization programs. This includes vaccines for hepatitis A and B. There is no adult-specific hepatitis vaccination program within NIP.

The VFC program serves children and adolescents without insurance, those eligible for Medicaid, American Indian/Alaska Native children, and children who are underinsured and receive care through Federally Qualified Health Centers and Rural Health Clinics. Through the VFC program, federally purchased vaccines are distributed to public health clinics and enrolled private providers, enabling vaccination of all eligible children.

The Section 317 Immunization Grant Program provides vaccines for children, adolescents and adults who primarily present at local health departments for immunization services but are not eligible for the Vaccine For Children (VFC) program. The Section 317 program is a discretionary funding program that primarily serves children whose parents are unable to afford to fully vaccinate their children. The majority of program funds are dedicated to routine childhood immunization programs, leaving a gap in coverage among adult programs. In 2006, CDC encouraged states to devote a portion of their 317 award for adult hepatitis B vaccination. State immunization programs determine whether vaccinating adults at risk for hepatitis A and B infection are a priority for their jurisdiction.

ISD funds a perinatal hepatitis B coordinator in 65 state and local health departments. Hepatitis B Coordinators work primarily with physicians and hospitals to ensure that pregnant women with hepatitis B are identified and that appropriate medical care is given to their babies to prevent the spread of HBV. In addition, Hepatitis B Coordinators are accessible to the public as a valuable resource of information for viral hepatitis. They can answer questions regarding hepatitis B immunization schedules and vaccine funding.

Center for Medicare and Medicaid Services (CMS)

CMS runs the Medicare and Medicaid programs – two national health care programs that provide health care to about 90 million Americans. The Medicare program finances health care services for elderly people and people with disabilities and is funded solely by the federal government. Medicare also offers a prescription drug benefit to beneficiaries. The Medicaid program finances health services for eligible low-income people and is jointly funded by federal and state governments. Both Medicare and Medicaid, as entitlement programs, may finance healthcare services to persons living with or at risk for hepatitis, including diagnostics, vaccines, and medication.

CMS also administers the Demonstration to Maintain Independence and Employment (DMIE) grant program established by the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA). The purpose of the demonstration is to cover individuals who have a specific physical or mental impairment that, without medical assistance, has the potential to lead to disability. DMIE considers both hepatitis C and HIV/AIDS severe physical or mental impairments that are covered under their grant programs.

CMS also regulates all laboratory testing (except research) performed on humans in the United States. CMS is charged with the implementation of the Clinical Laboratories Improvement Amendments of 1988 (CLIA). CLIA established quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. CMS is responsible for certifying laboratories and determining which tests they may or may not run. For labs, the main differences between being able to run the three classifications of tests (high complexity, moderate-complexity and waived) are the CLIA rules governing oversight, quality assurance, and personnel requirements. Hepatitis A, hepatitis B, and hepatitis C virus antibody and antigen tests are subject to CLIA waivers and are classified as high and moderate-complexity. There is a hepatitis C rapid test in the pipeline that may be eligible for a CLIA waiver.

Health Resources and Services Administration (HRSA)

HRSA directs national health programs which improve the health of the nation by assuring quality health care to underserved, vulnerable and special-need populations and by promoting appropriate health professions workforce capacity and practice, particularly in primary care and public health. HRSA is divided into four bureaus – the two most relevant are the Bureau of Primary Health Care and the HIV/AIDS Bureau.

Bureau of Primary Health Care (BPHC)

BPHC provides national leadership in developing, coordinating, evaluating, and assuring access to comprehensive preventive and primary health care services and improving the health status of the nation's underserved and vulnerable populations. In doing so, BPHC administers the Consolidated Health Center

Program, which funds a national network of more than 3,400 community health centers and clinics, migrant health centers, health care for the homeless centers, public housing primary care centers and school-based health centers.

Within BPHC is the Division of Health Center Development (DHCD). DHCD provides leadership and direction, including tactical planning for the development and expansion of new health centers, health systems infrastructure, and pharmacy services. Within DHCD is the Pharmacy Services and Assistance Branch (PSAB), formerly the Office of Pharmacy Affairs. PSAB assists states in expanding the number and types of organizations that participate in the 340B drug pricing program.

HIV/AIDS Bureau (HAB)

HAB administers the Ryan White Program that provides grants to states, cities, clinics, teaching hospitals, and other entities to provide primary care, medications and support services to persons living with HIV/AIDS. Ryan White Programs target people among whom HIV/HBV and HIV/HCV co-infection is prevalent, e.g., the poor, people of color, and current or former injection drug users. These resources can be used to provide hepatitis A and hepatitis B vaccines and hepatitis C testing, treatment, and medical management services to HIV/HCV coinfecting individuals. Each state and eligible city determines what medications and services will be covered.

The Ryan White Program includes Part A that funds metropolitan areas and Part B that funds states and territories, including the state AIDS Drug Assistance Programs (ADAPs). ADAPs provide access to HIV-related medications including hepatitis A and hepatitis B vaccines and hepatitis C treatments and diagnostics. Part C focuses on early intervention and primary care and Part D on comprehensive care and research for children,

Viral Hepatitis Policymaking and Programs at the Federal Level

youth, women, and families. Part F includes funds for AIDS Education and Training Centers (AETCs) that provide training and information to health care providers, including treatment protocols for the co-infected.

National Institutes of Health (NIH)

NIH conducts medical and behavioral research in its own laboratories, supports research in other institutions, and helps to train and inform the medical research community. NIH is composed of 27 subdivisions covering the whole of biomedicine.

In December 2004, a trans-NIH *Action Plan for Liver Disease Research* outlined major research goals for liver disease research. Included in the plan are 17 viral hepatitis specific goals including gaining a better understanding of the hepatitis B virus life cycle and hepatitis C disease process; evaluating the role of therapy; and expanding vaccine research to prevent transmission and/or mitigate disease progression.

National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)

NIDDK conducts and supports research on diabetes, digestive diseases, kidney and urologic diseases, and metabolic and endocrine disorders. The Liver Disease Research Branch within NIDDK, as a partner in the trans-NIH *Action Plan for Liver Disease Research*, conducts research to determine useful and reliable means of prevention, treatment, and control of viral hepatitis.

National Institute of Drug Abuse (NIDA)

NIDA identifies the health aspects of and prevention and treatment methods for drug abuse and addiction. Injection drug use is a major mode of transmission of HCV and injection drug users represent the majority of HCV cases. NIDA has responded to the recommendations

of the 2002 National Institutes of Health Consensus on Hepatitis C with treatment for active drug users with HCV on a case-by-case basis. NIDA has conducted research on the outcomes of those recommendations in relation to the barriers for treatment experienced by injection drug users.

National Institute of Allergy and Infectious Diseases (NIAID)

NIAID is responsible for conducting and supporting basic research on infectious, immunologic, and allergic diseases. The NIAID Hepatitis Research Program supports research on hepatitis B and hepatitis C. Research goals include preventing new infections and creating safe and effective vaccines to prevent infection and disease by understanding the development of the hepatitis virus and its effect on the immune system.

National Center for Complimentary and Alternative Medicine (NCCAM)

The mission of NCCAM is to explore complimentary and alternative healing practices and to educate medical researchers on these practices. In response to treatments for hepatitis C virus, which can be difficult to tolerate, NCCAM is conducting clinical trials in complimentary and alternative medicine that may be beneficial for individuals chronically infected with HCV.

Substance Abuse and Mental Health Services Administration (SAMHSA)

SAMHSA is charged with improving the quality and reliability of prevention, treatment, and rehabilitative services in order to reduce illness, death, disability, and cost to society resulting from substance abuse and mental illness. SAMHSA addresses hepatitis through its HIV/AIDS related programs by increasing access to preventive and treatment services for those at risk due

to drug and substance abuse. It is also expanding the capacity of community-based organizations to provide substance-abuse prevention, HIV/AIDS prevention and hepatitis C prevention services. In 2006, SAMHSA devoted one time funding for a hepatitis A and hepatitis B vaccination project for substance abuse treatment facilities. Not all states or facilities were eligible and no infrastructure funds were awarded.

Department of Veterans Affairs (VA)

The VA provides federal benefits to over 25 million veterans and their families. Services provided include medical care, disability compensation or pensions, education and training, and research. The VA is the largest single source of health care services for persons with hepatitis C infection in the U.S.

The National Hepatitis C Program is led by the VA's Public Health Strategic Health Care Group (PHSHG) which includes the AIDS Information Center; Center for HIV Research Resources; Center for Quality Management in Public Health; Hepatitis C Resource Centers; HIV/ Hepatitis C Clinical Program Office; HIV/Hepatitis C Prevention Program; HIV/Hepatitis C Training/Education Program and the Smoke Free Program. The program provides universal screening for risk of hepatitis C infection, testing and counseling for individuals at risk, education for patients and their families, and gives providers access to the best available information about hepatitis C.

Legislation

To develop a public health response to viral hepatitis in the U.S., bills have been introduced in a number of Congresses. Thus far no action has been taken on them. Highlighted below are the most relevant pieces of legislation.

Hepatitis C Epidemic Control and Prevention Act

In an effort to develop a public health response to hepatitis C virus (HCV) infection, Senators Edward Kennedy (D-MA) and Kay Bailey Hutchison (R-TX) and Representatives Edolphus Towns (D-NY) and Heather Wilson (R-NM) authored the Hepatitis C Epidemic Control and Prevention Act. The legislation seeks to establish, promote, and support a comprehensive prevention, research, and medical management referral program for hepatitis C virus.

National Hepatitis B Act

Authored by Senator Dianne Feinstein (D-CA) and Representatives Michael Honda (D-CA) and Charles Dent (R-PA), the National Hepatitis B Act seeks to develop a prevention, control, and medical management plan for the hepatitis B virus. This would include testing, counseling, and immunization services for health departments at state, local, and tribal levels. A Hepatitis B Coordinators Program would be added to ensure services are being provided. The legislation would include a surveillance program regarding the economic and clinical impact of hepatitis B.

Veterans Comprehensive Hepatitis C Health Care Act

Senator Frank Lautenberg (D-NJ) and Representative Rodney Frelinghuysen (R-NJ) authored the Veterans Comprehensive Hepatitis C Health Care Act to provide testing to all veterans who are identified to be "at risk" and/or request hepatitis C testing. For all veterans who test positive, this legislation also would provide follow up testing and treatment for hepatitis C with no co-payment. This legislation would provide for additional funding for hepatitis C detection and treatment programs and a maximum of three additional Hepatitis C Centers within the Veterans Affairs health care network.

Useful Links and Resources

Administrative Agencies

Federal Register

www.gpo.gov/su_docs/aces/aces140.html

Cabinet Agencies

www.whitehouse.gov/government/cabinet.html

Federal Grant Information

www.grants.gov

HHS

Department of Health and Human Services

www.hhs.gov

Office of Public Health and Science

www.osophs.dhhs.gov/ophs

Office of the Surgeon General

www.surgeongeneral.gov/sgOffice.htm

Office of Minority Health

www.omhrc.gov

National Vaccine Program Office

www.hhs.gov/nvpo

Agency for Healthcare Research and Quality

<http://www.ahrq.gov>

CDC

Centers for Disease Control and Prevention

www.cdc.gov

National Center for HIV, Viral Hepatitis, STD and TB Prevention

www.cdc.gov/nchstp/od/nchstp.html

Division of STD

www.cdc.gov/nchstp/dstd/dstdp.html

Division of Viral Hepatitis

www.cdc.gov/ncidod/diseases/hepatitis/index.htm

National Hepatitis C Prevention Strategy

www.cdc.gov/ncidod/diseases/hepatitis/c/plan/index.htm

Division of AIDS, STD, and TB Laboratory Research

www.cdc.gov/ncidod/dastlr/default.htm

National Immunization Program

www.cdc.gov/nip

Section 317 Immunization Grant Program

www.cdc.gov/PROGRAMS/immun03.htm

CMS

Center for Medicare and Medicaid Services

www.cms.gov

Ticket to Work and Work Incentives Improvement Act

www.cms.hhs.gov/twwiia/default.asp

Clinical Laboratory Improvements Amendments

www.cms.gov/clia

HRSA

Health Resources and Services Administration

www.hrsa.gov

Bureau of Primary Health Care

<http://bphc.hrsa.gov/>

HIV/AIDS Bureau

<http://hab.hrsa.gov>

NIH

National Institutes of Health

www.nih.gov

National Institute of Diabetes & Digestive & Kidney Diseases

www.niddk.nih.gov

National Institute on Drug Abuse

www.nida.nih.gov

National Institute of Allergy and Infectious Disease

www.niaid.nih.gov/default.htm

National Center for Complimentary and Alternative Medicine

<http://nccam.nih.gov>

SAMHSA

Substance Abuse and Mental Health Services Administration

www.samhsa.gov/

Center for Mental Health Services

www.samhsa.gov/centers/cmhs/cmhs.html

VA

Department of Veterans Affairs

www.va.gov

Public Health Strategic Health Care Group

<http://vhaaidsinfo.cio.med.va.gov/default.htm>

National Hepatitis C Program

www.hepatitis.va.gov

Non-Governmental Organizations

American Liver Foundation

www.liverfoundation.org

American Association for the Study of Liver Diseases

www.aasld.org

Asian Liver Center

<http://liver.stanford.edu>

Association of Immunization Managers

www.immunizationmanagers.org

Center for the Study of Hepatitis C at Weill Medical College of Cornell University

www.hepccenter.org

Hepatitis A, B and C Prevention Programs

www.hepprograms.org

Hepatitis B Foundation

www.hepb.org

Viral Hepatitis Policymaking and Programs at the Federal Level

Hepatitis C Advocate Network

www.hepcan.org

Hepatitis C Association

www.hepcassoc.org

Hepatitis C Caring Ambassadors Program

www.hepcchallenge.org

Hepatitis C Harm Reduction Project

www.hepcproject.org

Hepatitis C/HIV Multicultural Outreach

www.hepcmo.org

Hepatitis C Support Project

www.hcvadvocate.org

Hepatitis Education Project

www.hepeducation.org

Hepatitis Foundation International

www.hepfi.org

Hepatitis Magazine

www.hepatitismag.com

Hepatitis Web Study

www.hepwebstudy.org

Immunization Action Coalition

www.immunize.org

Julia Spears Foundation

www.helpwithhepc.org

Latino Organization for Liver Awareness

www.lola-national.org

National AIDS Treatment Advocacy Project

www.natap.org

National Alliance of State and Territorial AIDS Directors

www.NASTAD.org

National Association of Community Health Centers

www.nachc.org

National Association of State Alcohol/Drug Abuse Directors

www.nasadad.org

National Coalition of STD Directors

www.ncsddc.org

National Hepatitis C Advocacy Council

www.hepcnetwork.org

National Viral Hepatitis Roundtable

www.nvhr.org

O.A.S.I.S. Clinic

www.oasisclinic.org

Addendum

Director, Office of Management and Budget:
Rob Portman

Director, OMB Health Division:
Barry Clendenin

Branch Chief, OMB Health Financing Branch:
Keith Fontenot

Branch Chief, OMB Public Health Branch:
Marc Garufi

Department of Health and Human Services Secretary:
Michael O. Leavitt

Acting Deputy Secretary, Health and Human Services:
Eric D. Hargan

Assistant Secretary for Health:
Dr. John Agwunobi

Acting Surgeon General:
Rear Admiral Kenneth P. Moritsugu

Acting Director, Office of Population Affairs:
Evelyn Kappeler

Deputy Assistant Secretary for Minority Health:
Garth Graham

Director, National Vaccine Program Office:
Bruce G. Gellin

Agency for Healthcare Research and Quality Director:
Dr. Carolyn Clancy

Centers for Disease Control and Prevention Director:
Dr. Julie Gerberding

Director, Coordinating Center for Infectious Diseases:
Dr. Mitchell Cohen

Director, National Center for HIV, Hepatitis, STD and TB
Prevention:
Dr. Kevin Fenton

Director, Division of HIV/AIDS Programs:
Dr. Rob Janssen

Director, Division of Viral Hepatitis:
Dr. John Ward

Director, National Center for Immunization and
Respiratory Diseases:
Dr. Ann Schuchat

Director, Immunization Services Division:
Dr. Lance Rodewald

Center for Medicare and Medicaid Services Administrator:
Leslie V. Norwalk

Health Resources and Services Administration
Administrator:
Dr. Elizabeth Duke

Associate Administrator, Bureau of Primary Health Care:
Jim Macrae

Associate Administrator,
HIV/AIDS Bureau:
Dr. Deborah Parham Hopson

Viral Hepatitis Policymaking and Programs at the Federal Level

National Institutes of Health

Director:

Dr. Elias Zerhouni

Acting Director, National Institute of Diabetes & Digestive
& Kidney Diseases:

Dr. Griffin P. Rodgers

Director, National Institute of Drug Abuse:

Dr. Nora D. Volkow

Director, National Institute of Allergy and Infectious
Diseases:

Dr. Anthony Fauci

Acting Director, National Center for Complimentary and
Alternative Medicine:

Dr. Ruth L. Kirschstein

Substance Abuse and Mental Health Services
Administration Administrator:

Terry Cline

Director, Center for Substance Abuse Treatment:

Dr. H. Westley Clark

Acting Director, Center for Substance Abuse Prevention:

Dennis O. Romero

Director, Center for Mental Health Services:

A. Kathryn Power

Department of Veteran Affairs (VA)

Secretary:

R. James Nicholson

Chief Consultant, Public Health Strategic Healthcare
Group:

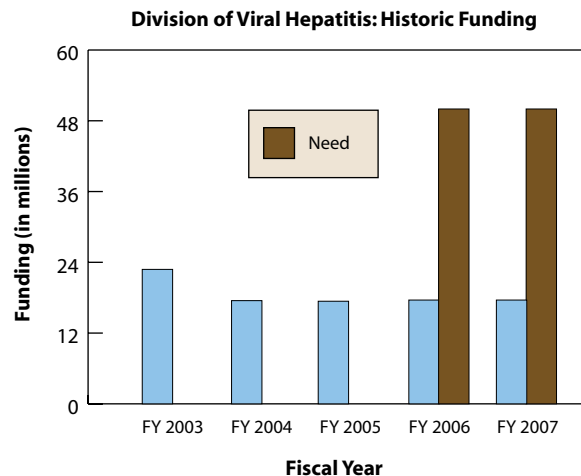
Ronald O. Valdiserri

Chief Officer, Office of Public Health and Environmental
Hazards:

Dr. Lawrence R. Deyton

Quick Facts: Hepatitis A, Hepatitis B and Hepatitis C

	HAV	HBV	HCV
What is it?	The hepatitis A virus is a viral infection that attacks the cells of the liver	The hepatitis B virus is a viral infection that attacks the cells of the liver	The hepatitis C virus attacks the liver, similar to HBV, but is more likely than HBV to cause chronic infection
How is it transmitted?	When infected feces enters the mouth of an uninfected person	When infected blood, semen or vaginal secretions enter the body of an uninfected person	HCV is transmitted by direct contact with infected blood
How is it spread?	Person to person by ingesting something that has been contaminated with the stool of a person with hepatitis A	Unprotected sex, sharing needleworks, needles/ticks/ sharps exposure, perinatally	Sharing needleworks, needles/ticks/sharps exposure, perinatally (the blood supply has been screened since 1992)
What happens?	There is no chronic infection and 15% of people infected with HAV will have relapsing symptoms over a 6-9 month period	Most HBV infections are cleared. If not, chronic HBV may develop and lead to liver failure, liver cancer or cirrhosis	Most persons infected develop chronic HCV, which can lead to liver disease. HCV is the number one reason for liver transplants
What treatment is available?	Immune globulin can be given before or within two weeks of coming in contact with HAV	Antiviral drugs are available to slow the reproduction of HBV	Antiviral drugs are available to treat chronic HCV infection. Some patients clear the virus
Is there a vaccine?	Yes	Yes	No
Is there a cure?	No	No	Yes/No. Not all that are treated clear the virus



Endnotes

- 1 Morbidity and Mortality Weekly Report Surveillance Summaries, "Surveillance for Acute Viral Hepatitis – United States, 2005". March 16, 2007/56(SSO); 1-24 Retrieved March 23, 2007 from <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5603a1.htm>
- 2 Morbidity and Mortality Weekly Report. "Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. October 16, 1998 / 47(RR19);1-39. Retrieved May 18, 2006 from <http://www.cdc.gov/mmwr/preview/mmwrhtml/00055154.htm>
- 3 Morbidity and Mortality Weekly Report Surveillance Summaries, "Surveillance for Acute Viral Hepatitis – United States, 2005". March 16, 2007/56(SSO); 1-24 Retrieved March 23, 2007 from <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5603a1.htm>



444 North Capitol Street, NW • Suite 339
Washington, DC 20001-1512
Phone: 202-434-8090
Fax: 202-434-8092
www.NASTAD.org