STALKING A FURTIVE KILLER: A REVIEW OF THE FEDERAL GOVERNMENT'S EFFORTS TO COMBAT HEPATITIS C

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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STALKING A FURTIVE KILLER: A REVIEW OF THE FEDERAL GOVERNMENT'S EFFORTS TO COMBAT HEPATITIS C

TUESDAY, DECEMBER 14, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 2 p.m., in room 2154, Rayburn House Office Building, Hon. Tom Davis (chairman of the committee) presiding.

Present: Representatives Tom Davis, Waxman, Towns and Norton.

Staff present: David Marin, deputy staff director/communications director; Robert White, press secretary; Drew Crockett, deputy director of communications; Susie Schulte, professional staff member; Teresa Austin, chief clerk; Sarah Dorsie, deputy clerk; Corinne Zaccagnini, chief information officer; Bill Womack, legislative director; Amy Westmoreland, legislative assistant, Karen Lightfoot, minority communications director/senior policy advisor; Sarah Despres, minority counsel; Josh Sharfstein, minority professional staff member; Earley Green, minority chief clerk; and Jean Gosa, minority assistant clerk.

Chairman TOM DAVIS. With a quorum being present, the Committee on Government Reform will come to order; and I want to welcome everybody to today's oversight hearing on the significant public health threat posed by hepatitis C.

Most people probably don't realize that hepatitis C is now the most common blood-borne viral infection in the United States, affecting nearly 4 million Americans. Hepatitis C is also a leading cause of chronic liver disease, now the 10th leading cause of death among adults in the United States.

In 1998, this committee held a hearing on the need to improve the Nation's response to hepatitis C. At that hearing, several specific points of action were recommended. Today, we will examine what progress has been made in responding to the hepatitis C epidemic. We also hope to identify areas for improvement.

Hepatitis C was only identified 15 years ago, so we still have a lot to learn about this disease. We have learned that significant obstacles to fighting hepatitis C exists. There is currently no vaccine to shield against hepatitis C virus. There are vaccines against hepatitis A and B; however, the structure of the hepatitis C virus has proved a difficult puzzle for medical researchers to solve.

Today, we will hear from NIH whether it's reasonable to expect availability of a hepatitis C vaccine in the near future. Pharmaceutical treatments are available but only successful about 50 percent of the time under ideal conditions. They are also attended by side effects, sometimes so devastating they often are not an option for many patients with hepatitis C infection.

Second, infection with hepatitis C virus generally carries no symptoms but gradually damages the liver over the course of many years or even decades. It's discovered only after a patient exhibits signs of serious liver disease, such as cirrhosis or liver cancer. Since the virus lasts for such a long period of time, it is possible for infected persons to disassociate or even forget about long-ago instances of drug use or other high-risk behavior. Thus, the individual doesn't address their own illness, nor do they take steps to stem the spread of the virus to others.

A final obstacle is that hepatitis C, while a serious public health issue, remains relatively unknown to the general public. Those affected often come from marginalized populations, intravenous drug users and prisoners, for example, lacking the political organization to effectively raise public awareness about the disease.

Public health officials face the challenge of informing, rather than panicking, the public about hepatitis C, a task made even more difficult given our still-evolving knowledge base. It seems to me that there is a misperception that hepatitis C is a disease affecting, "somebody else." However, social strata provide no prophylaxis. This misperception underscores the need to establish effective programs to educate both health care providers and the public at large about the dangers of hepatitis C and the high-risk activities that tend to spread it.

This hearing sets the stage to review our Nation's response to hepatitis C. Several questions we would like answered today include: How well are hepatitis C prevention strategies working? Are we screening enough people to identify persons at risk for infection? What progress has been made in the last 5 years toward the quest for vaccine and developing better and more effective treatments for hepatitis C? How well do the Federal agencies share information among themselves and with State health departments?

The current epidemic has challenged our public health system's capabilities and provides us with a chance to evaluate existing prevention, screening and treatment programs. The Department of Veterans Affairs [VA], has an excellent hepatitis C program and has taken the leading role in managing infection. I am pleased we have a witness on our first panel to discuss the proactive education, screening, treatment, counseling and surveillance measures taken by the VA over the past few years. We will take a look at how these programs are being implemented and what lessons can be provided to the general public health community.

In addition to the testimony from several medical and public health experts, we will hear the personal story of a teenage girl from Fairfax County whose father has hepatitis C. Erika Stein has helped lead a marketing program at her high school to raise awareness and get more Federal resources allocated for prevention and research for the disease. We look forward to her testimony.

The committee hopes to learn from the experiences of those who feel the effects of hepatitis C infection every day. I understand some of our witnesses this morning will express concerns about the success of current hepatitis C prevention efforts and identify areas where improvement is still needed. I look forward to a constructive dialog on these concerns. I know we all share the same goal at the end of the day, a public health system that can adequately respond to the hepatitis C epidemic.

We have an excellent roster of witnesses today. I want to thank all of them for appearing before the committee. I look forward to their testimony.

[The prepared statement of Chairman Tom Davis follows:]

Statement of Chairman Tom Davis
Committee on Government Reform Hearing
"Stalking a Furtive Killer: A Review of the Federal Government's Efforts to Combat Hepatitis C"
December 14, 2004

Good afternoon. I want to welcome everyone to today's oversight hearing on the significant public health threat posed by hepatitis C. Most people probably do not realize that hepatitis C is now the most common blood-borne viral infection in the United States, affecting nearly 4 million Americans. Hepatitis C is also a leading cause of chronic liver disease – now the 10th leading cause of death among adults in the U.S. In 1998, this Committee held a hearing on the need to improve the nation's response to hepatitis C. At that hearing, several specific points of action were recommended. Today we will examine what progress has been made in responding to the hepatitis C epidemic; we also hope to identify areas for improvement.

Hepatitis C was only identified 15 years ago, so we still have much to learn about this disease. We have learned that significant obstacles to fighting hepatitis C exist. There is currently no vaccine to shield against the hepatitis C virus. There are vaccines against hepatitis A and B; however, the structure of the hepatitis C virus has proven a difficult puzzle for medical researchers to solve. Today, we will hear from NIH whether it is reasonable to expect the availability of a hepatitis C vaccine in the near future. Pharmaceutical treatments are available, but are only successful about 50 percent of the time under ideal conditions. They also are attended by side-effects so devastating that they often are not an option for many patients with hepatitis C infections.

Second, infection with the hepatitis C virus generally carries no symptoms, but gradually damages the liver over the course of many years or even decades. It is discovered only after a patient exhibits signs of serious liver disease, such as cirrhosis or liver cancer. Since the virus lasts for such a long period of time, it is possible for infected persons to disassociate or even forget about long-ago instances of drug use or other high-risk behavior. Thus, the individual does not address their own illness, nor do they take steps to stem the spread of the virus to others.

A final obstacle is that hepatitis C, while a serious public health issue, remains relatively unknown to the general public. Those affected often come from marginalized populations – intravenous drug users and prisoners, for example – lacking the political organization to effectively raise public awareness about the disease. Public health officials face the challenge of informing, rather than panicking, the public about hepatitis C – a task made even more difficult given our still-evolving knowledge base. It seems to me there is a misperception that hepatitis C is a disease affecting quote-unquote "somebody else." However, social strata provide no prophylaxis. This misperception underscores the need to establish effective programs to educate both healthcare providers and the public at large about the dangers of hepatitis C and the high-risk activities that spread it.

This hearing sets the stage to review our nation's response to hepatitis C. Several questions we want answered today include: how well are hepatitis C prevention strategies working? Are we screening enough people to identify persons at risk for infection? What progress has been made in the last five years towards the quest for vaccine and developing better and more effective treatments for hepatitis C? How well do federal agencies share pertinent information among themselves and with state health departments?

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We have an excellent roster of witnesses today and I would like to thank all of them for appearing before the Committee and I look forward to their testimony.

Chairman TOM DAVIS. I would now like to yield to Ms. Norton for her opening statement and then go to Mr. Waxman.

Ms. NORTON. Thank you very much, Mr. Chairman.

Chairman Davis, I think you are performing a public service, an unusually important public service, with today's hearing. Of course, every hearing is a service to the public. But I must say the first question that came to me as I prepared for this hearing is why is this disease such a mystery to me and why is it, I believe, such a mystery to most of the people in this country? And I couldn't help but wonder whether we were simply sitting on a problem where you have a highly contagious disease like this which has no vaccine and no cure. Where is the public health campaign and public health outcry about this disease? Why am I sitting here, a Member of Congress, probably as ignorant about it as the average American? That is very troubling.

You consider the consequences, the contagion, when you don't know about a disease, that you can then pass on through intravenous drug use, you really are creating a public health menace, that alarms should be raised about it. People should be put on notice. Today's hearing for me is an opportunity to understand why and what we can do about it. Very dangerous disease. Most of the people who have it don't have any symptoms. Here you are passing along a terrible disease and don't know you have it and nobody is telling the public about it.

Here we are sitting in the most advanced country in the world when it comes to health matters, except when it comes to making, of course, health care available to everybody. Why is it that we aren't doing more about this disease?

Consider some of the consequences. This is one of the diseases that leads to terrible liver disease, and people who have liver disease need transplants. And about the most expensive way to deal with the disease is to take an organ out and put another one in. Yet there was a fivefold increase in liver transplants in the 1990's.

I wonder whether it is the nature of the disease and the people who have the disease that account for why we know so little about it and have done so little about the disease. Do we need a Ryan White to get the country's understanding, to get CDC's attention? Because that is what it took, frankly, with the AIDS crisis. If so, shame on us.

The fact that those who get this disease often are people who use drugs, people who are in prison, I should say nothing about the attention we pay to the disease. Unless there is another explanation, I'm going to have to start with a presumption that it's who gets the disease is responsible for why we haven't done more, about why we haven't done more about this disease.

Mr. Chairman, you are doing a great deal about it by having this hearing today that may start us on the way to truly raising the consciousness of the American people about hepatitis C.

Chairman TOM DAVIS. Thank you very much.

I now recognize the ranking member, Mr. Waxman.

Mr. WAXMAN. Thank you, Chairman Davis, for calling this hearing today on an important but often overlooked problem.

Inside the human body, the hepatitis C virus acts with unusual stealth. Infected individuals may feel fine for years and even dec-

ades and then, without warning, hepatitis C can awaken and cause irreversible cirrhosis, liver failure and death.

The stealth of the hepatitis C virus also has been evident in the body politic. Over the past 2 decades, our government has missed opportunities to take action to combat hepatitis C and to alert the public to a growing threat. Now we find ourselves facing a chronic blood-borne infection that affects 3 million Americans and kills 8,000 each year. We must first ask what went wrong, and then we must be clear about the opportunities we are missing even today to defeat hepatitis C.

By 1981, it was known that hundreds of thousands of patients were contracting chronic hepatitis C from blood transfusions. Even through the specific virus causing hepatitis had yet to be identified and there was no specific screening test, blood banks could have taken action to protect the public, because, at the time, research showed that by screening blood for evidence of liver disease in the donor thousands of cases of transfusion-associated hepatitis could be prevented. Such screening, however, was not required by the Food and Drug Administration, and it was not adopted widely by blood banks until 1987.

Two years later, in 1989, the hepatitis C virus was discovered at a specific screening test. Blood banks and hospitals could have looked back and identified people who had been transfused with infected blood, but FDA decided against requiring such a review.

The issue was revisited in the mid-1990's. Under the leadership of HHS Secretary Donna Shalala, the Food and Drug Administration oversaw notification of Americans transfused with tainted blood after 1992. In 1999, FDA proposed extending the notification back to individuals transfused prior to 1992, but the current administration has resisted finalizing this potentially life-saving rule.

There is a moral issue here. The government has neither required notification of people who did receive tainted blood nor conducted a broad public education campaign informing anyone about who needs to get tested. The result is that many people have no idea of the risks they face.

In 2000, Surgeon General David Satcher sought to write a letter to every American's home about the threat of hepatitis C. His effort was never funded.

In 2001, a national hepatitis C strategy was developed. While CDC has begun to pursue important parts of this strategy, many of its elements have yet to be fully funded and implemented. As a consequence, millions of Americans at risk remain unaware of the problem. Many who can benefit from treatment never get it. And even today many infections that can be prevented are not.

According to the Centers for Disease Control, 60 percent of the new hepatitis C infections are transmitted by intravenous drug use. Yet, across our country, many thousands of people who want to get into drug treatment programs, programs that are proven to work, can find no space available to them.

Scientific evidence also demonstrates that even those who continue to use drugs can be kept safe from hepatitis C. Two years ago, a consensus panel on hepatitis C convened by the National Institutes of Health recommended, "providing access to sterile syringes through needle exchange, physician prescription and phar-

macy sales." The panel advised that physicians and pharmacists should be educated to recognize that providing intravenous drug users with access to sterile syringes and education and safe infection practices may be lifesaving. Yet, since then, not much progress in this area has been made.

This is an area where right-wing ideology conflicts with sound public health practices. Everyone wants to stop illegal drug use, but because we know that some addicts will continue to use drugs, it is essential to support needle exchange and other life-saving measures. Those who oppose needle exchanges are like those who oppose comprehensive sex education for teenagers, which also has proven to be effective. Public health policy needs to recognize reality and be based on facts and science.

The infections that we fail to prevent today may not create problems for tomorrow, but, as the years and decades pass, our society will suffer the economic social burden of hepatitis C infections that were entirely preventable. This is a terrible legacy to our children. It's a terrible tragedy for those involved.

I hope this hearing will shed light on the dangers of the hepatitis C virus. We must work together to generate momentum for legislation to address hepatitis C and to expand access through drug treatment.

I thank the witnesses who are going to be here today and am looking forward to their testimony.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Hon. Henry A. Waxman follows:]

Statement of Rep. Henry A. Waxman
Hearing of the Committee on Government Reform
"A Review of the Federal Government's Efforts to Combat Hepatitis C"

December 14, 2004

Thank you, Chairman Davis, for calling this hearing today on an important but frequently overlooked problem.

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Over the past two decades, our government has missed opportunities to take action to combat hepatitis C and to alert the public to a growing threat. Now we find ourselves facing a chronic blood-borne infection that affects three million Americans and kills eight thousand each year.

We must first ask what went wrong. Then, we must be clear about the opportunities that we are missing, even today, to defeat hepatitis C.

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And even today, many infections that can be prevented are not.

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Scientific evidence also demonstrates that even those who continue to use drugs can be kept safe from hepatitis C. Two years ago, a consensus panel on hepatitis C convened by the National Institutes of Health recommended "providing access to sterile syringes through needle exchange, physician prescription, and pharmacy sales." The panel advised that "physicians and pharmacists should be educated to recognize that providing [intravenous drug users] with access to sterile syringes and education in safe injection practices may be lifesaving."

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The infections that we fail to prevent today may not create problems tomorrow. But as the years and decades pass, our society will suffer the economic and social burden of hepatitis C infections that were entirely preventable. This is a terrible legacy to leave our children.

Mr. Chairman, I hope this hearing will shed light on the dangers of the hepatitis C virus. We must work together to generate momentum for legislation to address hepatitis C and to expand access to drug treatment.

I thank the witnesses for coming, and I look forward to their testimony.

Chairman TOM DAVIS. Mr. Towns, any opening statement?

Mr. TOWNS. Thank you very much. I want to thank you, Mr. Chairman, for holding this hearing.

Beginning in 1995, Representative Chris Shays of Connecticut and I held a series of hearings on blood-borne illnesses and hepatitis C. Our concerns for the safety of the blood supply and the possible transmission of disease through transfusion led us to ask hard questions about the Federal policy.

During those hearings, we heard the moving testimony of the Honorable Joe Moakley, former Chair of the Rules Committee, from Massachusetts, who had contracted hepatitis C through a blood transfusion. Unfortunately, he died from the disease within a few years of those hearings. His death showed that hepatitis C can happen to anyone. It made me aware of the fact that education and prevention could not be solid components of the Federal public strategy.

As a result of those hearings, the Centers for Disease Control and Prevention agreed to engage in the first-ever public education campaign on hepatitis C, which included a requirement that the CDC take the unprecedented step of notifying those people who may have been infected through blood transfusions. Some public health officials are warning us that the number of deaths from this disease will triple in the next decade, from the estimate of 8,000 to 10,000 deaths per year to an incredible 24,000 to 30,000 deaths per year. Because the disease can be dormant for several years and only 30 percent of those who are infected have any symptoms of the disease, these estimates may be an understatement. But I'm hopeful we will not see such an explosion before we take action.

That is why I join with my colleague, Heather Wilson, to introduce H.R. 3539, the Hepatitis C Epidemic Control and Prevention Act. This bipartisan bill will direct the Secretary of Health and Human Services to establish, promote and support a comprehensive prevention, research and medical management referral program. For persons suffering from the hepatitis C virus, if passed, this bill will represent the first Federal effort to provide a strategic approach to combat this disease by requiring the development and implementation of a plan for public education, early detection, testing and counseling of patients. Mr. Chairman, I know that you are a supporter of this bill, and I want to thank you so much for that.

In March 2004, the U.S. Preventive Services Task Force, a panel called together by an agency of the Department of Health and Human Services, published recommendations which advised against hepatitis C screening in people who are not in current high-risk categories for the disease. The published recommendations appear to indicate neutrality on whether adults who are high risk should be screened. These recommendations directly contradicted recommendations of the NIH and the current accepted practice in the medical community. Mr. Chairman, may I suggest that we have a hearing on the apparent contradiction within the Federal Government on the issue of hepatitis C screening.

On that note, let me thank you again for holding this hearing; and I would like to thank the witnesses as well for being here and to say to you that, with you, I hope we can make certain that there is a serious and strategic Federal response to hepatitis C. Mr.

Chairman, we need to stay on this issue. This is a very serious problem.

Chairman TOM DAVIS. Thank you very much for your leadership on this as well, Mr. Towns; and I'm proud to be a co-sponsor of your bill.

We are going to move to our first panel of witnesses who will discuss efforts being taken at the Federal level to manage the hepatitis C epidemic. They will also describe their efforts to coordinate, educate, screen, treat, counsel and survey measures.

We have Dr. Rima Khabbaz, the Associate Director of Epidemiologic Science for the National Center for Infectious Diseases. She'll be providing testimony on behalf of the CDC. Dr. Eric Mast, the Acting Director of the Division of Viral Hepatitis at CDC, accompanies Dr. Khabbaz and is available to answer questions. So when we swear in witnesses we will have both of them sworn in.

Dr. Jay Hoofnagle of the Liver Disease Research Branch at NIH will provide testimony regarding research efforts in search of a vaccine and more effective treatment options; and Dr. Lawrence Deyton, the Chief Consultant of the Public Health Strategic Healthcare Group at the Department of Veterans Affairs, will discuss the VA's excellent hepatitis C program. He's accompanied by Dr. Michael Rigsby, who is the Director of the National Program Office for HIV and Hepatitis C at the Veterans Health Administration. Dr. Rigsby will also be available to answer questions posed by Members, so he'll be sworn as well.

Would you please rise with me and raise your right hands.

[Witnesses sworn.]

Chairman TOM DAVIS. It's our policy that we swear you in before you testify.

Dr. Khabbaz, I think I'll start with you—we will move straight on down the line—and I thank you for your efforts in this area and thank you for being with us today. We try to keep our 5-minute presentation. Your entire testimony is in the record. So thank you.

STATEMENTS OF RIMA KHABBAZ, M.D., ASSOCIATE DIRECTOR OF EPIDEMIOLOGIC SCIENCE, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTER FOR DISEASE CONTROL AND PREVENTION, ACCOMPANIED BY ERIC MAST, M.D., ACTING DIRECTOR OF THE DIVISION OF VIRAL HEPATITIS; JAY HOOFNAGLE, M.D., LIVER DISEASE RESEARCH BRANCH, DIVISION OF DIGESTIVE DISEASES AND NUTRITION, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE KIDNEY DISEASES, NATIONAL INSTITUTES OF HEALTH; AND LAWRENCE DEYTON, MSPH, M.D., CHIEF CONSULTANT, PUBLIC HEALTH STRATEGIC HEALTHCARE GROUP, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY MICHAEL RIGSBY, M.D, DIRECTOR OF THE NATIONAL PROGRAM OFFICE FOR HIV AND HEPATITIS C, VETERANS HEALTH ADMINISTRATION

Dr. KHABBAZ. Good afternoon, Mr. Chairman and members of the committee. I am Dr. Rima Khabbaz, Associate Director for Epidemiologic Science at the National Center for Infectious Diseases at the CDC; and I'm accompanied today by Dr. Eric Mast, the Acting Director of the Division of Viral Hepatitis. We are pleased to

be here, and we thank you for the opportunity to describe the activities that CDC has undertaken with our partners to implement the National Hepatitis C Prevention Strategy, which this committee was instrumental in initiating in 1999.

Hepatitis C virus [HCV], is indeed a very serious concern, as it is today the most common cause of chronic liver disease in the United States. It is the most common chronic blood-borne infection. About 4 million Americans have already been infected, and approximately 3 million are chronically infected, and about 30,000 Americans become newly infected each year. Unlike hepatitis A and B, there is no vaccine to prevent infection with HCV. Because the consequences of chronic liver disease from HCV may not become apparent for 10 to 20 years, many infected persons are not aware of their infection.

The two major objectives of the National Hepatitis C Prevention Strategy are identification of infected persons and prevention of new infections. These objectives are paramount to reducing the impact of HCV on the public.

Identification of HCV-infected persons as well as persons at risk of HCV infection is best achieved through the integration of hepatitis prevention services into community-based clinical and public health programs that serve at-risk persons. Because the majority of persons with hepatitis C do not have symptoms of liver disease, their identification requires that testing be done on persons with risk factors for infection.

CDC has conducted a number of community-based demonstration projects called Viral Hepatitis Integration Projects which have shown the feasibility and the effectiveness of including hepatitis prevention services in a variety of clinical and public health settings.

I would now like to take a few moments to highlight some specific components of the National Hepatitis C Prevention Strategy.

First, as it relates to health communications, CDC has developed evidence-based guidelines for identification and testing of persons at risk of hepatitis C. CDC has also provided a broad range of materials about hepatitis C for health care professionals and the public. These include Web-based, continuing medical education programs for health care professionals, a Hepatitis C Toolkit for primary care providers and their patients. We have brought with us samples of these materials on the table here and there for those interested, and it can also be found on CDC's Web site. CDC has also funded academic centers, health departments and nongovernmental organizations to carry viral hepatitis education and training activities.

Second, with regard to community-based prevention programs, currently, CDC funds 53 hepatitis C coordinators in States, large metropolitan areas and in the Indian Health Service. These coordinators work to accelerate the integration of hepatitis C testing, counseling and referral for medical evaluation into community-based programs that provide clinical and Public Health Services. Among the many activities in which the coordinators engage is the development of comprehensive State hepatitis C prevention plans, and at least 23 States have such a plan at this time.

Surveillance is another important component of the prevention strategy because it allows us to monitor trends as well as the effectiveness of prevention efforts. CDC continues to work to develop and maintain enhanced national surveillance systems for hepatitis C. Since 2003, chronic HCV infection has become reportable to CDC; and CDC has developed surveillance guidelines for case investigation and followup of persons of chronic HCV infection.

As there continues to remain a number of an unanswered questions concerning the epidemiology and the natural history of HCV infection, CDC has a number of studies under way or planned.

In conclusion, since 1998, CDC and its partners have made considerable progress in raising awareness about the prevention of hepatitis C both among health care providers and the public. In addition, many States have initiated hepatitis C prevention programs, which are being facilitated by the federally funded hepatitis C coordinators. However, our job is far from complete and much more remains to be done.

Thank you for your attention and for the opportunity to increase awareness about hepatitis C for this hearing, and I will be happy to answer any questions you may have.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Khabbaz follows:]

Testimony
Before the Committee on Government Reform
United States House of Representatives

CDC's Activities to Prevent Hepatitis C Infection

Statement of
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Good afternoon Mr. Chairman and Members of the Committee. I am Dr. Rima Khabbaz, Associate Director for Epidemiologic Science of the National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am accompanied today by Dr. Eric Mast, Acting Director of CDC's Division of Viral Hepatitis. We are pleased to be here today to describe the activities CDC has undertaken with partners to implement the *National Hepatitis C Prevention Strategy*, which this Committee was instrumental in initiating in 1998.

Background

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV), which is found in the blood of persons who have this disease. Although hepatitis C can lead to cirrhosis or scarring of the liver, to liver failure, and liver cancer, the consequences of chronic liver disease from hepatitis C may not become apparent for 10 to 20 years, so many individuals infected with HCV are not aware of their infection. HCV infection is spread primarily by exposures that involve direct passage of blood through the skin, and it is the most common chronic bloodborne infection in the United States. About 4 million Americans have already been infected, of whom approximately 3 million are chronically infected, and about 30,000 Americans become newly infected each year. Unlike hepatitis A and hepatitis B, there is no vaccine to prevent infection with HCV.

Risk Factors Associated with HCV Infection

Before blood donor testing for non-A, non-B hepatitis became available beginning in the mid-1980s, and then a specific test for HCV infection beginning in 1990, blood transfusions accounted for 10-25 percent HCV infections. However, specific testing of blood donors has reduced the risk of infection from a unit of blood to less than one in 1,000,000 units transfused.

Injection drug use is now the risk factor for infection among about 50 percent of persons with past HCV infection, and since the mid-1980s, injection drug use accounts for approximately two-thirds of new infections among Americans. Of persons injecting drugs for at least 5 years, 60-80 percent are infected with HCV, a risk that is 2 to 3 times higher than for the human immunodeficiency virus (HIV). This high rate of infection accounts for the 15-30 percent prevalence of HCV infection that has been found among inmates of correctional facilities. Other risk factors for infection include occupational exposure to blood through a needle stick from an infected person, transmission to an infant from an infected mother, and less efficiently through sex with an infected sex partner.

Consequences of Infection with HCV

Approximately 75-85 percent of persons with an acute hepatitis C virus infection develop a chronic infection, and about 60-70 percent of those persons develop chronic hepatitis. Lower rates of chronic infection and liver disease appear to occur among persons who were infected as children.

Over a period of 20 to 30 years, cirrhosis of the liver occurs in 10-20 percent of persons with chronic hepatitis C virus infection and liver cancer developing in 1-5 percent of them. Surveillance studies conducted by CDC and the National Institutes of Health (NIH) show that HCV accounts for 40-60 percent of chronic liver disease in the United States. Chronic liver disease is the tenth leading cause of death among adults in the United States, and HCV causes between 8,000 and 10,000 of these deaths each year. HCV is the most frequent indication for

liver transplantation in this country; the number of patients on transplant waiting lists has doubled in the past 5 years, and about 50 percent of these patients die while awaiting liver transplant.

About one quarter of HIV-infected persons in the United States are also infected with HCV. HCV is transmitted primarily by large or repeated direct exposures to contaminated blood. Therefore, coinfection with HIV and HCV is common among HIV-infected injection drug users (IDUs). Coinfection is also common among persons with hemophilia who received clotting factor concentrates before concentrates were effectively treated to inactivate both viruses (i.e., products made before 1987). As highly active antiretroviral therapy (HAART) and preventive treatment of opportunistic infections increase the life span of persons living with HIV, HCV-related liver disease has become a major cause of hospital admissions and deaths among HIV-infected persons. Persons living with HIV who are not already coinfected with HCV can adopt measures to prevent acquiring HCV. Such measures will also reduce the chance of transmitting their HIV infection to others.

Treatment of Chronic HCV Infection

Current antiviral treatment completely eliminates HCV infection in 50-55 percent of selected patients, with 95 percent of those remaining virus free for at least 5 years. While antiviral therapy is indicated for many patients with chronic HCV infection, treatment is less effective and may not be indicated for patients with severe liver disease. Also, alcohol abuse appears to worsen the outcome of HCV, and antiviral treatment is more difficult among persons with ongoing abuse.

In addition to the benefits of antiviral treatment, patients with chronic HCV infection can benefit from counseling, immunizations, and other services to prevent progression of chronic liver disease. Because alcohol use is one of the most important contributing factors to progression of chronic liver disease in HCV-infected persons, it is important to identify infected persons as early as possible so that they can be counseled to limit alcohol consumption. In addition, persons with HCV should be vaccinated against diseases, including hepatitis A and hepatitis B, that may produce further liver injury or increase their risk of death.

CDC's Current Prevention and Control Efforts

Identification of HCV-infected persons and prevention of new infections are the major objectives of the *National Hepatitis C Prevention Strategy.* Identification of infected persons provides the opportunity for medical evaluation to: 1) determine the extent of their chronic liver disease, 2) determine if they are candidates for antiviral therapy, 3) determine if they need treatment for other conditions such as alcohol or drug abuse that will worsen their HCV, and 4) provide health education about how to prevent HCV transmission to others.

Identification of HCV infected persons, as well as persons at risk of HCV infection, is best achieved through the integration of hepatitis prevention services into community-based clinical and public health programs that serve at-risk persons. Because the majority of persons with HCV do not have symptoms of liver disease, their identification requires that testing be conducted on persons with risk factors for infection. CDC has conducted a number of community-based demonstration projects – the Viral Hepatitis Integration Projects, or VHIPs --

which have shown the feasibility and effectiveness of including hepatitis prevention services in a variety of clinical and public health settings. I will now highlight some specific components of the *National Hepatitis C Prevention Strategy.*

Health Communications: CDC has developed evidence-based guidelines for identification and testing of persons at risk of hepatitis C. In addition, CDC has provided a broad range of materials about hepatitis C for health care professionals and the public. Examples include web-based continuing medical education programs for health care professionals, a *Hepatitis C Toolkit* for primary care providers and their patients, and health education materials for high school teachers. These materials are available on CDC's web site and can be found at: http://www.cdc.gov/ncidod/diseases/hepatitis. CDC has also funded 12 viral hepatitis education and training cooperative agreements with academic centers, health departments and non-governmental organizations.

Community-based Prevention Programs: To accelerate the integration of hepatitis C testing, counseling and referral for medical evaluation into community-based programs that provide clinical and public health services, CDC has made funding available for Hepatitis C Coordinators. Currently, there are 53 coordinators in States, large metropolitan areas, and in the Indian Health Service (IHS). One activity that coordinators have been involved in is the development of comprehensive State hepatitis C prevention plans. Currently, 23 States have a plan or are in the process of developing such a plan. In addition, CDC has funded the VHIPs in 21 State and local health departments and in the IHS to provide models and best practices for integration of viral hepatitis prevention services into clinical and public health programs, such as

those in STD clinics, drug treatment facilities, HIV/AIDS prevention programs, and correctional settings. Additionally, CDC, in collaboration with the IHS Division of Epidemiology, provides technical assistance to Tribes, IHS facilities, Urban Indian Health Programs, and other American Indian/Alaskan Native groups to implement hepatitis C prevention activities.

Surveillance and Program Evaluation: Since 2003, chronic HCV infection has been a condition that is reportable by States to CDC. In 2003, 19 States submitted case reports. CDC has also developed surveillance guidelines for case investigation and follow-up of persons with chronic HCV infection. CDC will continue to work to develop and maintain enhanced national surveillance systems in order to monitor the effectiveness of hepatitis C prevention efforts. In addition, a study is underway to evaluate the effectiveness of the VHIPs and determine future directions for such demonstration projects.

Research: There continue to remain a number of unanswered questions concerning the epidemiology and natural history of HCV infection that need to be answered to develop interventions to prevent transmission of HCV and to prevent disease progression among persons with chronic infection. Priority areas in which studies are underway or in the planning stages include those that determine: 1) incidence and risk factors for HCV transmission among household contacts of infected persons; 2) risk factors for transmission from mother to infant at birth; 3) risk of infection from intranasal cocaine use, tattooing, and body-piercing; 4) prevalence and incidence of infection in incarcerated populations; 5) risk of infection among steady heterosexual partners of HCV-infected persons; 6) risk factors for infection among persons on chronic hemodialysis; 7) the dynamics of HCV acquisition among injection drug users and the

effectiveness of harm reduction strategies in preventing infection; 8) disease burden, including chronic liver disease and liver cancer mortality; and 9) risk factors for health care related transmission.

In conclusion, since 1998, there has been considerable progress made in raising awareness about the prevention of hepatitis C both among healthcare providers and the public. In addition, many States have initiated hepatitis C prevention programs, which are being facilitated by the federally funded Hepatitis C Coordinators.

To help us make further improvements in this area, CDC has established a National Viral Hepatitis Roundtable in conjunction with representatives from national voluntary health organizations, nongovernmental organizations, professional societies, health insurers, industry, and other governmental agencies. The Roundtable is designed to coordinate efforts by CDC and our partners to address hepatitis C and other forms of viral hepatitis. It helps to make sure efforts of CDC and its partners are targeted and not duplicated, so we can all make maximum use of our resources.

Thank you very much for this opportunity to update you on what has happened with hepatitis C prevention since this was last addressed by this Committee. I will be happy to answer any questions you may have.

Chairman TOM DAVIS. Dr. Hoofnagle, thank you for being with us. It is a pleasure to have you. One of my staff members told me that your efforts, at least she thinks, helped save her life a couple of years ago, so thank you very much.

Dr. HOOFNAGLE. Thank you very much, Mr. Chairman and members of the committee.

My name is Jay Hoofnagle, and I'm the Director of the Liver Disease Research Branch for the National Institute of Diabetes and Digestive and Kidney Diseases, one of the Institutes at the National Institutes of Health. I'm pleased to be asked to present testimony today on behalf of the NIH and its commitment to research on hepatitis C.

As you have heard from Dr. Khabbaz, hepatitis C is a very important cause of liver disease. Between 1 and 2 percent of Americans are chronically infected with hepatitis C. Hepatitis C is now the most common cause of chronic liver disease and most common cause of cirrhosis and the major single cause for liver transplantation in adults, and it has become the most common cause of liver cancer in this country and most of the western world.

But, also important, hepatitis C is due to a virus and, as such, this is a potentially preventable, potentially treatable disease. That means that control of this virus will go a long way to the control of cirrhosis in this country.

We believe, Mr. Chairman, that the greatest promise for ultimate control of hepatitis C will come through advances in biomedical science and biomedical research, advances in the means of diagnosis and evaluation and treatment and prevention of this disease. Indeed, there are few areas of biomedical research at present that are more likely to result in immediate and tangible improvements in the health of Americans than research on hepatitis C.

As you know, the mission of the NIH is to advance biomedical research and thereby reduce the burden of disease and improve health of Americans. Hepatitis C is a shared interest at the NIH, not just by my Institute but also by the National Institute of Allergy and Infectious Diseases, the National Institute on Drug Abuse, the National Cancer Institute, the National Heart, Lung and Blood Institute, and the National Institute on Alcohol Abuse and Alcoholism.

The activities of the Institutes are coordinated through multiple committees, so that in fiscal year 2004 that was just completed the estimated total amount of NIH research on hepatitis C was $118 million. Importantly, this figure is a major increase from what was funded 5 and 10 years ago. For instance, between 1998 and 2003, the Congress allocated funding that allowed for the doubling of the NIH budget. During this same time, the budget specific for hepatitis C increased almost five-fold, stressing the importance of this research area and the ability of the NIH to allocate funding to emerging conditions of importance.

This hearing actually occurs at a special time for liver disease research in that the NIH has just completed a trans-NIH action plan for liver disease research. This is the result of a year of work and input from over 250 investigators, physicians and lay persons. It covers all of the diseases, but hepatitis C is a major focus of this action plan. The action plan outlines some goals and visions for the

next 5 to 10 years of research on liver disease, and some of my testimony will address the goals outlined in that plan. So in this brief introduction I want to discuss two areas of importance and research. The first is treatment and the second, prevention.

As to treatment: The first treatment for hepatitis C was licensed in 1991, and it is alfa interferons, given by injection for 6 to 12 months. As originally formulated, this regimen of therapy gave us sustained response in only 10 to 20 percent of patients at most.

During the last 5 years, we have been fortunate to see several advances in therapy of hepatitis C, the first, the introduction of the anti-viral drug ribavirin, and, the second, the development of long-acting interferons that are given once a week rather than daily or every other day and that are more effective. So that the currently recommended regimen for hepatitis C, the combination of peginterferon and ribavirin, is effective in 55 percent of patients with hepatitis C who have no other problems with their health. Indeed, in subgroups of patients, patients who have different strains of hepatitis C, strain 2 and 3, the response rate is greater than 80 percent. These results are heartening.

Also heartening is the fact that what we call sustained response is now shown to be durable and long lasting, and it appears to be a cure of this viral infection. Well, that's nice in a way, but remember that for 55 percent of these people that respond, there are 45 percent who did not. This treatment is difficult, and it's expensive and has many side effects. Clearly, new approaches of treatment are needed.

A major proportion of our portfolio now in funding research on hepatitis C is directed at improving therapy, and industry is also involved in this to a major degree. There have been more than 50 patent applications for new therapies of hepatitis C, and at least six of them are in early human trials. These are not ready for licensure or approval, but I can assure you that they look very promising. It is our hope that in the next 5 to 10 years, we will have therapy for this disease that will be effective in more than 90 percent of patients and will extend to those difficult-to-treat populations that are a problem at present.

Finally, as to prevention, as you have heard from the CDC, currently, there are recommendations toward prevention based on public health measures. Since the discovery of the virus in 1987, there has been an 80 percent drop of new cases of hepatitis C. It is quite heartening. But since the 1990's, this level of infection has stayed stable, and there has been very little further decrease. What is needed? Clearly, specific means of treatment are needed, vaccines and globulins that are effective against exposure to hepatitis C.

In this regard, major efforts are being made in this area, stimulated through workshops, initiatives, added funding, to request of applications for basic research on development of tissue culture, animal models and candidate vaccines. Phase one studies of experimental vaccines have been funded, and with the advances and knowledge about the immune system and with the focus on this issue, we believe that a vaccine against this disease will ultimately be available.

Mr. Chairman, let me conclude by thanking you for having this hearing highlighting this very important disease and express the gratitude of the basic and clinical research community in general for the confidence and trust that the U.S. Congress has put into us through continued support of the National Institutes of Health and their mission. We believe that real progress can be made in the control of hepatitis C, and I will be glad to answer any questions that you have of me on the issue.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Hoofnagle follows:]

Testimony Before the
Committee on Government Reform
United States House of Representatives

HEPATITIS C RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH

Statement of
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Mr. Chairman and Members of the Committee: I am Jay Hoofnagle, Director of the Liver Disease Research Branch in the Division of Digestive Diseases and Nutrition, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). This is the Institute that has major responsibility for hepatitis C research at the National Institutes of Health (NIH) of the Department of Health and Human Services (HHS). I am pleased to testify today regarding NIH efforts to combat hepatitis C infection. Through basic and clinical research studies, we can gain greater insights into the diagnosis of hepatitis C, find more effective treatments, and develop prevention strategies.

At the NIH, hepatitis C is a shared research focus of the NIDDK, the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Heart, Lung, and Blood Institute (NHLBI). In my testimony today, I will give you a brief overview of the public health burden of hepatitis C, the current status of research, planning, and coordination of efforts at the NIH, and our major goals for future research.

It is particularly appropriate for this Committee to have a hearing at this time on this topic. The hepatitis C virus was discovered just 15 years ago. Yet, today it is clear that hepatitis C is the most common cause of chronic liver disease in the United States, the most common cause of liver cirrhosis, the most common indication for liver transplantation, and now the most common cause of liver cancer. Hepatitis C is, thus, the most critical area of all liver disease research.

Hepatitis C research is particularly important for another reason. Hepatitis C caused by to a virus; and as such, this disease is treatable and potentially preventable. Control of this viral infection would eliminate the most common cause of cirrhosis in our country. Furthermore, recent research on hepatitis C has provided new tools that may make the control and prevention of this disease a practical reality, leading to decreases in the burden of this chronic liver disease, and bringing immediate and tangible benefits to large numbers of people.

OVERVIEW OF HEPATITIS C

The hepatitis C virus (HCV) is a pathogenic infectious agent that causes a major form of hepatitis, or liver inflammation, in humans. HCV is spread mainly through contact with infected blood and blood products. Currently, the main cause of HCV transmission in the U.S. is through the use of shared, unsterilized needles, syringes, and other drug paraphernalia among injection drug users. Transmission of HCV through blood transfusions, historically an important cause of transmission, has been largely eliminated in recent years due to routine screening of the blood supply for the virus. Sexual spread of hepatitis C occurs, but is not common.

Population surveys indicate that approximately 4 million Americans have been infected with HCV, of whom 3 million have chronic infection with the hepatitis C virus; the majority of these individuals are probably unaware of having this disease. Acute hepatitis C is uncommonly recognized because it is usually silent and not associated with symptoms or signs of liver disease. The greater health threat posed by hepatitis C virus infection is that the acute infection fails to resolve in most instances, and the disease advances to chronic hepatitis C, which may progress further to cirrhosis, potentially leading to liver failure, and even to liver cancer.

Not all patients with chronic HCV infection develop severe liver disease. Furthermore, progression of liver disease is typically slow. Thus, approximately 10 percent of persons with HCV infection develop cirrhosis per decade of infection. Liver cancer generally arises only after cirrhosis has been present for many years, at an annual rate of 1 to 3 percent per year. For these reasons, therapy of hepatitis C is generally recommended mainly for persons who have evidence of progressive liver disease.

Chronic hepatitis C is the most common reason for liver transplantation in the U.S., and results in an estimated 8,000 to 10,000 deaths each year in this country. The burden placed on the U.S. healthcare and economic systems by chronic hepatitis C is also great, estimated at $758 million spent in 2000 on medical costs and lost work hours due to the disease. (Sandler, R.S., Everhart, J.E., Donowitz, M., Adams, E., Cronin, K., Goodman, C., Gemmen, E., Shah,

S., Avdic, A., Rubin, R. The burden of selected digestive diseases in the United States. *Gastroenterology* 2002 May; 122(5); 1500-11.)

CURRENT STATUS OF RESEARCH ON HEPATITIS C

What is the current status of research on hepatitis C? I will discuss 3 areas: diagnosis, treatment, and prevention.

Diagnosis and evaluation: There are now accurate tests to diagnose hepatitis C infection. These are widely used and have been critical in screening of blood donors. The introduction of tests for hepatitis C has led to the disappearance of post-transfusion hepatitis and improvement in the safety of our blood supply. In 2000, Dr. Harvey Alter of the Department of Transfusion Medicine at the NIH Clinical Center and Dr. Michael Houghton of the Chiron Corporation were awarded the prestigious Lasker Award for their contributions to the discovery of the hepatitis C virus and development of means of testing blood to eliminate post-transfusion hepatitis C. While diagnosis of hepatitis C is now reasonably straightforward, evaluation of patients for the degree and stage of liver injury is still difficult and inaccurate relying upon liver biopsy and x-rays. Research is being focused on developing accurate means of assessing liver disease in persons with hepatitis C.

Treatment: There are improved means of treatment of hepatitis C. The initially approved therapy for hepatitis C was a 6- or 12-month course of treatment with standard interferon alfa. This therapy, however, resulted in sustained benefit in fewer than 20 percent of patients (1 in 5). Fortunately, in the last five years, therapy of hepatitis C has advanced, first with the introduction of the antiviral agent ribavirin and second with the development of an improved, long-acting interferon, called peginterferon. The currently recommended regimen of a combination of peginterferon and ribavirin results in sustained benefit in approximately 50 to 55 percent of persons with hepatitis C. In fact, among patients with certain strains of virus (called genotypes 2 and 3), response rates are greater than 80 percent. In addition, the response in persons with hepatitis C has now been shown to be more than a temporary improvement. A sustained response has been shown to be a complete eradication of the virus from the liver and

cure of the chronic infection. These advances in treatment of hepatitis C have been heartening, but we are working to achieve even better progress.

Prevention: Prevention of hepatitis C has been an area of special focus of research, but one of limited progress to date. Actually, the discovery of the hepatitis C virus and introduction of HCV testing was followed by an immediate and marked drop in the incidence of new cases of hepatitis C in the United States. Between the mid-1980s and 1995, the estimated number of new hepatitis C infections fell by 80 percent, but has remained relatively constant since 1995 at about 30,000 per year. Further progress in prevention, however, awaits advances in developing a specific means of prevention, such as an HCV vaccine. Work on this is ongoing, but the development of such a vaccine has been difficult. Unlike hepatitis A or B, antibodies to hepatitis C do not lead to recovery and fail to prevent infection even when present in high levels. Indeed, persons who recover from hepatitis C, either spontaneously or as a result of therapy, remain susceptible to re-infection. Thus, the conventional means of vaccine development have not been successful in hepatitis C and new approaches are being investigated.

CURRENT PROGRAMS, PLANNING, AND COORDINATION OF EFFORTS IN HEPATITIS C RESEARCH AT THE NIH

The NIH conducts, supports, plans, and coordinates hepatitis C research in a number of ways. First and foremost, the NIH supports a solid, ongoing portfolio of investigator-initiated hepatitis C research grants that are funded based on scientific merit as judged by the peer review system. To complement this investigator-initiated research, NIH Institutes and Centers initiate and propel research solicitations, scientific conferences, workshops, and public education. While hepatitis C research is pursued by multiple Institutes, there are mechanisms in place to assure coordination among the Institutes and Centers in the funding of research grants, research centers, and clinical trials. The Institutes and Centers work together under the auspices of a trans-NIH Hepatitis C Working Group to develop new initiatives, requests for applications, and ideas for workshops and symposia.

For fiscal year 2004, hepatitis C research was funded at a level of $118 million NIH-wide, the largest amounts of which came from the NIAID, NIDDK, NCI, NIDA, NIAAA, and NHLBI. Funding has risen markedly in the last few years, fueled by the recent doubling of the NIH budget as provided by the Congress and Administration. Let me point out that during this overall doubling of the NIH budget, funding for hepatitis C increased nearly five-fold, demonstrating the relative and emerging importance of research into this disease. Hepatitis C has been an area of high priority to the NIH during this critical period of our budget doubling.

In building the hepatitis C research portfolio, we recognize the importance of input from the scientific and lay community external to the NIH. I would like to provide just a few examples. One example of input that guides NIH program development can be found in the insights and recommendations we obtain from a wide range of conferences and workshops. For example, the NIH has sponsored critically important Consensus Development Conferences on hepatitis C in 1997 and 2002, and last spring we submitted to the Congress a report on our implementation of the recommendations we received from the 2002 Conference. The Conference was organized by the NIDDK in collaboration with the NIH Office for Medical Applications of Research and seven other NIH Institutes. Other participating Federal agencies included the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration, the Health Resources and Services Administration, and the Centers for Medicare and Medicaid Services within HHS; the U.S. Department of Veterans Affairs; and the Office of the Assistant Secretary of Defense. The proceedings of the Conference were published in the November 2002 issue of the journal *Hepatology* (Vol. 36 (5), Supplement 1; available at: http://consensus.nih.gov/cons/116/116cdc_intro.htm).

Consensus Development Conferences are a source of valuable information to help guide research directions at the NIH. The two Conferences on hepatitis C provided an overview of the current understanding of its cause, natural history, complications, prevention, and treatment. The statements of the Consensus Development Conference Panels also provide objective, evidence-based recommendations on the clinical management of this disease. In addition, the Panels were asked to develop a list of important areas for future research that would help improve the management of hepatitis C. These suggestions have been used to inform initiatives developed by the NIH and other Federal agencies.

Recent initiatives in hepatitis C spearheaded by the NIH relevant to important areas for future research identified by the 2002 Consensus Conference Panel include:

- $ A large, multi-institute supported RFA on "Hepatitis C: Natural History, Pathogenesis, Therapy, and Prevention" published in January 2003, that encouraged research project applications in the areas that were outlined in the recommendations from the Consensus Development Conference. Six Institutes participated in this RFA. Twenty-nine applications were supported that will help to advance the field of research on hepatitis C management.
- $ Several NIH workshops have addressed specific issues raised in the Consensus Conference, including "Hepatitis C and Renal Disease," "Hepatitis C in Prison Populations," "Hepatitis C and Substance Abuse," "Hepatitis C and the Brain," and "Hepatocellular Carcinoma: Screening, Diagnosis and Management." Several more workshops are planned, for example, on the subjects of alcohol and hepatitis C, and hepatitis C vaccines.
- $ Several clinical trials and networks in hepatitis C have been established, both *de novo* and as a part of existing clinical trial consortia, including studies of patients with advanced liver disease (HALT-C trial), African Americans with chronic hepatitis C (Virahep-C trial), liver transplant patients (A2ALL trial), patients with HIV infection (Adult AIDS Clinical Trials Group or AACTG), and children with chronic hepatitis C (Peds-C trial). Furthermore, pilot studies are presently in development to address acute hepatitis C, hepatitis C in injection drug users, complementary and alternative medicines and hepatitis C, and hepatitis C in prison parolees.
- $ The NIAID, in collaboration with the NIDDK and NIDA, has reissued a Request for Applications for Hepatitis C Cooperative Research Centers. These Centers promote multidisciplinary research and translation of basic research findings on the hepatitis C virus to practical problems. These Centers will be funded in fiscal year 2005.
- $ The NIAID also is conducting a phase 1 clinical trial using a prototype vaccine produced by private industry; renewing the Hepatitis Animal Model Network,

which will focus on the development of animal models to screen therapies and vaccines for hepatitis C and hepatitis B; and is supporting the HCV Sequence Database and developing an HCV Immunology Database to operate in conjunction with the HIV database.

Intersecting research and active collaborations in hepatitis C are found among many NIH components. The statutory Digestive Diseases Interagency Coordinating Committee (DDICC), which is chaired by NIDDK, serves to coalesce and synergize the efforts of the many NIH Institutes and Centers that support hepatitis C research, as well as the efforts of other Federal agencies. The Committee strives to promote the exchange of information and the formation of collaborative relationships among its member organizations in order to combat the full range of digestive diseases, including liver diseases.

To further strengthen the commitment of the DDICC to liver disease research, a Liver Disease Subcommittee was formed in 2003. This Subcommittee is composed of representatives from NIH components with significant support of or interest in liver disease research. The Liver Disease Subcommittee is in the final stages of producing an *NIH Action Plan for Liver Disease Research*, under the direction of the new NIDDK Liver Disease Research Branch, and with significant contributions from the scientific and lay community. It identifies current challenges and future opportunities for NIH-supported research on several types of liver disease, including hepatitis C.

The new NIDDK Liver Disease Research Branch, of which I am the Director, was established in 2003 to promote research efforts in critical areas of liver disease, such as hepatitis C. A major charge of the Branch is to improve collaborations and promote liver disease research in other NIH Institutes and Centers.

OUTREACH AND PUBLIC EDUCATION EFFORTS

Information-dissemination and public and professional education activities supported by the NIH in hepatitis C benefit from the coordinating focus provided by the National Digestive Diseases Information Clearinghouse of the NIDDK, and include the involvement of multiple NIH Institutes, other Federal agencies, and professional and lay organizations such as

the American Association for the Study of Liver Diseases, the American Liver Foundation, and the Hepatitis Foundation International. Information and facts sheets on hepatitis C and its treatment and prevention are also provided to the public online through two NIH websites maintained by NIDDK and NIAID, which are accessible, respectively, at: http://digestive.niddk.nih.gov/ddiseases/topics/hepatitis.asp and http://www.niaid.nih.gov/publications/hepatitis.htm. NIH-supported informational materials available on these websites include publications geared towards the general public, such as "What I Need to Know About Hepatitis C," "Chronic Hepatitis C: Current Disease Management," and "Hepatitis C: Information Resources." The Veterans Health Administration and the CDC maintain comprehensive hepatitis C websites with educational materials of relevance to veterans and the general public at: http://www.hepatitis.va.gov/, and http://www.cdc.gov/ncidod/diseases/hepatitis/c/index.htm.

NIH ACTION PLAN FOR LIVER DISEASE RESEARCH

As I alluded to previously, the NIH is now completing a new research planning process for liver diseases, including hepatitis C, under the auspices of the statutory Digestive Diseases Interagency Coordinating Committee. An *NIH Action Plan for Liver Disease Research*, produced in consultation with external scientific and lay experts, will be released very soon. We believe that this planning effort will help to guide future research directions.

This Action Plan is the result of consultation and advice from hundreds of researchers, physicians, and laypersons concerned with liver disease research. It outlines research goals for the future, goals that are short-, intermediate-, and long-term and low-, intermediate-, and high-risk. Hepatitis C was, of course, an important component in this Action Plan. While the final draft of the Plan is still undergoing review and approval, let me summarize the Action Goals that were particularly applicable to hepatitis C.

First, in the area of diagnosis and evaluation of patients, a major goal is to develop better means of assessing hepatitis C clinically, to determine its severity, stage, and presence of possible complications. Is the disease mild or severe? Early or late? Is cirrhosis present? Is liver cancer present? Currently, our tools are limited—we rely upon liver biopsy and

expensive and elaborate x-rays to assess the liver. A goal for research is to develop simple and reliable markers for hepatitis disease activity and stage, biomarkers for the presence of fibrosis or cirrhosis of the liver, and importantly, noninvasive markers for the presence of liver cancer, so that it can be detected readily at an early stage, when it is small and possibly curable by surgery. Thus, development of biomarkers for hepatitis C is a high priority and is already the focus of several trans-NIH initiatives in research.

Second, in the area of therapy, the current standard regimen of peginterferon and ribavirin therapy is unsatisfactory in several respects. It yields cures of disease in only half of patients; it is expensive; and it often requires prolonged treatment. Also, peginterferon and ribavirin have many side effects, and therapy is often not tolerated or cannot be used at all because of other medical problems—kidney failure, heart or lung disease, severe anemia, immunodeficiency, or psychiatric illness. One of the major goals for research in hepatitis C is to increase the response rate to therapy. This will require new drugs with new targets for the disease. The targets for therapy of hepatitis C have been uncovered by basic research on this virus, and they include a protease and a polymerase, similar to those of HIV, the AIDS virus. Investigators from both the NIH and private industry are involved in developing better therapies for hepatitis C. There have been more than 50 patent applications filed for new therapies of hepatitis C. At least six drugs are currently in early human trials. None of these agents are ready for licensure or approval, but preliminary results are promising and make us believe that a therapy will be available within the next ten years that is beneficial in more than 90 percent of patients with this disease. Research on therapy is focusing on developing new tools as well—a tissue culture system and small animal models that could be used to screen new drugs and new approaches to treatment of this disease. Furthermore, clinical trials are under way to help refine current treatments of hepatitis C and new uses of the medications that we have, such as use of long-term peginterferon or long-term ribavirin to control (rather than cure) hepatitis C. These trials are funded in collaborative fashion by NIDDK, NIAID, NIDA, NIAAA, and NCI.

Third, in the area of prevention, a major goal for research in the next ten years is to develop a hepatitis C vaccine. Understanding of the immune response to hepatitis C, and the mechanisms by which people recover from this infection, are areas of research that are directed

at how the immune response can be manipulated to prevent infection or ensure recovery once infection has occurred. Hepatitis C vaccine development is a major area of research by the NIH. In early 2005, NIAID, in collaboration with NIDDK, will be hosting a workshop on "Progress in Developing Hepatitis C Vaccine." It is important to point out that the difficulties we face in combating hepatitis C are similar in many respects to those faced in HIV infection. Thus, research and progress in developing an HIV vaccine are likely to impact on research on a HCV vaccine. Alternative approaches to vaccine formulation that work against HIV are likely to work against HCV and *vice versa*.

We believe that the *NIH Action Plan for Liver Disease Research* will produce useful guideposts for prioritization in NIH program development, and will help synergize crosscutting research efforts across the NIH.

CONCLUSION

Mr. Chairman and Members of the Committee, I hope that these few examples convey the firm commitment of the NIH to combating hepatitis C. The central mission of the NIH is to conduct and support biomedical research aimed at decreasing the burden of disease in the United States. In hepatitis C, I believe that the NIH's mission is being well served and that the future is encouraging for the ultimate control, cure, and prevention of hepatitis C in the American population. Let me conclude with a note of special thanks to the members of the Congress of the United States on behalf of the community of scientists who work in hepatitis C. Thank you for the continuing support of biomedical research through which we hope to improve the health of Americans.

I appreciate the opportunity to address the Committee on behalf of the NIH and would be pleased to respond to any questions you may have.

Chairman TOM DAVIS. Dr. Deyton.

Dr. DEYTON. Thank you, Mr. Chairman and committee members. We appreciate the opportunity to be here today.

Hepatitis C has been and continues to be a high priority for the Department of Veterans Affairs. Veterans who use VA for health care are affected by hepatitis C in greater proportion than the Nation as a whole, and VA cares for more people with hepatitis C than any other medical system in the country. VA has established a comprehensive approach to hepatitis C similar to that recommended by former Surgeon General Dr. Koop and others in testimony before this committee 6 years ago.

VA's public health approach to hepatitis C contains five integrated components that I will highlight: No. 1, screening and testing; No. 2, patient and provider education; No. 3, access to excellent clinical care; No. 4, data-based quality improvement; and, No. 5, research.

First in the area of screening and testing, it is VA policy to provide screening for hepatitis C risk factors for all veterans who receive VA health care and to offer testing for those with risk or anyone who desires to be tested. Since 1999, Mr. Chairman, over 4 million veterans in VA care have been screened for hepatitis C risk factors, and over 200,000 have been diagnosed with hepatitis C infection. A recent external review of over 50,000 medical records showed that over 98 percent of VA patients have been screened for risk factors, and over 90 percent of those at risk have been tested for hepatitis C.

VA leads the Nation in testing for hepatitis C. Our success in screening and testing has its foundation in the second component of our public health approach, that is, an aggressive program of patient and provider education. We've provided to your staff examples of our education program, including copies of 29 single-topic patient education brochures on hepatitis. We distributed literally millions of these brochures throughout the VA health care system in order to inform veterans about hepatitis C. We have partnered with veterans' service organizations and various advocacy groups to promote hepatitis C awareness. We have also conducted an aggressive provider education program, including giving grand round lectures on hepatitis C at nearly every VA hospital in the Nation. We have held national education conferences attended by nearly 1,000 VA health care providers. We have developed recommendations on hepatitis C treatments and distributed them in print and electronic form, on pocket cards and by software downloadable into provider's handheld PDAs. In addition, we've identified a lead hepatitis C clinician in every VA hospital in the country. These are our main points of contact to transmit education and treatment updates.

Identification of veterans infected with hepatitis C who use VA health care system necessitates the third component of our public health approach, and that is excellent clinical care. Excellent clinical care for hepatitis C includes, one, careful medical assessment of liver function; two, identification of and treatment of important co-morbidities of especially mental health, substance abuse disorders and HIV infection. The third area is providing anti-viral drug therapy when indicated, with close medical monitoring during the 6 to 12 months of therapy and treatment of its frequent side

effects, which Dr. Hoofnagle mentioned. The fourth area is management and prevention of complications associated with cirrhosis and end-stage liver disease when they occur and, finally, liver transplantation when no other option exists.

The VA's hepatitis C resource centers program works to improve clinical care, including regular updating of our anti-viral treatment recommendations, expanding the population of patients who can be safely treated for hepatitis C, increasing skills of our liver specialists in managing the psychiatric complications of hepatitis C treatment, and in managing cirrhosis and end-stage liver disease, and expanding the cadre of health care providers trained to deliver hepatitis C care beyond liver specialists, who are in very short supply, to include primary care providers, mid-level practitioners and clinical pharmacists as well as development of guidelines for establishing hepatitis C patient and family support groups so important in successful care.

Anti-viral therapy is not recommended for all hepatitis C patients, and some who are eligible turn it down because of the potentially severe side effects, long duration of therapy and relatively poor success rates of the currently available drugs. Recently, VA has treated approximately 9,000 veterans each year with anti-viral medications for their hepatitis C infection.

In addition, VA has an active liver transplant program. Last year, over 400 veterans were evaluated for possible liver transplant, and VA performed 87 liver transplants.

VA's national electronic medical records system allows us the unique opportunity to undertake the fourth component of our public health program for hepatitis C, that is data-based quality improvement. In 2000, we established the National VA Hepatitis C Case Registry. This registry tracks, in a confidential manner, the detailed medical data on VA patients who have tested for or have been diagnosed with hepatitis C. This information helps both our national program and our local clinicians improve the quality of patient care. Through the end of fiscal 2004, over 273,000 veterans have been added to that registry. This is the largest organized prospective collection of clinical data on persons with hepatitis C in the world.

The final component of the VA public health program in hepatitis C is to promote and support research to improve the health of veterans living with hepatitis C. In fiscal 2003, VA funded 15 projects at a cost of more than $2.4 million, and VA investigators leveraged over $4.1 million in non-VA funding to support 104 different hepatitis C research projects.

In conclusion, VA's comprehensive public health approach to hepatitis C has been successful in achieving the goals outlined to this committee 6 years ago. VA's approach to hepatitis C has elements that may be useful for other large health care systems, for health insurance companies, employers, public health departments, private practitioners and the public at large.

While proud of these accomplishments, we recognize much remains to be done to identify veterans with hepatitis C and provide

them with the best medical care possible. That is our commitment to serve the men and women who have served our Nation so nobly.

This concludes my remarks. Dr. Rigsby and I would be happy to answer any questions about the VA program.

[The prepared statement of Dr. Deyton follows:]

Statement of
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Chief Consultant, Public Health Strategic Health Care Group
Veterans Health Administration
Department of Veterans Affairs
Before the
Committee on Government Reform
U. S. House of Representatives

December 14, 2004
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Mr. Chairman and Members of the Committee:

I am pleased to be here today to talk about VA's comprehensive medical programs for veterans with hepatitis C. Accompanying me is Dr. Michael Rigsby, Director of VA's National HIV/Hepatitis C Program.

Mr. Chairman, VA is justifiably proud of its significant accomplishments as the Nation's leader in hepatitis C screening, testing, and treatment. No other health care system cares for more patients living with hepatitis C. VA's leadership role is widely recognized. VA hepatitis C experts serve a number of other federal agencies and advocacy groups as consultants, subject matter experts, and collaborators in the development of educational and public awareness campaigns. VA efforts in hepatitis C have benefited from close collaboration and partnership with Veterans Service Organizations and other veteran and non-profit groups, as well as with other government agencies such as the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Federal Bureau of Prisons (FBOP).

Background

Hepatitis C infection affects over 4 million Americans and is the most common blood-borne infection in the United States. According to the CDC, overall prevalence rate of hepatitis C infection in the U. S. population is estimated to be approximately two percent. The most common risk factors for infection with hepatitis C are injected drug use and history of blood transfusion. Approximately 75-85 percent of those infected with hepatitis C virus develop chronic infection.

Among those with chronic infection, the risk of developing significant liver damage varies considerably, with approximately 10-20 percent developing cirrhosis after 20-30 years of infection.

Antiviral therapy with interferon and ribavirin is indicated for some, but not all, patients with mild to moderate degrees of liver damage from hepatitis C. This treatment has limited efficacy, however, and significant toxicity. Among carefully selected patients, up to 50 percent who complete a 6-12 month course of treatment will have no evidence of active viral replication for at least 6 months after treatment is completed. However, among patients who have factors associated with poor treatment responses (including African Americans, those who are obese, those with genotype 1 infection, and those with ongoing alcohol use), the effectiveness of the treatment is considerably lower. Although our understanding of who might benefit from antiviral drug treatment is changing, only a minority of infected patients has historically been considered suitable for antiviral therapy, and many patients have other medical conditions that make antiviral treatment difficult or unsafe. Therefore, the actual number of infected patients who can be successfully treated using currently recommended antiviral drug therapy is low. In patients who have already developed advanced liver disease, liver transplant may be the best or only available treatment option.

Hepatitis C and Veterans

Reliable blood tests for hepatitis C became available in the early 1990s, and by the mid-1990s several small, VA facility-specific reports had suggested that rates of infection among veterans receiving health care from VA might be higher than those in the general U. S. population. In contrast to these reports, a national study published by the CDC in 1999 found that the infection rate among adult Americans with any lifetime history of military service was 1.7 percent - slightly lower than the 1.8 percent in the overall population. However, veterans who use VA health care services have demographic and socioeconomic characteristics that differ from those of the overall veteran population. These characteristics might be associated with a higher risk of hepatitis C.

In 1999, therefore, in an attempt to understand the magnitude of the hepatitis C problem among veterans receiving VA care, VA asked all veterans having blood drawn for any reason on a single day to consent to hepatitis C testing. In this group of over 26,000 veterans, which was not necessarily representative of all veterans in care but which reflected the most systematic approach to date, 6.6 percent were found to be infected with hepatitis C.

In 2001, Dr. Jason Dominitz of the VA Puget Sound Health Care System began a national hepatitis C prevalence study using rigorous scientific methodology to produce a statistically valid sampling of veterans receiving health care from VA. The purpose of the study was to estimate the prevalence of anti-hepatitis C antibody and evaluate factors associated with infection among users of VA medical centers. The results of the study, scheduled for publication next month, show a prevalence rate of 5.4 percent. Patients in the prevalence study also provided detailed risk information. The risk factors associated with infection were among those already recognized as risks in the general population, including injected drug use and tattoos. No risks specifically associated with military service or military combat were identified.

VA Hepatitis C Programs

Because of the early reports suggesting the possibility that veterans had a high prevalence of hepatitis C infection, VA recognized that hepatitis C infection was of special concern and began a series of steps aimed at identifying veterans with hepatitis C and providing them with appropriate medical evaluation, care, and, as clinically appropriate, the best available antiviral drug therapies. VA established a National Hepatitis C Program in 2001. In creating this Program, VA endorsed a comprehensive public health approach to hepatitis C in the VA health care system. The essential components of this approach include screening and testing, patient and provider education, clinical care, data-based quality improvement, and support for research to improve the health of veterans living with hepatitis C. To support the work of the Hepatitis C Program, resources were also allocated for the development of a national Hepatitis C

Clinical Case Registry, an electronic database of patients with hepatitis C who received care in the VA health care system at any time after January 1, 1996. I will discuss the registry in greater detail later in my statement.

In 2002, the Hepatitis C Resource Center (HCRC) program was launched to take advantage of field-based expertise in hepatitis C care in order to develop and disseminate innovative practices and tools to improve patient care. Under this program, four centers were selected in a national peer-reviewed application process and were given funding for five years. These four centers are located in the Northwest (Seattle/Portland), Minneapolis, San Francisco, and West Haven.

Screening and Testing

VA believes that every veteran at risk for hepatitis C should know his or her infection status so that appropriate education, referral, and medical assessments can take place. Since 1998, it has been VA policy to provide screening for hepatitis C risk factors to all veterans receiving VA health care. With the veterans' informed consent, VA provides testing for those who are found to be at risk. Automated clinical reminders to prompt providers to perform hepatitis C risk assessment were added to VA's national electronic medical record system. From FY 2002 through FY 2004, screening and testing for hepatitis C were adopted as official performance measures.

As a result of these efforts, since 1999, over 4 million veterans in VA care have been screened for risk factors and over 200,000 were diagnosed with hepatitis C infection. During each of the past three years, screening and testing performance has been evaluated using the External Peer Review Program (EPRP), a national yearly review of approximately 50,000 medical records by trained, professional reviewers. The EPRP results have demonstrated steady improvement in screening and testing. In fiscal year 2004, over 98 percent of patients had been screened for risk factors, and over 90 percent of those at risk had been tested for or diagnosed with hepatitis C.

VA continues to refine and enhance the screening and testing processes by encouraging research that examines the epidemiology of and risk factors for

hepatitis C infection among veterans receiving VA health care, and by helping VA health care providers make better use of information available in VA's electronic medical record to supplement patient-reported risk information.

Treatment

Effective hepatitis C treatment must include a wide range of interventions, including education of patients and their families; careful medical assessment (frequently including liver biopsy); identification of and treatment for important co-morbidities (particularly mental health and substance use disorders); prescription of antiviral therapy when appropriate; management and prevention of the complications associated with cirrhosis and end-stage liver disease; and liver transplantation when no other options exist. The VA health care system, as the largest integrated health care system in the United States, is uniquely able to provide this full range of treatment services to patients with hepatitis C.

The rate of progression of liver damage from hepatitis C is variable. Alcohol use is an important modifiable risk factor for accelerated disease progression. VA is actively investigating and piloting simple interventions that will assist patients with hepatitis C to reduce or eliminate alcohol use as a way of maintaining liver health.

Antiviral therapy with various forms of interferon plus ribavirin is appropriate for many patients with mild to moderate liver damage from hepatitis C, and for some patients with more advanced liver disease. However, the treatment duration is 6 to 12 months, and the drugs used frequently produce side effects including fatigue, flu-like symptoms, anemia, and depression. Because of concerns for patient safety and impaired treatment efficacy, patients with histories of mental health disorders or substance abuse were, in the past, routinely denied therapy. VA, however, has taken a leadership role in expanding the population of patients who can be safely treated by investigating and piloting innovative programs that link mental health/substance abuse care and liver specialty care, and by developing educational programs to increase the knowledge and skills of liver specialists in recognizing and managing psychiatric

complications of hepatitis C treatment. Through VA's capitated reimbursement system, the Veterans Equitable Resource Allocation (VERA) system, VA aligns financial incentives to support the care of patients requiring expensive pharmaceutical treatment.

These steps to increase and support antiviral treatment efforts, as well as recent improvements in treatment response rates with newer drugs, have led to increased numbers of veterans receiving treatment. In each of the past two fiscal years, VA has treated approximately 9,000 veterans with antiviral drugs. A number of studies and published reports have indicated that many patients are still not suitable candidates for treatment because of other medical conditions, ongoing hazardous levels of substance abuse, and failure to accept referral to liver specialty care. Still others decline to undergo treatment when it is recommended. These barriers reflect both a complex set of psychosocial issues and the hard reality that current treatments are difficult to tolerate and too often fail to produce the desired outcome of viral eradication. For many patients with only mild liver disease after many years of infection with hepatitis C, the decision to postpone or forego antiviral therapy is appropriate and understandable. For other patients, more pressing medical or psychiatric issues need to be addressed first. For still others, misperceptions or lack of accurate information about hepatitis C disease and treatment need to be addressed. For all these reasons, it is impossible to say what percentage of patients with hepatitis C should be treated, but it is VA's position that all patients need sufficient information and medical evaluation to reach an informed decision about the most appropriate treatment in consultation with a knowledgeable medical professional.

The number of trained liver specialists in the VA health care system, and, indeed, in the United States, is not sufficient to support a system of hepatitis C care that relies exclusively on these highly trained medical specialists. VA believes that efficiency and effectiveness of care is maximized when specialists' time is devoted to those activities that truly require their unique knowledge and skills. Much of the work of patient counseling, medical evaluation, management of treatment side effects, and follow-up for complications of hepatitis C infection

can be performed by generalists or other health care providers. Provider education activities in VA have specifically targeted these groups (i.e. primary care providers, mental health professionals, mid-level practitioners, clinical pharmacists, and addiction counselors) to improve their knowledge, skill, and confidence in providing hepatitis C care.

Improving quality of care

Hepatitis C is a complex, chronic disease with variable natural history, for which diagnostic tests have become available only relatively recently and universally effective treatment is still lacking. Thus, clear indicators and measures of quality in hepatitis C care are not as well established as they are for many other medical conditions in which evidence regarding the efficacy of various interventions has been extensively evaluated and tested. However, even in this relatively new and rapidly evolving field, VA believes that quality of care can be maximized through constant dissemination of new information and best practices, measurement and reporting of meaningful outcome data, and the identification and correction of problems as they occur.

Therefore, a key mission of the HCRC program is to disseminate innovative practices and approaches to hepatitis C care. This work includes the development of guidelines and recommendations based on critical review of the latest research results; creation, testing and dissemination of innovative systems for clinical care delivery; dissemination of information in appropriate educational formats for patients, providers, and community; and the development, testing, and implementation of tools to make information available to providers and patients at a time and in a format that they can use to make decisions about treatment options. In particular, the work of the HCRC program has focused, to a large extent, on ensuring that patients are not inappropriately excluded from any of the available treatment options because of lack of information, understanding, or expertise on the part of the patients or their medical care providers. VA has demonstrated leadership in addressing the needs of hepatitis C patients who also suffer from mental health or substance use disorders. The HCRC programs

are learning that these veterans, who were formerly excluded from anti-hepatitis C therapy, can be safely and effectively treated if given appropriate support and interdisciplinary care. VA's comprehensive health care system (which includes psychiatric care and addiction services) is uniquely able to provide the range of medical care these patients typically require.

The Hepatitis C Case Registry is another important tool for quality improvement and programmatic planning. The objectives of the Registry are to identify VA patients who have been tested or diagnosed as having hepatitis C, describe their clinical status, track their use of clinical services, and improve the quality and efficiency of VA hepatitis C care. Patients are automatically added to the Registry based on either diagnostic codes or results from blood tests for hepatitis C. Through the end of FY 2004, over 273,000 unique patients had been added to the Registry. Of these, 184,067 had at least one VA inpatient admission or outpatient encounter in FY 2003.

Research

VA's Biomedical Laboratory Research and Development Service (BLR&D) and Clinical Science Research and Development Service (CSR&D) have provided funding for studies on hepatitis C that are important to advancing our understanding of hepatitis C among veterans. Since 1995, VA has funded a range of projects that address the prevalence and demographics of hepatitis C virus (HCV) infection in veterans, basic virus-cell interactions, development of improved diagnostic tests for HCV, clinical studies on predictors for HCV treatment response, and development of novel vaccine approaches for the prevention of HCV. One important example of the studies funded by BLR&D/CSR&D is the prevalence study conducted by Dr. Jason Dominitz, which I mentioned earlier in this statement. To take another example of this research, VA's Palo Alto Research Enhancement Award Program (REAP) is dedicated to identifying novel diagnostic and prognostic tests to develop new therapeutic techniques.

VA funding of hepatitis C research has more than tripled since FY 1999, when VA spent $657,013 on 6 projects. In FY 2003, the last year for which statistics are available, VA funded 16 projects with funding of more than $2.4 million. VA investigators also leveraged over $4.1 million in non-VA funding for 104 hepatitis C research projects in that same year.

VA Sharing Lessons Learned

VA is sharing its many lessons and best practices with the larger medical and public health community. We have a comprehensive Web site for providers, patients, and the public that now has over 22,000 visitors and 140,000 page views a month. This website (www.hepatitis.va.gov) showcases the multimedia materials created through VA expertise for patients and health care providers along with extensive listings of other sources of other health information. We have had ongoing collaborations and communication on hepatitis C care and research with NIH, CDC, the FBOP, and others. VA hepatitis C experts have presented findings at national and international medical and scientific meetings and published in peer-reviewed medical journals. For example, last month alone, VA staff led nearly 40 presentations at the annual meeting of the American Association for the Study of Liver Diseases. VA resource centers – our HCRC's are a prime example – are seen as part of the "remarkable transformation of VA Care," to quote the *Annals of Internal Medicine*. Our leadership in the area of hepatitis C is receiving wide recognition. At a roundtable discussion convened by the US Medicine Institute for Health Studies on Federal efforts in hepatitis C, VA's comprehensive public health approach to hepatitis C was held up by that group as "an important model for other clinical and public health programs."

Future Directions

VA recognizes that there is much work yet to be done for veterans at risk for and living with hepatitis C. Although new cases of hepatitis C are currently infrequent, prevention of new infections through education, substance abuse treatment, and further research and surveillance of hepatitis C epidemiology will

remain a high priority. This commitment to disease prevention illustrates VA's role as an important part of the larger U. S. public health effort to decrease chronic viral infections.

For veterans already infected, better strategies are needed to address the modifiable risk factors for hepatitis C-induced liver damage, such as alcohol consumption, obesity, and exposure to other liver pathogens and toxins. VA also will work to expand the percentage of hepatitis C patients who can safely receive and possibly benefit from antiviral drug therapy. Research to develop new drugs and new strategies for using existing drugs will likely remain a high priority for VA and the larger health care community for many years to come. Finally, VA recognizes that many veterans have already lived with chronic hepatitis C for decades and are now developing advanced liver disease with cirrhosis and its many complications, including liver cancer. The rising incidence of liver cancer related to hepatitis C is well documented. VA has recently joined with the National Institutes of Health in conducting an international conference on the topic of liver cancer and will continue to work with researchers, clinicians, and epidemiologists to determine the most effective strategies for screening, diagnosis and treatment of hepatitis-C related liver cancer. VA also has a well-established and active liver transplant program, and the number of liver transplants performed at VA's four liver transplant centers has increased. Hepatitis C is now the most common cause for liver transplant among veterans in VA care.

Conclusion

The commitment of VA leadership to hepatitis C is unwavering. This chronic viral infection is a major concern for veterans in VA care, has the potential to result in significant illness and mortality, and disproportionately affects veterans with multiple other medical problems. Veterans with hepatitis C are among those most dependent on VA medical services and other benefits. In serving these American veterans, VA leads the Nation in hepatitis C care.

Mr. Chairman, this concludes my statement. Dr. Rigsby and I will now be happy to answer any questions that you or other members of the Committee might have.

Chairman TOM DAVIS. I want to thank all of you for your testimony and your work in this area.

Dr. Khabbaz, let me start. When HIV-AIDS was emerging, as was noted before, and this is true with other diseases, a lot more information and publicity were available about the disease that seems to be lacking in this instance despite some efforts on your part and others to try to increase awareness of this and some of the preventive measures that people can take. What do you attribute that to and do you have any thoughts about how we change it?

Dr. KHABBAZ. Thank you, Congressman, for the question.

HCV is, by and large, thought of as being a silent epidemic in terms of a large number of people with asymptomatic infections in the acute phase of the infection. And 75 to 85 percent of those go on to develop chronic infection, and there's a subset that develop chronic disease. So it has been around with us for a long time undetected.

As part of the National Hepatitis C Prevention Strategy, identification of infected persons, prevention of the disease, part of that strategy is putting information out. And CDC has been working to put such information out. I mentioned the brochures and the fact sheets, and we have worked with partners as well to develop educational materials both for health care providers and for the public.

Chairman TOM DAVIS. Do you think there are thousands of people walking around that are infected now and have no idea because the symptoms haven't appeared yet?

Dr. KHABBAZ. That is one element out there, but, as I alluded to in my remarks, the best approach to reaching those people is integration of prevention programs, hepatitis prevention programs into existing health and public programs, and we have initiated that.

Chairman TOM DAVIS. And only 23 States have comprehensive hepatitis C prevention plans today. That is a good way to get at it, is to get the States involved. We had trouble to get a State medical officer here today to testify. I know they are handling a lot of different emergencies and so on, but that is a problem and that is something we can look at from this area in trying to put some incentive or stick in the hands of these States so that they wake up. Would that be helpful?

Dr. KHABBAZ. As I mentioned in my remarks, I think there is more to be done. CDC has funded hepatitis C coordinators, 53 of them in State health departments, and we have one with Indian Health Service. And one important function of these coordinators is to develop prevention plans, comprehensive prevention plans. Correct, 23 States have those plans, and 5 other States are developing plans. CDC also provides assistance to States and some of the plans are shared, available on the Web site and shared with States to develop their own plans. More needs to be done.

Chairman TOM DAVIS. Dr. Hoofnagle, currently, there is no vaccine against hepatitis C. Why in the age of preventive medicine is it so hard to develop an effective hepatitis C vaccine? Do you think it is realistic to expect a vaccine in the next 5 to 10 years? What can we do to help that along? Is it a funding issue? What are some of the variables?

Dr. HOOFNAGLE. The problem is with the virus and how you respond to it. The difficulty is that if you are one of those lucky people who recover from hepatitis C, you are not protected against reinfection. The antibody in hepatitis C—this is nature and not something we did—is not very protective. If nature can't do it, how can we come along and do better?

Well, one clue is that 30 percent of people recover. Why do they recover? It appears to be not just antibody. The usual thing, that we stimulate with a vaccine like hepatitis A or B vaccine, you get antibody. Maybe you also have to stimulate T cells or other forms of the immune system to clear the virus. This is the kind of new information that's arising, that perhaps you can't get sterilizing immunity, but you can induce parts of the immune system so that the person who gets exposed and gets infected will recover on their own.

And I'm a little optimistic about a vaccine being available. I think it might not be the typical type of vaccine, like hepatitis A or B vaccine, but it would be a vaccine that promotes recovery, and that might be almost as good as a regular vaccine.

Chairman TOM DAVIS. Thank you very much.

Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

We are dealing with a disease that people wouldn't realize they had for years, maybe even decades, is that right?

Dr. HOOFNAGLE. That's correct.

Mr. WAXMAN. And it suddenly would take hold? How would it manifest itself if somebody had a reactivated hepatitis C?

Dr. HOOFNAGLE. Hepatitis C is a long-drawn-out disease and causes inflammation and damage to the liver. You don't feel your liver very much with inflammation. It is not like a sore throat or a skin rash. You don't see it until the liver is fairly badly damaged; and, at that point, it may be a little bit late to do something or to treat. So if we wait for symptoms to appear, we are waiting for the point that the liver is starting to fail; and you need to do something about this disease while there is just inflammation and a little bit of damage to the liver. There are blood tests that show that the liver is inflamed and ways to screen tests for those.

Mr. WAXMAN. So the obvious public health matter before us is to try to get to the people who may have hepatitis C and get them in to be tested and get them into treatment before the symptoms manifest themselves.

Dr. Khabbaz, there was a group of people who had blood transfusions prior to 1992. It is a discrete group. We know who had blood transfusions prior to 1992. I guess the FDA did not recommend a look back to notify those people who had those blood transfusions prior to 1992. Many of them are infected and don't realize it. From a medical standpoint, wouldn't it be valuable to let these people know that they have hepatitis C and that they should do something about it?

Dr. KHABBAZ. Yes. As I mentioned, part of the hepatitis C prevention strategy and an important component is identifying people who are infected. And you are correct. Limited look-back was initiated. However, the thought was that it was difficult to reach people, most of the people, infected in terms of when you look at blood

transfusion basically before the mid-1980's when a nonspecific test was introduced. Before that, there was quite a bit of transmission via blood. And in 1992, when the specific hepatitis C test was introduced, is when the transmission dropped to less than one in a million. To reach those people and reach the other groups at risk, one of the important things is to make sure that clinicians, health care providers routinely ask about risk factors, transfusion and others, and then offer the test, as you have alluded to.

Mr. WAXMAN. I suppose when people came in for medical care they might get this routine test as part of their physical examination. But, as I understand it, most of the people who now have hepatitis C are IV drug users. Sixty percent of the people have hepatitis C. I doubt many of them come in for medical care.

I know CDC is trying to reach people and inform them. If you have a group that could be contacted directly, it seems to me there is a moral argument to contact them. If you don't do that, the strong argument then is to have a public education campaign. If CDC had more money, would you be putting money into trying to inform the public of the risks that they may be having with hepatitis C and get them in for the tests?

Dr. KHABBAZ. Let me make a few comments.

In terms of reaching people and reaching the groups that we know of for hepatitis C, you know, we feel that people do see providers for a number of reasons. So, basically, the approach to educate health care providers not just in the private sector but the public sector as well and the demonstration projects that we have had, the viral hepatitis integration projects to provide care, you know, screening and testing and then forward patients for management and all that sort of thing within the context of programs that provide care, a comprehensive approach has been shown to be feasible and effective. That is one component. There is public education material that we put out. Thirty thousand separate materials are requested from the CDC.

Mr. WAXMAN. Let me interrupt you, because the light is on. I have time for one more question, and I wanted to ask Dr. Hoofnagle a question.

It seems to me one of the strategies ought to be, especially if we have all these IV drug users, we ought to discourage them from using drugs, which means get them into treatment programs. But, second, if they are not going to be into a treatment program because the program is not available, wouldn't it be wise for us to have them use clean syringes and have the government make that available? That was one of the recommendations that was given by the National Institutes of Health group that looked at this whole problem. Don't you think that would make sense from a public health point of view?

Dr. HOOFNAGLE. I have to defer to my CDC people about public health issues. The consensus conference was not officially the Federal Government. They are an independent panel the Federal Government calls together.

Mr. WAXMAN. That make it even more credible, doesn't it?

Dr. HOOFNAGLE. It does.

Mr. WAXMAN. And they recommended we have a clean syringe program. Doctor, do you want to respond to that in the time that I don't have available to me?

Dr. KHABBAZ. In terms of drug treatment centers, this is a good place for primary and secondary prevention for hepatitis and other blood-borne infections. In my understanding, in terms of the harm reduction interventions, while they make sense, it has been shown to be effective for HIV but are lacking for HCV. There are some differences in the epidemiology when you look at drug users in terms of, even though they are all blood-borne infections, but in terms of who gets them there and how, there are some differences out there. Quickly after starting drug use, people get them, and it takes a long time.

Mr. WAXMAN. Wouldn't sterile syringes and safe injection practices decrease the public health problem for HIV and hepatitis C?

Dr. KHABBAZ. Strategies and prevention programs to drug users would seem to make a difference, I would think.

Mr. WAXMAN. Thank you.

Chairman TOM DAVIS. Thank you.

Ms. Norton.

Ms. NORTON. I have a great respect for science in this country, and I'm bothered we can't get a straight answer on Mr. Waxman's question. If something can be transmitted by dirty needles, the question is you say to a scientist, you say to a doctor, would it be better to have an exchange of clean needles?

I want to quote from the NIH consensus panel: Urge the government to institute measures to reduce transmission of hepatitis C virus among intravenous drug users, including providing access to sterile syringes through needle exchange, physician prescription and pharmacy sales. May I just ask both of you, do you agree with that recommendation of the NIH consensus panel? I'm asking you as doctors, do you agree with that or are you in disagreement with what this panel has said?

Dr. HOOFNAGLE. No, I'm in agreement that would be a good policy.

Ms. NORTON. Dr. Khabbaz, are you in agreement or disagreement with what these experts in this field have said?

Dr. KHABBAZ. Again, I don't disagree, as I told Congressman Waxman, that those and other harm reduction interventions make sense and it would be helpful. I don't, for hepatitis C specifically—and Dr. Mast can add to my comments—I'm not aware that it shows it is effective.

Ms. NORTON. This is what this panel has said. The reason I ask is because it is very bothersome. The one set of people I expect to get straight answers are people that base their information on science. I'm not asking whether you are for it or against it. I'm asking you whether this is a way of preventing the spread of what you yourself have said is a silent killer. I'm asking you as a doctor and as a scientist. And Dr. Mast, if you want him to——

Chairman TOM DAVIS. Will the gentlelady yield? I would like to throw something in the mix. I ask unanimous consent that the gentlelady from the District be given an additional minute, and I will just intervene to opine a question.

This is an issue we have fought over up here, needle exchange programs, and argued about, particularly with the District of Columbia. I have always had some concern that if you are a veteran and go to a veterans hospital we charge you for a needle. If you are an average Joe, you go to a hospital, they charge you for a needle. If you are on Medicare, they charge you for a needle. But if you are using illegal drugs, they give you a free needle and what are the policy implications of that.

We understand that using a clean needle is better for you than using a dirty needle, and we agonize over this, and in different parts of the country, jurisdictions react differently. I think the way we have dealt with it in the District is we decided they could do what they wanted to do with their own money and not use Federal money, and it seemed to work itself out but not without a lot of debate.

The gist of the question is—and maybe you are not in a position overall to say what the ramifications are to the message of giving out free needles when you are trying to get people to stop using drugs altogether. But, clearly, a clean needle is better than a dirty needle. We argued about this, too, because we have competing policy goals.

Dr. KHABBAZ. I don't disagree. I agree.

Ms. NORTON. I'm looking for a way to get at the silent killer. I was interested in the testimony from you, Dr. Khabbaz: Current anti-viral treatment completely eliminates the infection in 50 to 55 percent of selected patients, with 95 percent of those remaining free for—virus free for 5 years. That would seem to put a premium on getting some people before this progressive liver disease and all the attending consequences.

I'm looking for signs of a national campaign, and I have spoken of my ignorance of this disease. I think it's your testimony, Dr. Hoofnagle, about outreach and public education efforts, and the testimony at page 7 talks about coordinating focus provided by the National Digestive Diseases Information Clearinghouse—I kind of don't understand that, but perhaps you could explain why that is a clearinghouse. I don't much care, but that's interesting. I didn't think of this as a digestive disease. But, moving right along, including the involvement of multiple NIH agencies, other Federal agencies, professional lay organizations. And online you have two NIH Web sites. I can't find a focus for this disease. I can't find somewhere in NIH or in CDC, somewhere in the Federal Government where somebody regards it as his mission to educate the public that millions are walking around with this silent disease or to tell people that we actually can do a great deal if you get to us early, as your testimony has indicated.

So I am looking for who it is who is in charge of helping us to spread the word to eliminate the disease, to get people into treatment, and the rest of it.

Dr. HOOFNAGLE. Well, what you are referring to there is the NAIAD Digestive Disease Clearinghouse, which is the mechanism we use to provide information to people, to physicians, doctors, interested in the diseases that we are involved in as far as research. It is not mandated as an educational program to go out to all

Americans. It's largely a mechanism that we use to get out information.

Ms. NORTON. Who is it that is in charge of getting the word out to average Joes like people on this panel?

Dr. HOOFNAGLE. Well, I would turn to my colleagues here at the CDC again about that.

Dr. KHABBAZ. I've alluded to the efforts that we have in the health communication arena. Let me just expand. I've already mentioned we have the brochures and posters and pamphlets and information on hepatitis C for health care providers and for the public, are available and have been translated into Spanish and Russian, and about 30,000 separate pieces of such educational material are actually distributed each month on request to the public and doctors. There's also a tool kit that was developed for physicians and their patients and about 143,000 providers have received this tool kit. There's a hotline. The CDC funds cooperative agreements with nongovernmental organizations, academic centers, and health departments to develop training and education materials and to evaluate them. And so there's a lot of material being developed by CDC and by partners and others.

I would also mention the roundtable that CDC has initiated to bring together all the partners working in this arena, governmental and nongovernmental organizations, to make sure that we are all coordinated in terms of information and approach to prevention.

Chairman TOM DAVIS. Thank you. This is the last question. Go ahead and answer if you want to.

Dr. MAST. Ms. Norton, we agree with you that health education and communication is a major component of the National Hepatitis C Prevention Strategy, and CDC has developed a broad range of materials both for the general public, for persons at risk, and for health care providers. We've done our best to make those materials accessible to people and will continue to do our best to make those materials accessible to people.

Chairman TOM DAVIS. Thank you very much. Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman. Let me begin with you, Dr. Khabbaz. Why is it that CDC does not require all States to provide surveillance on hepatitis C?

Dr. KHABBAZ. That is an important question. Actually surveillance for hepatitis C has a number of components. With regard to acute hepatitis, acute hepatitis C, it is reportable actually, and the organization that makes the disease reportable is not CDC. It's the Council of State and Territorial Epidemiologists that actually have representatives of State epidemiologists, the ones who decide on a disease being reportable, and then States adopt its recommendation. So acute hepatitis C has been reportable for many years, and so we gather and put out reports and follow trends of disease. And in 2003 actually, working with the Council and State Territorial Epidemiologists [CSTE], chronic hepatitis C viral infection has also become reportable, and 19 States have actually provided reports. There are challenges to doing chronic hepatitis C surveillance in terms of gathering——

Mr. TOWNS. Nineteen States.

Dr. KHABBAZ [continuing]. And verifying these reports and clearly more States need to come on board, and that work is going on

to train and to provide investigation material and all. So we have made progress but there's more to do, as I mentioned earlier.

Mr. TOWNS. You know, let me just say I don't feel there's a sense of urgency here. I hate to say that but just sort of casually 19 States out of the 50, maybe next year there will be 20, and this just sort of casual kind of thing, that really bothers me, because we're talking about a life and death issue. And I'm disturbed by it.

Let me ask again, in your testimony you note that States have initiated hepatitis C prevention programs and that these programs use Federal funds. Let me ask this: The number of States that have such programs, you indicated, the amount of Federal funds allocated per program, could you tell me that, the amount of money allocated?

Dr. KHABBAZ. I don't have the numbers with me but will be glad to give you those numbers.

Mr. TOWNS. Mr. Chairman, could we leave the record open to receive that information?

Chairman TOM DAVIS. Could you try to get that to the committee, and we'll keep the record open for that. Thank you.

Mr. TOWNS. The other question is do States have to match these funds?

Dr. KHABBAZ. My understanding, and Dr. Mast may want to elaborate some more, is that these funds are made available through cooperative agreement. So States do not have to match funds. Funds are made available to support programs in prevention, State coordinators, education and surveillance. Now, many States have actually put in funds and supplemented those Federal resources to carry out hepatitis C prevention activities, but they're not mandated to do so.

Dr. MAST. The basic concept is we fund a single hepatitis C coordinator in every State and their responsibility is to integrate hepatitis C activities into existing State programs. So they work with other communicable disease programs, with STD, HIV programs to integrate hepatitis C activities into existing State programs. So that's the concept that we're promoting.

Mr. TOWNS. The reason why I'm asking is I'm trying to figure out why every State would not want to have one.

Dr. MAST. We offered funding to all States to have a hepatitis C coordinator, and all but two States have requested and are currently funded.

Chairman TOM DAVIS. Can I just ask which two States haven't asked?

Mr. TOWNS. Yes. Which two States?

Dr. MAST. The two States that currently don't are Kentucky and South Dakota.

Mr. TOWNS. Let me get Dr. Hoofnagle. Can you tell us about the Federal Interagency Working Group? I need to know a little bit more about that hepatitis C working group.

Dr. HOOFNAGLE. The hepatitis C working group is an informal group of people from each of the institutes that funds research on hepatitis C that get together to coordinate our initiatives, if we have a new idea like, say, put together a workshop to see which other institutes would be interested in contributing.

Mr. TOWNS. I see my time has expired, Mr. Chairman. So thank you very much.

Chairman TOM DAVIS. Thank you very much. Let me just thank this panel. We've got another panel we are going to go to and hear from them, some of the personal stories, but I want to just thank you all for——

Ms. NORTON. Mr. Chairman, could I ask one moment——

Chairman TOM DAVIS. Without objection, Ms. Norton, you can ask another question.

Ms. NORTON. The reason I asked about a national campaign, it has to do with statistics that show that 60 percent of those infected are intravenous drug users. I hope that you will take back to CDC, particularly given your answer on what kind of campaign you're conducting, posters and the rest of it, and, you know, a lot of these people are in jail. They will come home to communities like the District of Columbia. They're going to come home to the big cities and spread this disease, and we don't know anything about this disease in this city. Their own Congresswoman doesn't know anything about it, and I would imagine that I'm like many other Members of Congress and many other people who run cities, and I am going to ask you, based on your testimony today, whether you would take back to CDC the need to do a real national campaign so that we can apparently make available treatment which could keep this disease from progressing.

You have testified it's a preventable disease, and I have to tell you I don't think you're doing anything to help us prevent this disease, which even those of us who ought to know better don't know, and we need a campaign to reach people who are in jail, to reach people who are inclined to take drugs, and campaigns about posters and the rest of it clearly are not doing the job as these figures go up, and I just have to leave you with that message and hope you will take it back and try to come forward with a campaign.

Chairman TOM DAVIS. Let me ask, Dr. Deyton, we didn't get really into the success you have had at VA on this, but what elements of VA's hepatitis C program could be exported to the general public do you think?

Dr. DEYTON. Certainly, Chairman Davis, the educational materials that we've developed and distributed throughout the VAs around the country for both patients, their families, and providers are publicly available. They're on our Web site, and we're happy to make them available to anyone else.

Chairman TOM DAVIS. So we don't have to reinvent the wheel on this case?

Dr. DEYTON. No, sir. No, sir. And these materials are already being used by CDC and NIH. It's just a matter of getting it in the right hands. And I have to say that I think that the VA's success, and we've still got a ways to go, but the VA's success is—it's a multicomponent issue. It's the screening and testing, it's the education, it's the care, but it's a partnership, Mr. Chairman, between the health care system and the public and our national leadership and advocacy groups. We in the VA have been very lucky that this is an issue that the veterans service organizations, Vietnam Veterans of America, and specific advocacy groups around this issue, some of which are here in this room today, have been passionate

about for some time, and it's given us a lot of external support to do what we knew we needed to do. So I think it's a marriage, sir, and many components, including leadership from communities, from Governors, from health directors, health department directors, etc., are very important to get this important disease into the public's mind.

Chairman TOM DAVIS. Thank you.

Mr. Waxman.

Mr. WAXMAN. Mr. Chairman, Dr. Deyton's point I think is well taken, but I would point out that the veterans health system is an integrated approach to screening, diagnosis, and treatment, and for people who are not part of the VA, it doesn't work like a system. Others with hepatitis C, even if they have health insurance, often struggle to get the care they need. We don't often find ourselves in an integrated health care model.

I would like to ask two things for the record. Dr. Khabbaz, there was a National Hepatitis C Strategy, and I'd like to have you supply for us what elements of the strategy have not yet been implemented because I assume that everything has not yet been implemented; otherwise we wouldn't be holding a hearing today about how this problem is still a major concern.

Chairman TOM DAVIS. You can followup on that and we'll put it in the record.

Mr. WAXMAN. Yes. So this will be furnished to us for the record of those elements of the strategy that have not yet been fully implemented or funded.

And third, Mr. Chairman, Congressman Cummings and I recently wrote NIH Director Dr. Zerhouni about harm reduction, and I would ask that his response on the effectiveness of harm reduction be placed into the record for today's hearing.

Chairman TOM DAVIS. Without objection.

[The information referred to follows:]

OCT-07-2004 12:14 P.02/11

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

OCT 0 7 2004

The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Waxman:

Thank you for your letter, co-signed by Representative Elijah E. Cummings, in which you express concern regarding the presentation of scientific evidence on the efficacy of syringe exchange and "harm reduction" programs to prevent the spread of HIV and other blood borne illnesses. I have enclosed a brief response to the areas of interest you identified in your letter.

I hope you find this information useful. If you have further questions or need additional information, please contact Dr. Steve Gust, Interim HIV/AIDS Coordinator at the National Institute on Drug Abuse, at 301-443-6480.

An identical letter is being sent to Mr. Cummings.

Sincerely,

Elias A. Zerhouni, M.D.
Director

Enclosure

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1. Strategies That Have Proven Successful in Reducing The Risk of HIV Infection Among IDUs.

One successful strategy for reducing the risk of HIV among injection drug users (IDUs) is to provide drug abuse treatment. Drug treatment programs provide a good setting for reaching IDUs and their partners with HIV prevention and care messages and interventions. It also can be a bridge to other needed services, such as primary health care, mental health, or other social services.

Numerous studies, primarily focused on methadone maintenance treatment (MMT), have shown that substance abuse treatment programs can have a dramatic effect on HIV transmission among opiate injectors, reducing their risk as much as 4- to 6-fold.[1,2] Drug abuse treatment works principally because it helps IDUs decrease the number of injections or helps them stop injecting altogether. Less use leads to fewer drug-related risk behaviors, and that in turn leads to fewer exposures to HIV. The beneficial effects of MMT are most evident when treatment lasts a sufficiently long time and when methadone doses are high enough to effectively block drug craving: One study showed that 3.5 percent of methadone patients who had been in treatment continuously for 18 months had become infected with HIV, compared to 22 percent of out-of-treatment IDUs;[3] another study showed that at 36 months, 8 percent of IDUs in treatment had become infected,[4] as compared to 30 percent of injectors not in treatment. An analysis of 20 years of social and medical data on 622 MMT patients in New York City showed that those patients who received methadone doses of 80 mg or more were significantly less likely to have HIV infection than patients who received smaller doses.[5] The protective value of higher doses was independent of a number of other risk factors, including year of last cocaine injection, needle sharing in shooting galleries, number of IDU sex partners, income, and race/ethnicity. Moreover, among non-injection cocaine users, drug treatment has also been shown to decrease cocaine use from an average of 10 days per month at baseline to 1 day per month at 6 months. Reduction in cocaine use was associated with an average 40 percent decrease in HIV risk across gender, and ethnic groups, mainly as a result of fewer sexual partners and less unprotected sex.[6]

Drug addiction treatment[7] is an essential component of a comprehensive prevention program to reduce risk of HIV and other blood-borne infections among IDUs. Since the late 1980s, studies have shown that treatment works because drug users in treatment stop or reduce their drug use and related risk behaviors, including use of non-sterile syringes and unsafe sex. Drug treatment programs also serve an important role in providing up-to-date information on HIV/AIDS, hepatitis, and other sexually transmitted diseases (STDs), counseling and testing services for these infections, and referrals for their clients to obtain medical and social services.

However, the majority of those needing treatment are not currently in a treatment program. The NIDA Community-Based Outreach Model[8, 9] was designed to reach out-of-treatment IDUs who are unable or unwilling to stop using and injecting drugs and who cannot or will not access drug treatment. Compared to those in treatment, out-of-treatment IDUs are at significantly greater risk of HIV and other infections because they are more likely to inject drugs more frequently, to share drugs, syringes, and other injection equipment, and to practice unsafe sex while under the influence of drugs. The outreach program developed by NIDA attempts to reduce HIV risk through education on the risk factors for HIV transmission and by teaching effective skills in reducing those risks.

The Federal Government has extensively examined the effectiveness of syringe exchange programs (SEPs) dating back to 1993, including reviews by the Government Accountability Office.[10] Several non-governmental organizations, including the American Psychiatric Association, and others have also endorsed the use of SEPs as effective public health interventions. The current scientific literature supports the conclusion that SEPs can be an effective component of a comprehensive community-based HIV prevention effort.

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2. **The Role Played by Harm Reduction Programs in Stemming the Spread of HIV in the United States.**

3. **The Relative Rate of HIV Infection in Cities That Have Implemented Harm Reduction Programs Versus Those That Have Not.**

As a public health agency, the goal of the National Institutes of Health (NIH) and specifically the National Institute on Drug Abuse (NIDA) is to improve the quality of the Nation's addiction treatment and prevention, using science as the vehicle. The term 'harm reduction' has various meanings depending upon the context in which it is used, and is not viewed as a scientific term for any particular approach to addressing drug addiction. However, a great deal of research has been conducted on methods of reducing risks to health, such as syringe exchange programs (SEPs).

Research shows that SEPs, when implemented as part of a comprehensive HIV/AIDS prevention strategy, can be an effective public health approach to reduce the spread of HIV and other blood borne pathogens in the community. SEPs reduce the circulation time of contaminated injection equipment and thereby reduce opportunities for reuse of contaminated injection equipment and the transmission of new infections.[1-2] A number of studies conducted in the U.S. have shown that SEPs do not increase drug use among participants or surrounding community members and are associated with reductions in the incidence of HIV, hepatitis B, and hepatitis C in the drug-using population.[3-7]

Hurley, et al.,[8] reviewed published and unpublished reports from 1984 to 1994 on HIV seroprevalence among IDUs in 81 cities across Europe, Asia, and North America with and without SEPs. On average, seroprevalence increased by 5.9 percent per year in the 52 cities without SEPs and decreased by 5.8 percent per year in the 29 cities with SEPs. The average annual change in seroprevalence was 11 percent lower in cities with SEPs. Thus, in cities with SEPs, HIV seroprevalence among IDUs decreased on average, but in cities without SEPs, HIV seroprevalence increased, suggesting that SEPs led to a reduction in HIV incidence among IDUs.

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4. Evidence Comparing HIV Treatment Regimen Compliance Among IV Drug Users vs. Non-IV Drug Users.

HIV-infected drug abusers can achieve positive health outcomes if they have access to and adhere to treatment with antiretroviral drugs (ART). Studies have also demonstrated the importance of ongoing interventions to reduce drug abuse and associated risk behaviors in order to maximize the health benefits of ART. However, there is cause for concern that health outcomes in drug abusers infected with HIV may be inferior to non-drug users. The often chaotic lifestyles of drug abusers combined with their increased likelihood of co-occurring medical and psychiatric conditions can complicate their treatment and prevent their achieving the same health outcomes as non-drug users. Access to medical care is another crucial factor. Individuals who receive HIV treatment later in the course of their disease are more likely to have viral rebound associated with development of resistance to ART than those who receive early treatment.[1] Finally, preclinical or basic research studies indicate that some drugs of abuse affect the immune system, the target of HIV infection, which may also impact vulnerability to infection and course of illness.

Factors associated with treatment compliance in drug abusing populations are discussed below.

Adherence to HIV treatment among drug users

The cumulative research indicates that non-adherence to antiretroviral therapy (ART) occurs in both drug users and non-drug users, reflecting the difficulty of adhering to complex regimens which require high accuracy in dosing schedule and compliance with dietary instructions. Estimates are that about 40 percent of patients receiving ART have significant problems with adherence.[2] A study of adherence among non-drug-using patients found 53.1% reported taking all medication on time according to dietary instructions, i.e., were fully adherent.[3] It is important to recognize that not only do treatment outcomes depend upon adherence to medication regimens, but also the risk of developing resistant HIV strains may be related to the level of sustained treatment adherence.[1]

A number of predictors of poor ART treatment adherence have been demonstrated in research studies. These include illicit drug use, as well as depression, alcohol use, poor self-efficacy, and certain health beliefs. However, the evidence from individual studies is not consistent--in some cases no differences are found between drug users, former drug users and non-drug users, and in other cases clear evidence of poorer adherence and lower HIV viral suppression is found in active drug users. Examples of this research follow:

- In one study, the strongest predictor of poor ART adherence in drug users was active cocaine use (27% in abstinent users vs. 68% in active users). Other factors included female gender, being unmarried, screening positive for depression and use of alcohol.[4]
- In a cohort of HIV infected women adherence was found not to be stable over time, with factors such as active drug/alcohol use, more frequent antiretroviral dosing, younger age, and lower initial CD4 lymphocyte count predicting poor ART adherence.[5]
- Lucas, et al.,[6] identified the effects of substance abuse status on utilization of highly active anti-retroviral therapy (HAART), medication adherence, and virologic and immunologic responses to therapy in a cohort of HIV-1-infected patients attending an urban HIV clinic. Active drug use was strongly associated with underutilization of HAART, non-adherence,

and inferior virologic and immunologic responses to therapy. Former drug users and non-drug users were similar in all outcomes.

- Another study by this group[7] indicated that switching from non-use to substance abuse was strongly associated with worsening ART use and adherence, and less frequent HIV-1 RNA suppression, compared to remaining free of substance abuse. Conversely, switching from substance abuse to non-use was strongly associated with improvements in ART use, adherence and treatment outcomes.
- Not all studies support an association between drug abusers and poor adherence. A study of factors relating to adherence to antiretroviral therapy among pregnant women indicated that adherence to antiretroviral therapy was not significantly associated with use of illicit drugs. Analyses were based on pharmacy claims data in a sample of 549 HIV-infected women who were prescribed antiretroviral therapy and who delivered live infants.[8]

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5. The Use of Harm Reduction Strategies in Areas Other Than HIV and Drugs, Such as Speed Limits, Seat-Belt Laws, Minimum Age of Alcohol Consumption, and Public Education and Peer Outreach Concerning Smoking.

The reduction of risk for injury and death has been the focus of research in a number of fields. In traffic safety, reduced speed limits[1] and seat-belt laws[2] have reduced the likelihood of crashes and the severity of injuries sustained in those crashes. The Insurance Institute for Highway Safety has published a selection of findings on the prevention and consequences of increased speed limits in several editions of *Status Report* including, "Seven straight years: deaths higher after 65 mph speed limits than before" in 1994 and "Faster travel and the price we pay" in 2003. More information is available on the Insurance Institute for Highway Safety's website at http://www.highwaysafety.org. The Centers for Disease Control and Prevention's (CDC) National Center for Injury Prevention and Control houses a Task Force on Community Preventive Services which has published findings on seat-belt use interventions and the effectiveness of safety belt use laws. CDC's reports have been featured in publications including numerous issues of the *Morbidity and Mortality Weekly Report* (MMWR) and Volume 21 of the *American Journal of Preventive Medicine* (AJPM).[3] More information is available on the National Center for Injury Prevention and Control's website at http://www.cdc.gov/ncipc/.

Research in the alcohol field has shown that crashes and injuries have been reduced by raising the drinking age,[4,5] reducing the allowable blood alcohol concentration (BAC) for drivers,[6] and enacting zero tolerance laws for younger drivers.[7,8] Research has also shown that providing a brief intervention to reduce a person's drinking lowers the probability of making a subsequent visit to an emergency room.[9]

Education aimed at better informing the public on smoking and health issues are an important part of tobacco control and prevention efforts.[10] It is vital that the public understand that, to date, the only proven way to reduce the enormous burden of disease and death due to tobacco use is to prevent youth from beginning to smoke, and to help smokers, both youth and adults to quit.[11] Today, we have much to offer people who smoke and want to quit, including effective behavioral treatments and medications.[12] The evidence strongly suggests that people who keep trying to quit do succeed, although many will require numerous attempts before being successful.[13]

Recently, a number of new tobacco products with claims purported to reduce health risk have entered the market.[14-16] Unlike smoking cessation products, tobacco products do not undergo rigorous, objective scrutiny either for their constituents or for the accuracy of their health claims. A greater science base is required before we will know what effect these new products will have on the health of the public.[17-19]

To be effective, education, and outreach efforts must take into account the knowledge, attitudes, and behaviors – among other factors – of the intended audience.[20] To understand these and related issues, the National Cancer Institute (NCI) has developed and implemented the Health Information National Trends Survey (HINTS), which collects nationally representative data about the American public's use of cancer-related information and perception of cancer risks. HINTS contains questions about tobacco product use, including tobacco products purported to reduce health risk. These data will be useful to help shape future public education efforts.[21]

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Mr. WAXMAN. Thank you very much.

Mr. TOWNS. Let me ask for the record as well, of the $118 million, Dr. Hoofnagle, how much was actually spent, for the record? You don't have to tell me today. For the record. And what kind of correlation exists between NIDDK and the other agencies and institutes within NIH that are doing hepatitis C research? How are these research dollars being used? Can you give me some percentage on the amount devoted to basic research, the amount devoted to treatment, the amount devoted to the vaccine? I'd be delighted if you would submit that for the record.

Chairman TOM DAVIS. We will try to get that as well. Any other comments you would like to make? If not, you don't have to.

Dr. KHABBAZ. I just wanted to thank you for bringing visibility to hepatitis C, and I want to thank Miss Stein for her interest and for bringing us here today.

Chairman TOM DAVIS. She has been great. We're going to hear her on the next panel, what she and a group at Robinson High School are trying to do.

Thank you all very much, and we'll take a 3-minute break and then move to the next panel.

[Recess.]

Chairman TOM DAVIS. We're ready to move to the second panel. I want to thank our witnesses for appearing. Invited to join us on our second panel is Dr. Michael Rudman, the founder of the Frederick County Hepatitis Clinic. Dr. Rudman will provide the committee with an assessment of current Federal efforts to combat hepatitis C. Ms. Ann Jessie, the Founding Executive Director of the Hep C Connection, she's here to discuss the potential costs of an inadequate response to hepatitis C and support systems available to people living with the disease. Captain John Niemiec, the first vice president of the Fairfax County Professional Fire Fighters and Paramedics, is here to discuss the risks posed to first responders and the necessity of education about the disease. And last but certainly not least, Ms. Erika Stein, from Robinson Secondary School, is with us today to tell us her personal story of her efforts to raise awareness and increase funding of prevention and research of hepatitis C, and we have some of her Robinson classmates here with you today.

Could we have you stand up, and just say thank you very much. We waited until 2 p.m. for the hearings so they could get in a full day of class ahead of time.

Dr. Rudman, why don't we start with you and we'll move on down. Thank you for being with us.

Dr. RUDMAN. Thank you, Chairman Davis, for giving me the opportunity to share with you something of what it's like to provide medical care for people with hepatitis C and to share with you my assessments of the effectiveness of the current Federal efforts to——

Chairman TOM DAVIS. Dr. Rudman, I've just been reminded I need to swear all of you.

[Witnesses sworn.]

Chairman TOM DAVIS. You can proceed.

STATEMENTS OF MICHAEL RUDMAN, M.D., FOUNDER, FREDERICK COUNTY HEPATITIS CLINIC, INC.; ANN JESSE, FOUNDING EXECUTIVE DIRECTOR, HEP C CONNECTION; JOHN NIEMIEC, FIRST VICE PRESIDENT, FAIRFAX COUNTY PROFESSIONAL FIRE FIGHTERS AND PARAMEDICS; AND ERIKA STEIN, ROBINSON SECONDARY SCHOOL DECA STUDENT (FATHER HAS HEPATITIS C)

Dr. RUDMAN. Since March 2000 I've been the Medical Director of the Frederick County Hepatitis Clinic. This is a small not-for-profit community-based organization in central Maryland that has provided comprehensive medical care to victims of hepatitis C, care without regard to insurance or financial status. We have now treated over 1,000 patients for hepatitis C, most of them coming from marginalized populations that have no other access to care.

Our patients come from as far away as Colorado, Florida, Tennessee, Louisiana, Pennsylvania, West Virginia, and the extremes of Maryland. They come because they're sick or because they are afraid, or both, and they come to us because they have nowhere else to go.

The majority of people with hepatitis C will not suffer serious effects from the disease; however, a significant minority will. Dr. JB Wong and others have projected that in the decade of 2010 to 2019, 190,000 Americans will die of this disease and this will represent a loss of 1.83 million years of human life under the age of 65. Dr. Wong's group modeled the economic cost of the epidemic and put it at $75 billion in health care and societal costs. Now, that's for the decade to come. This decade will be almost that high. Twenty percent of the people with chronic hepatitis will get cirrhosis. That represents 540,000 Americans. Reducing the disability and death from HCV is the goal of our clinic. Each number represents a human life, a world full of sensibilities and possibilities.

It seems like everyone I talk to sees this as a question of money or the lack of it. Let me tell you what our clinic in Frederick County has done with an annual budget of $60,000 to $70,000 with one full-time employee, with a few part-timers and a bunch of hard-working volunteers.

Last year, thanks to our strategic partners, including Frederick County physicians, the Frederick Memorial Hospital, Frederick County Health Department, Schering Plough, Roche, and other pharmaceutical companies, and a grant from our Board of County Commissioners, our clinic distributed $1.5 million in goods and services to our target populations. As small and as fragile as we are, the clinic is now one of Maryland's largest hepatitis providers and is the only source of comprehensive hepatitis care dedicated to Maryland's uninsured and underinsured. Imagine what could be done with adequate funding.

Most federally funded HCV studies have not carefully examined how the disease is expressed in marginalized populations. Indeed, many of these people were excluded from the NHANES survey upon which our current estimates of disease prevalence are based. These people are truly invisible both to the Federal Government and to academia. They're also where the burden of this disease, its prevalence, disability, and mortality, is concentrated. Our clinic targets these special populations infected with hepatitis C, the poor

and working poor, the chemically dependent, the mentally ill, and HIV coinfected. They comprise a little over half of our clientele and our experience in dealing with special populations suggests that HCV tends to be especially virulent in them; that is, more likely to produce disability and death. Effective interventions such as screening, education, vaccination and treatment, may reap even larger benefits in this population than in the general public.

When each client first arrives at our clinic, we do a comprehensive health assessment. One of every 16 people arrives at their first visit with end-stage liver disease, too late for much of anything except comfort measures, transplantation, or death. Our goal is to prevent this from happening in the other 15. We educate, counsel and support our clients. People who are headed for cirrhosis get antiviral therapy.

Of the clients that our clinic selects for treatment, 48 percent have the most severe stages of viral hepatitis, stage III and stage IV fibrosis. This is an important indication of just how sick this invisible population is. There are hundreds of thousands of people all over the country with stage III and stage IV liver disease right now that are not getting any counseling, not getting any treatment. Our clients often have a history of substance abuse and/or psychiatric problems, and we have to optimize treatment for these co-occurring illnesses prior to, during, and after treatment. This is the challenge and the dividend of treating HCV, its special populations. The way we look at it, helping our patients to become healthy means more than just curing hepatitis C.

Because antiviral treatment can be difficult, we provide a lot of support for our clients, and the result is that 85 percent of those who start therapy finish it and the majority of them who finish it eliminate the virus permanently. For them treatment is a once and done deal. Today HCV is the only chronic viral infection that can be called curable.

Chairman Davis, you asked for our comments on the Federal efforts to combat this disease. Your Honor, if I could use your combat metaphor, let me describe the situation from the point of a view of a lowly platoon leader in the battlefield of HCV. Sir, our troops are getting hammered. The battle plans that have been drawn up in the form of NIH consensus statements and CDC guidelines have not been implemented. The few units that remain in action must scrounge for food and ammunition in the wilderness. Let me illustrate these points from my experience as a Maryland physician.

The State of Maryland, mind you, is not a poor State. We are national leaders in biomedical research and in medical education. Our Governor, Robert Ehrlich, a distinguished former Member of the House of Representatives, is Maryland's first Governor to begin addressing hepatitis C, and we're very excited about this. However, let me share with you a few surprising facts about the past, present, and future of HCV in Maryland, a state of affairs which our Governor inherited.

I serve as a current member on Governor Ehrlich's Hepatitis Advisory Council, and I have learned a lot about how Maryland sees this epidemic. HCV is Maryland's second most commonly reported infectious disease. It already has affected 100,000 Marylanders, of which or whom at least 20,000 will develop cirrhosis and 5,000 will

die. It will cost the State over $2 billion in health care and societal costs over the coming years.

Yet Maryland's Department of Health and Mental Hygiene, following the Federal Government's lead on HCV, has not one person in the entire government designated to work on HCV, not one. We do not have a hepatitis coordinator. In the 16 years since the virus has been identified, the State of Maryland has yet to spend $1 for HCV control or HCV education. Maryland presently denies 90 percent of its 8,000 to 10,000 HCV infected prisoners access to any screening, any education, or treatment for HCV. Maryland does get Federal funds to treat HCV and co-infected patients; that is, patients with HIV. You see, HCV is a major cause of death in HIV patients and the Federal Government provides funding for HIV and some of that could be used to treat HCV, but only if you have HIV. HCV patients who don't have HIV get nothing. They have the right to remain permanently silent, the right to die of a treatable disease.

Congress can improve its efforts in combating HCV and other infectious diseases by addressing the process by which health care funding is allocated, making certain that the diseases that are the most prevalent, costly, lethal, and responsive to intervention receive priority funding. However, effective HCV intervention will require a lot more than Federal funds. It will require a degree of cooperation between mental health, addictionology, prison, and public health, and infectious disease disciplines that have never before been achieved. It will require the development of fully integrated cross-cutting teams that work well together instead of competing at the Federal trough for funds, and unless this type of platform for cooperation is crafted into the wording of funding proposal goals and objectives, the results will be suboptimal.

Congress may want to look at allocating funds for HCV training programs and primary care teaching settings. Family practice, internal medicine, nurse practitioner, and physicians' assistant training programs can easily integrate HCV treatment into existing inhouse substance abuse, STD, HIV, and mental illness programs to provide the total package necessary for optimizing clinical outcomes, and graduates for these programs will then go out into the community and provide good service for years to come.

On behalf of all the people with HCV and their families and their friends and the doctors who struggle to treat it, I respectfully implore you, Congressmen, please help us. We need your help, not just Federal funds but Federal leadership, and we need it now. Thanks for your attention.

[The prepared statement of Dr. Rudman follows:]

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Chairman Davis thank you for giving me the opportunity to share with you something of what it is like to provide medical care for people with hepatitis C and to share with you my assessment of the effectiveness of current federal efforts to combat the disease.

Since March of 2000, I have been medical director of the Frederick County Hepatitis Clinic, Inc. This is a small not-for-profit community-based organization in central Maryland that has provided comprehensive medical care to victims of HCV – care without regard to financial status. We have now treated over 1000 patients for hepatitis C, most of them coming from marginalized populations that have no other access to care for this disease. Our patients have come from as far away as Colorado, Florida, Tennessee, Louisiana, Pennsylvania, WV, and the extremes of Maryland. They come because they are sick or afraid, or both; and they come to us because they have no other place to go.

Chronic viral hepatitis can be a very subtle disease. When symptoms are present at all they may be non-specific—like tiredness, joint and muscle aches, or depression. Often there are no symptoms at all until very late in its course. The disease starts with inflammation the liver blood vessels. Then over a period of two decades scar tissue is laid down. Eventually the walls of scar tissue coalesce, isolating the remaining liver tissue cells into little islands called follicles that have impaired access to blood and digestive systems. This is what the term cirrhosis means: scar tissue and nodules. Over time, about eight years from the onset of cirrhosis, these islands of liver cells may undergo transformation into liver cancer.

The majority of people with HCV will not suffer serious effects from the disease. However a significant minority will. JB Wong and others have projected that in the decade of 2010 to 2019, 190,000 Americans will die from this disease. This will represent a loss of 1,830,000 years of human life under the age of 65. Dr. Wong's group modeled the economic cost of the epidemic and put it at $75 billion in health care and societal costs. Twenty percent of people with chronic hepatitis will get cirrhosis: that's about 540,000 Americans. Reducing the numbers that represent disability and death is our goal. Each number represents a human life, a world of sensibilities and possibilities.

The state of Maryland will lose about twice as many people to HCV in the next 16 years as were murdered at the World Trade Center. We see this coming, and we have the means to prevent this. What does it say about us, if, when the day is done, we have not done our very best to stop it?

It seems like everyone sees this as a question of money or the lack of it. Let me tell you what the folks in Frederick County Maryland have done to combat this disease with an annual budget of 60,000 to $70,000, with one full time employee, our hard working executive director, a few part-timers, and a bunch of committed volunteers. Last year -- thanks to our strategic partners including Frederick county physicians, the Frederick Memorial Hospital, the Frederick County Health Department, Schering Plough,

Roche, and other pharmaceutical companies, and a grant from our Board County Commissioners -- we distributed over $1.5 million in goods and services to our target populations. As small and fragile as we are, the clinic is now one of Maryland's largest hepatitis providers and the only source of comprehensive hepatitis care dedicated to Maryland's uninsured and under-insured. Imagine what could be done with adequate state and federal funding.

In addition to providing clinical services to the poor, we have hosted three major HCV conferences for health care providers. We have produced several multimedia programs for the general public. I will leave one of these with you, a DVD program called "Celebrating Shelley." It is a 10-minute textbook on the human impact of this disease.

Most federally funded HCV studies have not carefully examined how the disease is expressed in marginalized populations. Indeed many of these people were excluded from the NHANES survey upon which our current estimates of disease prevalence are based. These people are truly invisible to both the federal government and to academia. They are also where the burden of this disease – the prevalence, disability, and mortality of infected people – is concentrated. Our clinic targets "special" populations infected with HCV – the poor and working poor, chemically dependent, mentally ill, and HIV co-infected. They comprise a little over half our clientele. Our experience in dealing with special populations suggests that HCV tends to be especially virulent in them -- that is, more likely to produce disability and death. Effective interventions such as screening, education, vaccination, and treatment may reap even larger dividends in these high-risk populations than in the general public.

When each client first arrives at the clinic, we do a comprehensive health assessment. One of every sixteen people arrives at their fist visit with end-stage liver disease, too late for much of anything except comfort measures, transplantation, or death. Our goal is to prevent this from happening in the other 15. We educate, counsel, and support our clients. We try to figure what else is going on. Hepatitis C often does not travel alone. Do our clients have other serious physical or mental diseases? Are there current alcohol or drug problems? Could they tolerate treatment if it were necessary? We do a damage assessment. How bad is the liver scarring? A liver biopsy helps us to determine whether or not anti-viral treatment is necessary and if there is other concurrent liver disease. Is HCV causing serious problems in other areas besides liver disease? Everyone gets counseling about the natural history of the disease, about life style changes. People who are heading for cirrhosis get antiviral therapy.

Of the clients that our clinic selects for treatment, 48% have the most severe stages of viral hepatitis – stage III or IV fibrosis. This is an important indication of just how sick this invisible population is. There are hundreds of thousands of people all over the country with stage III and IV liver who are not getting any counseling, not getting any treatment.

Our clients often have a history of substance abuse and/or psychiatric issues. We must optimize treatment for these co-occurring illnesses prior to, during, and after treatment. This is both the challenge and the dividend of treating HCV in special populations. The way we look at it, helping our patients to become healthy means more than curing hepatitis C. It is also means helping our clients lose the destructive habits and mind-sets that may have lead to the disease in the first place. For some of our clients,

it means learning to take care of oneself, learning to care about others, and getting back to work. Seeing this happen in our clients, again and again, is what motivates us.

Because antiviral treatment can be difficult, we provide a lot of support for our clients. The result is that 85% of those who start therapy finish it, and the majority of those that do clear the virus permanently. For them, treatment is a once and done deal. Today, HCV is the only chronic viral infection that can be called "curable."

Chairman Davis, you asked for my comments on federal efforts to combat this disease. Your Honor, if I may extend your use of the combat metaphor, let me describe the situation from the point-of-view of a platoon leader in the battlefield of HCV. Sir, our troops are getting hammered. The battle plans that have been drawn up in the form of NIH consensus statements and CDC guidelines have not been implemented. The field soldiers are out of ammunition and there is no food for the troops. The few units that remain in action must scrounge for food and ammo in the wilderness. Let me illustrate these points from my experience as a Maryland physician.

The state of Maryland, mind you, is not a poor state. We are national leaders in both biomedical research and in medical education. Our governor, Robert Ehrlich, a distinguished former member of this body, is Maryland's first governor to begin addressing Hepatitis C. We are very excited about having a governor who is willing to address this disease.

However, let me share with you a few surprising facts about the past, present, and future of HCV in Maryland, a condition which our governor inherited. I serve as a current member of Governor Ehrlich's Hepatitis Advisory Council and have learned a lot about how Maryland sees this epidemic. HCV is Maryland's second most commonly reported infectious disease. It has already infected 100,000 Marylanders, of whom at least 20,000 will develop cirrhosis and 5000 will die. It will cost the state over $2 billion in health care and societal costs over the coming years.

Yet Maryland's Department of Health and Mental Hygiene, following the federal government's "lead" on HCV, has not one person in the entire state government designated to work on HCV. In the 16 years since the virus has been identified, the State of Maryland has yet to spend $1 for HCV control or education programs.

Maryland presently denies about 90% of its 8-10,000 HCV-infected inmates access to *any* screening, education, or treatment for HCV. Maryland does get federal funds for HIV treatment, and some of those funds can be used to treat HCV in co-infected patients. (HCV is a major cause of death in HIV patients). However, inmates without HIV get nothing. They have the right to remain permanently silent-- the right to die of a treatable disease.

The net result of the federal funding policy at the state level is a human rights and legal liability nightmare. Our current policy of purposeful failure to identify HCV in at-risk inmates without HIV – a don't-ask-don't-tell policy – and denying access to basic health care based on a negative HIV status – will be successfully challenged. Our state, and others like it, will be found negligent and liable for damages unless they stop this policy now. All states, not just Maryland, need clear ethical, cost-effective, legally defensible, and scientifically sound mandates for care of HCV in inmate populations AND they need adequate federal funding to implement them. And if we do it for inmates, because we must, I think we should do it for people on the other side of prison bars, because we can.

Congress can improve its efforts in combating HCV and other infectious diseases by addressing the process by which health care funding is allocated – making certain that the diseases that are the most prevalent, costly, lethal, and responsive to intervention receive priority funding. However, effective HCV intervention will require more than federal funds. It will require a degree of cooperation between the mental health, addictionology, prison and public health, and infectious disease disciplines that has never before been achieved. It will require the development of fully integrated, crosscutting teams that work well together instead of competing at the funding troughs. Unless this type of platform for cooperation is crafted into the wording of funding proposal goals and objectives, results will be sub-optimal -- money and lives will be wasted.

Congress may want to look at allocating funds for HCV training programs in primary care teaching settings. Family practice, internal medicine, nurse practitioner, and physicians' assistant training programs can easily integrate HCV treatment into existing in-house substance abuse, STD, HIV, and mental illness programs to provide the total package necessary for optimizing clinical outcomes. Graduates of these programs will be in a good position to provide cutting edge services for the communities that they will serve for years to come. Currently, gastroenterologists usually handle this disease. I think this has been a mistake. This epidemic is too big and too complex. Our nation's history of handling this disease up until now speaks for itself: we must train and involve people who understand human, family, and community dynamics – who treat patients as a whole. If there was ever a condition that requires the mindset of a trained primary care provider, it is hepatitis C.

These interventions and others you will hear about will make a big difference in battle against hepatitis C. Done correctly, they will also strengthen our entire public health infrastructure. On behalf of all the people with HCV, their families and friends, I respectfully implore you, Congressmen, please help us. We need your help -- not just federal funding but federal leadership--and we need it now. Thank you for your attention.

Respectfully Submitted

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Chairman TOM DAVIS. Thank you very much.

Ms. Jesse.

Ms. JESSE. My name is Ann Jesse. I'm both the founding member of the National Hepatitis C Advocacy Council, a national coalition of hepatitis C advocacy organizations, and also the Founding Director of Hep C Connection, a national nonprofit network support system for people living with hepatitis C. I thank you, Mr. Chairman, for the opportunity to once again address this grave public health threat before the Government Reform Committee.

I remember well when shortly after my hepatitis C diagnosis in 1994, former Surgeon General Dr. C. Everett Koop described the hepatitis C epidemic as one of the most significant preventable and treatable public health problems facing our Nation. At that time he said it was a graver threat than the AIDS crisis. Despite the ominous warnings of experts like Dr. Koop and his successor, Dr. David Satcher, the general public and many people in the health care and public health communities still remain uninformed about the threat imposed by the current hepatitis C crisis.

As early as 1991, Dr. Miriam Alter of the Centers for Disease Control and Prevention warned us that hepatitis C was a sleeping giant. Although others soon realized the far reaching personal and societal threats posed by this sleeping giant, the warnings were not acted upon with sufficient rigor to contain a problem of such magnitude. So today we are faced with a public health crisis that is growing day by day. This crisis will continue to grow in destructive capacity for the foreseeable future until we meet this foe with sufficient funds and the rigor to control it.

To be sure, the alarm must be sounded. Based on incidence and prevalence data and our current knowledge about the clinical course of hepatitis C, we can expect that of the 5 million people estimated to be infected, at least 1.25 million will develop cirrhosis and 125,000 will require liver transplantation for liver failure and/or liver cancer. To give you some frame of reference to comprehend the magnitude of these figures, think of the number of people in a city the size of New Orleans, Los Angeles, or San Antonio, TX. Now try to imagine that every man, woman, and child in the city is suffering from hepatitis C-related cirrhosis of the liver. That is what this treacherous giant called hepatitis C has in store for us unless we act immediately to intervene in the public health crises.

Another way to comprehend the magnitude of the problem is to consider how the number of people infected with hepatitis C compares to other well-publicized health problems with which we are very familiar.

We have the sign over here. HIV is notably absent from this graphic over to my right. The reason is that because of the way HIV/AIDS is reported, it is currently not possible to determine how many new infections occur each year. However, according to the CDC, an estimated 570,000 people in the United States were living with HIV/AIDS in 2003 compared to an estimated 3 to 5 million people living with chronic hepatitis C. I think this statistic is always amazing and alarming to the general public.

We must take control of the crisis and look at integration into preexisting programs, but this alone is not adequate. The National Hepatitis C Advocacy Council appreciates the fact that there are

several individuals in the Department of Health and Human Services who understand the magnitude of the hepatitis C crisis and are willing to dedicate the efforts needed to intervene effectively. However, those of us who understand the urgency of the crisis have been stymied because the response at the Federal level to this crisis has thus far been starkly insufficient to deal with the magnitude of the problem. We feel strongly that an effective disease control and prevention program must be tailored to fit the specific characteristics of the disease being targeted.

In other words, effective programs are disease specific and take into account the characteristics of the disease, such as how it is transmitted, the national course of the disease, the population at risk, and available treatment options. Herein is the foundational problem with the current DHHS plan which attempts to address the hepatitis C crisis solely by integrating Hep C prevention control into preexisting HIV/AIDS and sexually transmitted disease programs. Although HCV and HIV have some shared routes of transmission, they are distinctly different viruses and diseases. The risk groups and relative risks of acquiring these two very different viruses from certain activities are simply not the same. An integration-only approach we feel is doomed to failure.

Should HCV prevention and control efforts be integrated into existing HIV/AIDS and STD programs? Of course. But HCV prevention and control efforts must go far beyond integration if we hope to bring this crisis under control. In terms of the potential costs of the inadequate response, I can assure you that the hepatitis C crisis grows more seriously each day.

A landmark study published recently by Dr. John Wong, to whom Dr. Rudman referred, laid forth the dire consequences of the currently unchecked hepatitis C crisis. He predicted several devastating personal, societal, and fiscal developments, and I believe we have that to our right again. The accuracy of Dr. Wong's predictions are already declaring themselves in the rising rates of chronic liver disease, increased incidence of liver cancer, and increasing demand for liver transplantation. We are only at the beginning of this devastating course. It will grow far worse unless we take immediate action to change the current tide.

The good news is that we have not yet squandered our opportunity to change the ultimate outcome of this public health crisis. In the past decade great advances have been made in the treatment of hepatitis C, and with the appropriate therapy nearly 50 percent of those treated for their disease are able to successfully clear the virus and halt further disease progression. If we act now and successfully identify and treat those at greatest risk for the development of liver failure and/or liver cancer, we can save lives, salvage productivity and ultimately decrease the burden of this disease.

Unlike HIV, which requires life-long antiviral therapy, the treatment for HCV is limited. A successful course of therapy is completed in 24 to 48 weeks. For those who clear the virus know that additional antiviral therapy is required. For all intents and purposes these patients have been cured of chronic hepatitis C.

The bottom line is that identifying and treating hepatitis C is clearly cost effective, and we have those figures again to the right.

Hepatitis C national advocacy and community-based organizations have put forth heroic efforts to try to provide much needed intervention and control services. Funded virtually exclusively by private fundraising and small nonFederal grants, the organizations of the National Hepatitis C Advisory Council have conducted local screening, counseling and testing programs, worked with corrections facilities to improve Hep C efforts for the incarcerated population, collaborated with harm reduction programs to provide Hep C education to at-risk populations, authored a comprehensive patient-oriented book about Hep C, and countless other daily efforts by a legion of unsung heroes across the land. We are doing the best we can on what amounts to a wing and a prayer and a passionate commitment to those afflicted with this disease, but we are sadly aware that our efforts are barely scratching the surface of what needs to be done to address the crisis.

We, the DHHS agencies, the State and local health departments and the Hepatitis C advocacy organizations, must have funding to do the work we know must be done and that we are fully prepared to do. Hepatitis C is everyone's disease. Many of the millions of Americans infected with HCV are average citizens just like you and me, our family members and friends: Middle-aged working class men and women who may have had a blood transfusion due to surgery, injury, or childbirth; young adults who had transfusions as premature babies; military veterans of Vietnam, Desert Storm and the young men and women coming home from Afghanistan and Iraq; hard-working productive men and women who experimented briefly with drugs in the folly of their youth and are now paying the price.

Unlike most viral diseases from the common cold to influenza to AIDS, HCV is a treatable illness. In other words, unlike many other afflictions, we have the opportunity to intervene in this crisis with a potential to achieve a viral cure in approximately half of those treated. We have a rare opportunity with HCV, and we must not squander it.

I am one of the many faces of hepatitis C and I stand before you today as one of the lucky ones. Not only am I a treatment veteran but I am also a successful responder to treatment for this insidious disease. Unlike so many unsuspecting people infected with hepatitis C, I was fortunate enough to get tested, and unlike many people currently struggling with hepatitis C, I had adequate insurance coverage and was thus able to afford treatment. Above all, I was fortunate to have successfully cleared the virus and remain virus-free 6 years later.

In gratitude for my good fortune, the misfortune of the millions of others infected with hepatitis C, not to mention the more than 2 million Americans who are not aware they are infected, that misfortune is never far from my mind. I cannot forget about them and neither should you. Just as I pled for attention before this same congressional committee in March 1998, I repeat my plea with even greater passion today. We have a moral, professional, and fiscal responsibility to the American people to act now to implement a fed-

erally funded comprehensive hepatitis C prevention and control program. It is not only our responsibility, it is the only humane option possible.

Thank you for your time and attention.

[The prepared statement of Ms. Jesse follows:]

Stalking a Furtive Killer:
A Review of the Federal Government's Efforts to Combat Hepatitis C
Testimony of Ann Jesse for the National Hepatitis C Advocacy Council
December 14, 2004

I. INTRODUCTION

My name is Ann Jesse. I am a founding member of the National Hepatitis C Advocacy Council, a national coalition of hepatitis C advocacy organizations and the founding Executive Director of Hep C Connection, a national nonprofit network and support system for people living with hepatitis C. I thank you, Mr. Chairman, for the opportunity to address this grave public health threat.

Former Surgeon General Dr. C. Everett Koop described the hepatitis C epidemic as, "one of the most significant preventable and treatable public health problems facing our nation.... a graver threat than the AIDS crisis."[1] The hepatitis C epidemic is often called "the silent epidemic" because despite the ominous warnings of experts like Dr. Koop and his successor Dr. David Satcher, the general public and many people in the health care and public health communities still remain uninformed about the threat posed by the current hepatitis C crisis.

Dr. Miriam Alter of the Centers for Disease Control and Prevention warned us in 1991 that hepatitis C was "a sleeping giant."[2] Others soon realized the far-reaching personal and societal threats posed by the sleeping giant. But the warnings were not acted upon with sufficient rigor to contain a problem of such magnitude. So today, we are faced with an awakened giant, a public health crisis that is growing day by day. The crisis will continue to grow in destructive capacity for the foreseeable future, until we meet this foe with sufficient funds and rigor to control it. Those of us in this room today have an urgent and crucial responsibility to change the course of this crisis.

II. WHY BE CONCERNED ABOUT HEPATITIS C?

As you have heard, approximately 4-5 million Americans are currently infected with the hepatitis C virus, and an estimated 30-35,000 new infections occur each year. Hepatitis C is an insidious and often silent disease for many years. The early quiescent nature of chronic hepatitis C is one of the most fundamental reasons it poses such a perilous public health threat. The vast majority of people currently infected with the hepatitis C virus are unaware they are infected. Without proactive screening, many of the millions infected will not be diagnosed until they develop serious complications. And in the interim, these millions of infected Americans run the risk of unwittingly infecting countless others with this potentially life-threatening virus.

Chronic hepatitis C ultimately leads to cirrhosis in 20-30% of those infected with 10% progressing to liver-failure or liver cancer for which liver transplantation is the only proven lifesaving measure available. Over the past decade, the incidence of liver cancer has increased greatly, as has the number of people in need of liver transplantation. Most experts attribute these alarming trends to the current hepatitis C crisis.

Based on incidence and prevalence data, and our current knowledge about the clinical course of hepatitis C, we can expect that of the 5 million people currently infected, at least:

- **1, 250,000 will develop cirrhosis**
- **125,000 will require liver transplantation for liver failure and/or liver cancer**

To give you some frame of reference to comprehend the magnitude of these figures, think of the number of people in a city the size of New Orleans, LA or San Antonio, TX or Indianapolis, IN or San Diego, CA. Now try to imagine that every man, woman, and child in the city is suffering from hepatitis C-related cirrhosis of the liver. That is what this treacherous giant called hepatitis C has in store for us – unless we act immediately to intervene in this public health crisis.

Another way to comprehend the magnitude of the problem is to consider how the number of people infected with hepatitis C compares to other well-publicized health problems with which we are all familiar (see Figure 1).[3, 4, 5, 6, 7] HIV is notably absent from this graphic. The reason is that because of the way HIV/AIDS is reported, it is currently not possible to determine how many new infections occur each year. However, according to CDC, an estimated 570,000[8] people in the US were living with HIV/AIDS in 2003, compared to an estimated 3-5 million people living with chronic hepatitis C.

III. TAKING CONTROL OF THE HEPATITIS C CRISIS

A. Integration into Pre-Existing Programs Alone is Inadequate

The National Hepatitis C Advocacy Council appreciates the fact that there are several individuals in the Department of Health and Human Services who understand the magnitude of the hepatitis C crisis and are willing to dedicate the efforts needed to intervene effectively. However, those of us who understand the urgency of this crisis have been stymied because the response at the federal level to this crisis has been starkly insufficient to deal with the magnitude of the problem. Specific and well-defined steps are necessary to bring the hepatitis C epidemic under control.

An effective disease control and prevention program must be tailored to fit the specific characteristics of the disease being targeted. In other words, effective programs are disease-specific and take into account the characteristics of the disease such as: how it is transmitted, the natural course of the disease, the population at risk, and available treatment options. Herein is a foundational problem with the current DHHS plan which attempts to address the hepatitis C crisis **solely** by integrating hepatitis C prevention and control into pre-existing HIV/AIDS and sexually transmitted diseases (STDs) programs. Although HCV and HIV have some shared routes of transmission, they are distinctly different viruses and diseases. The risk groups and relative risks of acquiring these two very different viruses from certain activities are simply not the same.[9, 10, 11, 12, 13, 14] An integration only approach is doomed to failure.

Should HCV prevention and control efforts be integrated into existing HIV/AIDS and STD programs? Of course! But HCV prevention and control efforts must go far beyond integration if we hope to bring this crisis under control. The response to the current HCV epidemic must be similar in scope and magnitude to the threat it poses. Trying to address the HCV crisis with the current plan and funding is akin to trying to stop a hemorrhaging artery with a band-aid. It simply will not work. A significantly more substantial response is urgently needed.

B. The Potential Costs of an Inadequate Response

The hepatitis C crisis grows more serious each day. A landmark study published by Dr. John Wong in the *American Journal of Public Health*[15] laid forth the dire consequences of the currently unchecked hepatitis C crisis. He predicted several devastating personal, societal, and fiscal developments (see Figure 2). The accuracy of Dr. Wong's predictions are already declaring themselves in the rising rates of chronic liver disease, increased incidence of liver cancer, and increasing demand for liver transplantation. But we are only at the beginning of this devastating course; it will grow far worse unless we take immediate action to change the current course of the hepatitis C crisis.

The good news is that we have not yet squandered our opportunity to change the ultimate outcome of this public health crisis. In the past decade, great advances have been made in the treatment of hepatitis C, and with appropriate therapy, nearly 50% of those treated for their disease are able to successfully clear the virus and halt further disease progression. In other words, we are at a crucial juncture in this crisis. If we act now and successfully identify and treat those at greatest risk for the development of liver failure and/or liver cancer, we can save lives, salvage productivity, and ultimately decrease the burden of this disease.

From a fiscal standpoint, immediate intervention in the hepatitis C crisis is a matter of simple arithmetic. Funding for hepatitis C education, counseling, testing and treatment will be offset by future savings through the prevention of liver complications such as chronic liver disease, liver failure, liver cancer, and liver transplantation.

Unlike HIV, which requires life-long antiviral therapy, the treatment for HCV is limited. A successful course of therapy is completed in 24-48 weeks. For those who clear virus, no additional antiviral therapy is required. For all intents and purposes, these patients have been cured of chronic hepatitis C. The bottom line is that identifying and treating hepatitis C is clearly cost effective (see Figure 3).

C. Establishing an Effective Hepatitis C Prevention and Control Program

While integration of hepatitis C prevention and control activities into existing HIV/AIDS and STDS programs can only be seen as a partial response to the hepatitis C crisis, these programs *do* provide a good working model for what an effective hepatitis C prevention and control program should look like (see Figure 4).

The focus of CDC's current **National Hepatitis C Prevention Strategy** is integration into existing HIV/AIDS and STD programs. We believe this approach was taken because lack of funding prevented virtually any other approach. Clearly, CDC is well-aware of what is needed for effective control and prevention as evidenced by numerous existing programs such as the National Immunization Program. But given that their hands have been figuratively tied because of an inability to fund what they know to be the necessary components of an effective hepatitis C prevention and control program, they have resorted to the only avenue left open to them. They have tried to establish a network to begin coordinated efforts at the state level by establishing the

Hepatitis C Coordinators program. However, limited funds cover the salaries for these positions without providing any funding for these professionals to actually conduct hepatitis C prevention and control activities. So their hands, too, have been tied. Thirty-three states currently have hepatitis C prevention and control plans prepared and ready for execution – but have been unable to act upon those plans due to lack of funds. Similarly, SAMSHA is ready and willing to take part in hepatitis C prevention and control efforts, but have been unable to act because of the absence of a directive to spend funds on such activities.

Hepatitis C national advocacy and community-based organizations have put forth heroic efforts to try to provide much-needed prevention and control services. Funded virtually exclusively by private fund-raising and small non-federal grants, the organizations of the National Hepatitis C Advocacy Council have:

- conducted local screening, counseling, and testing programs
- worked with corrections facilities to improve hepatitis C efforts for the incarcerated population
- collaborated with harm reduction programs to provide hepatitis C education to at-risk populations
- authored a comprehensive, patient-oriented book about hepatitis C
- countless other daily efforts by a legion of unsung heroes

We are doing the best we can on what amounts to a wing and a prayer, and a passionate commitment to those afflicted with this disease. But we are sadly aware that our efforts are barely scratching the surface of what needs to be done to address this crisis. We – the DHHS agencies, the state and local health departments, and the hepatitis C advocacy organizations – must have funding to do the work we know must be done and that we are fully prepared to do.

IV. SUMMARY

Former Surgeon General Dr. C. Everett Koop summarized the current status of the hepatitis C crisis by saying: *We are at the edge of a very significant public health challenge - not unlike the AIDS epidemic. We have an infectious disease that is an undisputed threat to the public health. It is a viral disease that millions of people harbor without knowing they have it. It is a disease these millions will carry for a decade or more - possibly spreading to others - while it develops into a serious threat to their health. We can treat the disease during this quiescent period and we can eliminate the infection for a large portion of the infected, preventing progression to serious disease.... we have a long way to go very quickly if we are to prevent the very serious public health consequences of this disease.*

Hepatitis C is **everyone's disease**. Many of the millions of Americans infected with HCV are average citizens just like you, me, our family members, and friends:

- middle-aged working class men and women who may have had a blood transfusion due to surgery, injury, or childbirth
- young adults who had transfusions as premature babies
- military veterans of Vietnam, Desert Storm, and the young men and women coming home from Afghanistan and Iraq

- hard-working, productive men and women who experimented briefly with drugs in the folly of their youth

Unlike most viral diseases from the common cold to influenza to AIDS, HCV is a treatable illness. In other words, unlike many other afflictions, we have the opportunity to intervene in this crisis with the potential to achieve a viral cure in approximately half of those treated. We have a rare opportunity with HCV; we must not squander it.

We are at a critical juncture. We are faced with an awakened giant, the hepatitis C crisis. Ignoring this giant will lead to dire personal, societal, and fiscal consequences. Opting to fund a comprehensive hepatitis C prevention and control program now will save hundreds of thousands of lives, millions of years of pain and suffering, and billions of dollars in direct and indirect costs.

Again, hepatitis C is **everyone's disease**. Dr. Koop's message is clear: *Hepatitis C does not discriminate. It affects people of all ages, gender, and sexual orientations. It is not a "disease of the poor." It affects people from all walks of life, in every state, in every country. Most important, it affects a large number of individuals, a group in the United States that is as large as the populations of every capital city, in every state combined. All Americans must understand the risk that this disease poses. We must help America become a leader in the fight against this disease, both here at home and around the world.*[16]

I am one of the many faces of hepatitis C, and I stand before you today as one of the lucky ones. Not only am I a treatment "veteran," but also a successful responder to treatment for this insidious disease. Unlike so many unsuspecting people infected with hepatitis C, I was fortunate enough to get tested. And unlike many people currently struggling with hepatitis C, I had adequate insurance coverage and was thus able to afford treatment. Above all, I was fortunate to have successfully cleared the virus. I remain virus-free more than six years later.

In gratitude for my good fortune, the misfortune of the millions of others infected with hepatitis C, not to mention more than two million Americans who are not aware they are infected, is never far from my mind. I cannot forget about them, and neither should you. Just as I pled for attention before this same Congressional Committee in March of 1998, I repeat my plea with even greater passion today.

We have a moral, professional, and fiscal responsibility to the American people to act **now** to implement a federally-funded, comprehensive hepatitis C prevention and control program. It is not only our responsibility, it is the only humane option possible.

Thank you for your time and attention.

APPENDIX: FIGURES 1-4

Figure 1:

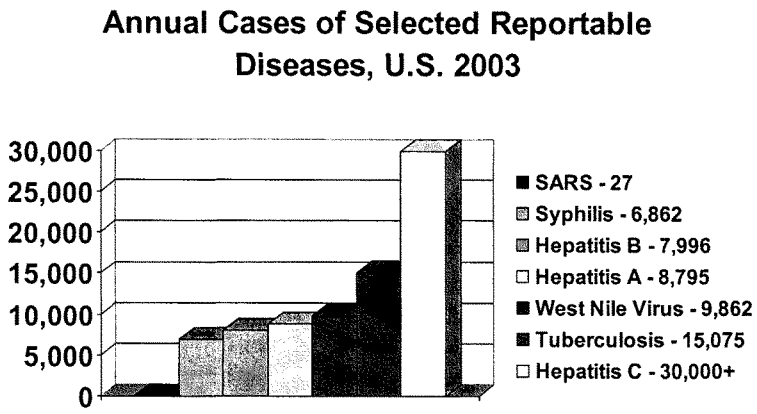

Figure 2: Projected HCV-Related Morbidity, Mortality, and Costs in the United States, 2010-2019[15]

HUMAN COSTS	
Deaths from HCV-related chronic liver disease	165,900
Deaths from hepatocellular carcinoma	27,200
Years of advanced liver disease	960,000
Years of life lost	3.1 million
SOCIETAL & FISCAL COSTS	
Direct medical costs	$10.3 billion
Cost of lost productivity due to disability	$21.3 billion
Cost of lost productivity due to premature death	$54.2 billion

Figure 3

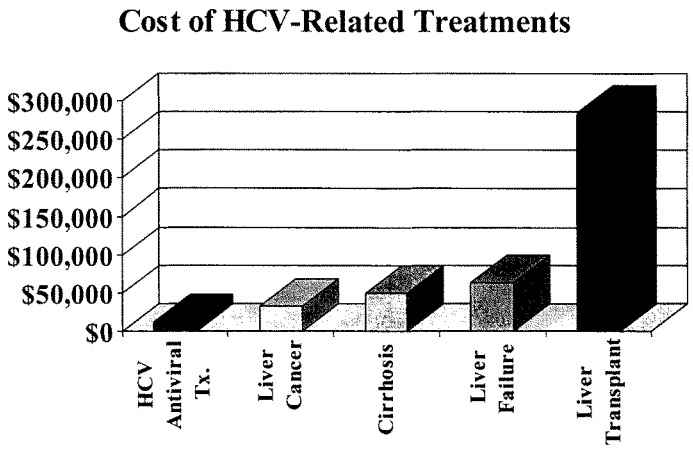
Cost of HCV-Related Treatments
$300,000
$250,000
$200,000
$150,000
$100,000
$50,000
$0
HCV Antiviral Tx.
Liver Cancer
Cirrhosis
Liver Failure
Liver Transplant

Figure 4: Hepatitis C Prevention and Control Program Model

DHHS Comprehensive Hepatitis C Prevention and Control Plan

Education

Surveillance

Harm Reduction

Counseling and Testing

Treatment Referrals and Support

Research

Implementation Oversight and Funding Distribution via DHHS Agencies

State Health Departments (Hepatitis C Coordinators)

Local Health Departments

Partnerships with National Hepatitis C Advocacy Organizations

Partnerships with Community-Based Hepatitis C Organizations

Partnerships with Academic/Research Community

Coordinated Efforts with HIV/AIDS, STD, & Harm Reduction Programs

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Chairman TOM DAVIS. Thank you very much, Ms. Jessie.

Mr. Niemiec, thanks for being with us.

Mr. NIEMIEC. Good afternoon, Mr. Chairman. My name is John Niemiec, and I'm a captain with the Fairfax County Fire and Rescue Department. I appear before you today on behalf of my department and the Fairfax County Professional Fire Fighters and Paramedics-International Association of Fire Fighters Local 2068, and my colleagues from the Fairfax County Sheriff's office.

I would like to thank you, Congressman Davis, and the committee for holding this important hearing today, and I commend you for shining a spotlight on a public health issue that is of vital concern to the Nation's fire fighters.

I would also like to thank Mr. Jay Walker, the students from Robinson High School, DECA, and especially Erika Stein for their unselfish campaign in promoting hepatitis C awareness and future legislation.

I am here today because Hep C is a real concern for first responders. Because hepatitis C is transmitted blood to blood, first responders face an increased risk of exposure to the virus. Hep C can be a lethal virus that is five times more prevalent here in the States population compared to the HIV virus, and yet, the American people receive little information as it relates to the hepatitis C virus. The Centers for Disease Control and Prevention estimate that approximately 1 out of every 50 Americans, that is 1 out of every 50 Americans, is infected with hepatitis C virus. Individuals who are Hep C infected can be asymptomatic up to 20 to 30 years. Often by the time the disease is even diagnosed, the disease has already progressed to cirrhosis, liver cancer, end-stage liver disease, or the need for a liver transplant. In those cases, if it had been caught earlier, there may have been a chance to slow the progression of the disease with behavior changes, such as limiting alcohol consumption.

Currently there is no vaccine for hepatitis C. Often individuals who were administered the hepatitis A and/or the hepatitis B vaccine believe they are protected against hepatitis C. This is not the case and these misperceptions show that we need a better public education campaign about the disease. Because the virus consistently mutates, there are six genotypes and over 80 subtypes, manufacturing a vaccine for hepatitis C is problematic.

Typically the treatment regimen is 6 to 12 months of injections and oral medications. While treatment has advanced over the last 10 years, more needs to be done. In about 50 percent of the patients, current treatment does not eliminate the disease. Also, treatment for Hep C can cause significant physical and mental side effects, which means the patient receiving treatment may require additional support from medical providers and patient support groups to optimize their treatment outcome.

As mentioned, first responders face an increased risk of exposure to the disease. Hep C has not only infected but also has affected a number of first responders within the fire service and law enforcement arenas. Fairfax County Fire and Rescue currently has 10 fire fighters infected with the virus while the city of Philadelphia Fire Department has over 200 fire service personnel stricken by

this disease. On a personal note, I have a younger sibling infected with this virus.

The time to educate, prevent, and screen the at-risk population is now. Medical experts with knowledge about this virus continue to echo the urgent need to screen at-risk populations such as first responders and individuals who had blood transfusions prior to 1992. Therefore, I urge all congressional leaders to embrace, promote, and fund the Hepatitis C Epidemic Control and Prevention Act not only for first responders but for the American people as well.

Thank you for your time and consideration, and I'd be happy to answer any and all questions.

[The prepared statement of Mr. Niemiec follows:]

Testimony of John R. Niemiec, Captain, Health Programs Officer,
Fire and Rescue Department, Fairfax County, Virginia

Before the Committee on Government Reform in the United States House of Representatives

December 14, 2004

Mr. Chairman, my name is John Niemiec, and I am a Captain in the Fairfax County Fire and Rescue Department. I appear before you today on behalf of my department, the Fairfax County Professional Fire Fighters and Paramedics-International Association of Fire Fighters Local 2068, and my colleagues from the Fairfax County Sheriff's Office.

I would like to thank Congressman Davis and the Committee for holding this important hearing today, and commend you for shining a spotlight on a public health issue that is of vital concern to the nation's fire fighters. I would also like to thank Mr. Jay Walker, the students from Robinson High School DECA, and especially Erika Stein, for their unselfish campaign in promoting Hepatitis C awareness and future legislation.

I am here today because Hepatitis C is a real concern for first responders. Because Hepatitis C is transmitted blood-to-blood, first responders face an increased risk of exposure to the virus. Hepatitis C can be a lethal virus that is five times more prevalent in the United States' population compared to the HIV virus and yet, the American people receive little information as it relates to the Hepatitis C virus. The Centers for Disease Control and Prevention estimate that approximately 1 out of every 50 Americans is infected with the Hepatitis C virus.

Individuals who are Hepatitis C infected can be asymptomatic for 20-30 years. However, often by the time the disease is even diagnosed, the disease has already progressed to cirrhosis, liver cancer, end-stage liver disease, or the need for a liver transplant. In those cases, if it had been caught earlier there may have been a chance to slow the progression of the disease with behavioral changes, such as limiting alcohol consumption.

Currently, there is no vaccine for the Hepatitis C virus. Often individuals who were administered the Hepatitis A and/or Hepatitis B vaccinations believe they are protected against Hepatitis C.

This is not the case, and these misperceptions show that we need a better public education campaign about the disease. Because the virus consistently
mutates, there are 6 genotypes and over 80 subtypes causing the manufacturing of vaccine for Hepatitis C to be problematic.

Typically, the treatment regime is for 6 - 12 months of injections and oral medications. While treatment has advanced over the last 10 years, more needs to be done. In about 50% of the patients, current treatments do not eliminate the disease. Also, treatment for

Hepatitis C can cause significant physical and mental side-effects, which means that patients receiving treatment may require additional support from medical providers and patient support groups to optimize their treatment outcomes.

As mentioned, first responders face an increased risk of exposure to the disease. Hepatitis C has not only infected but has also affected a number of first responders within the fire service and law enforcement arenas. Fairfax County Fire and Rescue has 10 fire fighters infected with the virus while the City of Philadelphia Fire Department has over 200 fire service personnel stricken by this disease. On a personal note, I have a younger sibling infected with the Hepatitis C virus.

The time to educate, prevent, and screen the "at-risk" population is now. Medical experts with knowledge about this virus continue to echo the urgent need to screen the "at-risk" populations such as first responders and individuals who had blood transfusions prior to 1992.

Therefore, I urge that all Congressional leaders embrace, promote, and fund The Hepatitis C Epidemic Control and Prevention Act not only for first responders but for the American people as well.

Thank you for your consideration. I would be happy to answer any questions that you may have.

Chairman TOM DAVIS. Thank you very much.

Erika, thanks for being here with us. You're a cleanup hitter here.

Ms. STEIN. Thank you. First of all, I would like to thank you, Congressman Davis, for everything you have done for us and, Congressman Towns, for everything that you also have done for us. Thank you.

I was 5 years old when my father was first diagnosed with hepatitis C. At the time I really didn't understand what this meant but I could tell that my mother seemed to be very concerned and I sensed that something was gravely wrong. By the time I was in fourth grade my father's physician started him on a course of interferon in hopes of ridding him of the virus. My dad had to give himself painful injections of the drug several times a day and the drug caused him to become seriously ill. I can remember vividly my dad lying on the couch with a fever of 102 and shivering as if he had a bad case of the flu.

During the time my dad was on interferon he became depressed and seemed like a completely different person to me. The smallest event could cause my dad to literally go ballistic, almost like he had changed into the Incredible Hulk. Our family experienced a great deal of stress and turmoil throughout the interferon treatment and we were all thankful to reach its end.

Although he went through nearly 6 months of sheer torture, the interferon treatment had no effect on his hepatitis C virus. Needless to say, we were all heart broken at the failure of the treatment.

Several years later my dad became a patient of the Halt C study and was started on a course of Pegylated interferon with Ribavirin at the National Institutes of Health. Before beginning the treatment, he was given a liver biopsy and they discovered he had cirrhosis of the liver. He finished the less painful course of the interferon treatment only to find out once again that it had no effect on the virus. My dad felt as if he had failed the treatment, but in truth the treatment failed him.

In the fall of 2003, I was in my advanced marketing class and we were deciding what we should focus on as a public relations project for the school year. I introduced the idea of doing a project on hepatitis C because it was real life for me and our Robinson DECA chapter has always dealt with serious issues that impact the lives of people who are greatly loved. We discovered that a bill had been introduced in May 2003 that would allot $90 million for research and education on the hepatitis C virus.

As you know, Congressman Davis, our DECA chapter takes on tough issues. We've worked on the Ricky Ray Hemophilia Relief Fund Act, the Good Samaritan law which protects users of automative defibrillators, and most recently the Dirty Diamond Act. I learned that Senator Kay Bailey Hutchison had introduced bill S. 1143; so I immediately contacted her office to see what we could do to help. I was then put into contact with Sharon Phillips, president of the Hepatitis C Advocacy Network based in Texas, and she was instantly by our side. She and Lorren Sandt of the Hepatitis C Caring Ambassadors Program flew to Virginia and came to educate our advanced marketing class. After Lorren and Sharon's

powerful visit, where we learned that 4 million Americans were infected with hepatitis C and 10,000 Americans die each year of the virus, our chapter unanimously decided that hepatitis C would be our public relations project.

Since October 2003, nearly 500 marketing students from Robinson Secondary School have been working on Capitol Hill, visiting congressional offices and persuading health legislative assistants to encourage their members to co-sign the Wilson-Towns Hepatitis C Epidemic Control and Prevention Act, H.R. 3539. We have letters, phone calls, and e-mails of encouragement from hundreds of hepatitis C patients across the country.

I have a story to tell you concerning some of the frustrations that come along with explaining hepatitis C to the public. A year ago this month, 80 Robinson marketing students went to New York City for our annual marketing field study. We planned a side trip at 5 a.m. to visit Rockefeller Center and be a part of the studio audience of the Today Show. Of course being good marketing students, we couldn't miss the opportunity to promote our five fruits and vegetables a day campaign, our child safety civic consciousness project, and of course the hepatitis C public relations campaign. Each student was manned with a poster, except only five posters out of the 80 were allowed into the Today Show fenced-in area. We were told that "the Today Show has a family audience and the sexually oriented hepatitis C thing would not be appropriate for the audience." Security literally threw away our posters because they thought hepatitis C is a sexually transmitted, dirty disease.

Chairman Davis, when we began this project a year ago, no one wanted to talk about hepatitis C. Even a congressional aide told one of our students that the number of recorded deaths from his State who are infected with hepatitis C was not enough to pass the bill. Just one death is too many. The American people have the right to know about this silent epidemic. Our government needs to be proactive so we are not caught off guard like we were with the HIV/AIDS virus in the 1980's.

In this audience today are representatives from the hemophiliac community who know all too well about viruses that are spread through our blood supply. Our DECA chapter spent 7 years working on the Ricky Ray bill with hemophiliacs like Ellis Sulser and Dana Kuhn, who are currently co-infected with hepatitis C and HIV. Will our generation have a chance to survive hepatitis C? The answer is yes, Chairman Davis, if we can stimulate research and education during the 109th session of Congress.

Chairman Davis, as I close my speech I would like to say I know you're here representing your constituents and we believe you care about Americans like my father, Gene Stein. If we don't provide some funding for research and education for hepatitis C, it will impact each and every one of our lives.

Thank you.

[The prepared statement of Ms. Stein follows:]

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Committee on Government Reform Hearing-***Stalking a Furtive Killer: A Review of the Federal Government's Efforts to Combat Hepatitis C.***

HEPATITIS C TESTIMONY

DECEMBER 14, 2004.

I was 5 years old when my father was diagnosed with hepatitis C. At the time I really didn't understand what this meant but I could tell that my mother seemed to be very concerned and I sensed that something was gravely wrong. By the time I was in 4th grade my father's physician started him on a course of interferon in hopes of riding him of the virus. My dad had to give himself painful injections of the drug several times a day and the drug caused him to become seriously ill. I can remember vividly my dad lying on the couch with a fever of 102 and shivering as if he had a bad case of the flu. During the time my dad was on interferon he became depressed and seemed like a completely different person to me. The smallest event could cause my dad to literally go ballistic almost like he had changed into the Incredible Hulk. Our family experienced a great deal of stress and turmoil throughout the interferon treatment and we were all thankful to reach its end. Although he went through nearly six months of sheer torture, the interferon had no effect on his hepatitis C virus. Needless to say, we were all heart broken at the failure of the treatment.

Several years later my dad became a patient of the Halt C study and was started on a course Pegylated interferon with Ribavirin at the National Institute of Health. Before beginning the treatment he was given a liver biopsy and they discovered that he

had cirrhosis of the liver. He finished the less painful course of the interferon treatment only to find out once again that it had no effect on the virus. My dad felt as if he had failed the treatment but in truth the treatment failed him.

In the fall of 2003 I was in my advanced marketing class and we were deciding what we should focus on as a public relations project for the school year. I introduced the idea of doing a project on hepatitis C because it was real life for me and our Robinson DECA chapter has always dealt with serious issues that impact the lives of people who are greatly loved. We discovered that a bill had been introduced in May of 2003 that would allot $90 million dollars for research and education on the hepatitis C virus. As you know Congressman Davis, our DECA chapter takes on tough issues. We've worked on the Ricky Ray Hemophilia Relief Fund Act, The Good Samaritan Law which protects users of automative difibulators, and most recently the Dirty Diamond Act. I learned that Senator Kay Bailey Hutchison had introduced bill S.1143, so I immediately contacted her office to see what we could do to help. I was then put into contact with Sharon Phillips, president of the Hepatitis C Advocacy Network based in Texas and she was instantly by our side.

She and Lorren Sandt of the Hepatitis C Caring Ambassadors Program flew to Virginia and came to educate our advanced marketing class. After Lorren and Sharon's powerful visit where we learned that 4 million Americans were infected with hepatitis C and 10,000 Americans die each year of the virus, our chapter unanimously decided that hepatitis C would be our public relations project.

Since October of 2003, nearly 500 marketing students from Robinson Secondary School have been working on Capitol Hill, visiting congressional offices, and persuading

health LA's to encourage their members to co-sign The Wilson/Towns Hepatitis C Epidemic Control and Prevention Act HR3539. We have letters, phone calls and e-mails of encouragement from hundreds of hepatitis C patients across the country.

I have a story to tell you concerning some of the frustrations that come along with explaining hepatitis C to the public. A year ago this month 80 Robinson marketing students went to New York City for our annual marketing field study. We planned a side trip at 5:00 A.M. to visit Rockefeller Center and be a part of the studio audience of the Today Show. Of course being good marketing students we couldn't miss the opportunity to promote our 5 Fruits and Vegetables a Day campaign, our Child Safety Civic Consciousness project, and of course the hepatitis C public relations campaign. Each student was manned with a poster, except, only five posters out of 80 were allowed into the Today Show fenced in area. We were told, "The Today Show has a family audience and the sexually oriented hepatitis C thing would not be appropriate for the audience." Security literally threw away our posters because they thought hepatitis C is a sexually transmitted, dirty disease.

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with hemophiliacs like Ellis Sulser and Dana Kuhn, who are currently co-infected with hepatitis C and HIV. Will our generation have a chance to survive hepatitis C? The answer is yes Chairman Davis, if we can stimulate research and education during the 109th session of Congress.

Chairman Davis, as I close my speech, I would like to say, I know you are here representing your constituents and we believe you care about Americans like my father, Gene Stein. If we don't provide funding for research and education for hepatitis C, it will impact each and every one of our lives. As they say we can pay now or we can pay dearly 10 years from now when it may be too late for millions of Americans and dads just like mine. Thank you for this opportunity and please expect to see a DECA member in your office looking for support after the bill has been reintroduced.

# # #

Bio for Erika Stein-

Erika Stein is a 4th year member of Robinson Secondary School DECA, in Fairfax, Virginia. DECA is an association of marketing students that consists of over 180,000 members internationally. Erika is currently a senior and has been active in varsity as well as competitive cheerleading; she has earned several academic awards, and will be majoring in advertising at the University of Tennessee at Knoxville. Erika as held several offices as a member of DECA. Currently she is the Virginia DECA Executive Vice President and is Project Director for her DECA chapter's hepatitis C Public Relations campaign.

Erika is a vocal advocate for hepatitis C as her father is a victim. As a junior she involved her 300 member DECA chapter last year in promoting the Wilson/Towns Hepatitis C Epidemic Control and Prevention Act. The students have been actively lobbying both houses of congress for the past two years and are very pleased that Congressman Tom Davis has agreed to the hearing today.

Chairman TOM DAVIS. Erika, thank you very much. I'm going to start with Ms. Norton.

Ms. NORTON. Thank you very much, Mr. Chairman. I think probably this question is best offered to Dr. Rudman. I'm trying to find evidence of some Federal involvement commensurate with this disease. Your clinic—is it a clinic—has an annual budget of $60,000 to $70,000 a year and you have one full-time employee, etc. How much of that is Federal funding?

Dr. RUDMAN. We have no Federal funding. We have no State funding. The only funding that we have on a governmental level is local from our Board of County Commissioners.

Ms. NORTON. How is that, no Federal funding and no State? Have you tried to get funding from either of these two entities?

Dr. RUDMAN. Yes. Actually, our little clinic got together with RJO and our STD clinic and our sexually transmitted disease clinic and our hospital and our mental health programs and our emergency room and our in-patient psychiatric ward and Johns Hopkins University's top scientists and we came up with a grant proposal for a $447,000 viral integration project. And it turns out that we were actually awarded a $447,000 grant, but then the funding for that project was cut.

Ms. NORTON. Grant from whom?

Dr. RUDMAN. CDC.

Ms. NORTON. When was that?

Dr. RUDMAN. Earlier this year.

Ms. NORTON. The entire grant?

Dr. RUDMAN. It was a $3.5 million grant and they advertised it for seven programs. We were one of the seven programs that was approved. Then what happened, the funding was cut in half and we were cut in the final cuts.

Ms. NORTON. Was this for treatment, for surveillance?

Dr. RUDMAN. For prevention of hepatitis A and B in at risk populations and hepatitis C. We were also screening for HIV, but we would have been probably the only program that offered treatment for hepatitis C. So that made us kind of special.

Ms. NORTON. Do any of you know of any programs in Maryland and Virginia? I know of none in the District of Columbia, private or public, which are geared toward this population who may get or who have hepatitis C?

Dr. RUDMAN. That's the point I've tried to make.

Ms. NORTON. Are you the only program in Maryland?

Dr. RUDMAN. I'm afraid so. And that is a very sad thing.

Ms. NORTON. Any program that you know of in Virginia? Mr. Chairman, I was just trying to find traces of public health involvement in what turns out to be a public health menace that you have uncovered with this hearing. We have heard today that 60 percent of the HIV—60 percent of those with hepatitis C are HIV drug users. We have heard testimony that many of them are in prison. And we have heard testimony that the outreach consists of things like going on-line and posters. I'm afraid that the problem here is not the disease but perhaps who gets the disease. This is exactly the problem with HIV/AIDS, precisely the problem with HIV/AIDS. Until a little boy, a little white boy and a wonderful poster child got HIV/AIDS, we didn't wake America up to what now everybody

embraces, that whoever has the disease deserves our help. And if you don't believe that, do you understand that you are not going to quarantine them from society, and we learned that the hard way as AIDS got into our blood supply. And now, of course, nobody identifies AIDS with gay people. It's all across the aboard. And that's exactly what's going to happen here. It's not going to be identified with people who have been in jail or people who are drug users. And I don't think we should have to wait for a poster child to deal with the disease.

We have zero funding in this tri-State area on the part of public health funding. I think what we are dealing with here, Mr. Chairman, is a second-class disease. And I say so because I was shocked until your staff told me why it could possibly be that you had to have HIV/AIDS in order to get treated for hepatitis C. It is counterintuitive, not true, she said, but it's probably because the funding stream is available only for HIV, and nobody has put a red cent into separately funding hepatitis C. We have to do something about it. I'm pleased that we can get some money from someplace.

So, Mr. Chairman, I can't thank you enough for your leadership. You have awakened my consciousness by having this hearing. I hope what you have uncovered in this hearing, we will resolve to do for hepatitis C what the country has done for HIV/AIDS.

Chairman TOM DAVIS. I thank you very much. I think the people before us today have done more than we have. They have brought it—I think keyed it up for us in terms of how we can follow through, what legislation we can pass and what we can do in terms of awareness. Mr. Towns has been a leader and has been the head of the pack, and you are recognized for questions.

Mr. TOWNS. Thank you very much, Mr. Chairman. Thank you for your kind words.

Dr. Rudman, the panel before you said that every State had a coordinator except I think South Dakota and Kentucky. They didn't say Maryland didn't have one.

Dr. RUDMAN. Well, that may be because he didn't know Maryland—Maryland did have one, but she was fired, I think for doing a good job. You see, not every State wants a hepatitis C coordinator, because that's going to make people want to spend State dollars to take care of disease in local communities and people who run budgets say, we will have to take money away from other projects or we will have to raise taxes. So we don't want people to know about this disease. And that's what we're running into. It's almost as if it's a secret they don't want to get out.

And so our Department of Health does not have one person working, one person in the entire State Health Department working on hepatitis C. And there is some discouragement, I think, in talking about it, because they'll say well, we can't do anything about this anyway, we don't have any money. So it's a nice thing to have good projects. And the State plans—I have looked at State plans all over the country, which is what I do for the State of Maryland. Having a plan doesn't mean anything unless you have the funds to implement them. And that's the problem. We have a plan in Maryland and we have 39 action points on it, and we have implemented 6 of them, and those 6 we would have had to implement for other reasons anyway. So we have actually implemented

zero hepatitis C action plans. And I think other States are having the same problem.

You know, we need clear guidelines that are ethical and legally defensible and scientifically sound, but we also need funds to implement them, and the States are strapped.

Mr. TOWNS. Thank you very much, Dr. Rudman. Let me say, I really appreciate the testimony of all of you. I really do, but I just want to single Erika out, because you know, we feel about—and people talk about young people not doing anything positive. But Erika, I want you to know you touched me, the fact that you are involved in this issue and the fashion that you are involved in it. I wish the media was fair. Tonight you would be the leading thing on every news station throughout the United States of America because of what you are doing in such a positive way. I salute you and I thank you for your support of our legislation. I appreciate that as well. So continue to do so. And eventually, I think that if enough people hear us that somebody is going to get the message. I think that my son said to me and I think it's appropriate to comment on here, he said, sometimes it takes some people 2½ hours to watch 60 Minutes. That means they can't watch it. It takes them a lot longer. It takes our country a lot longer to understand where we need to go and what we need to be about.

I thank you all for coming here today and say to you, do you have any suggestions or recommendations for us, the Members of Congress, that we might be able to pursue? I would just like to spend my last few seconds hearing from you on that issue.

Ms. STEIN. I would really say that encouraging other Members of Congress to co-sign on the bill, and even on the Senate side, to get them to sign onto the bill. As you can see, it's vital that we have the funding to do the things that we need to do. And I think the biggest problem here is the American public isn't aware of this. Something needs to be done about this. I don't know what you have to do, but I don't think it's going to be effective by doing posters and brochures. Something more needs to be done. And I don't think it should be necessary that we need a poster child for it to go along with the disease. It shouldn't be that way. When you see that an average American is being diagnosed with this—my father has no idea how he contracted it. He never used drugs, and the only reason he found out he had it is because he was getting a new life insurance policy. People need to be aware of it. It's not fair to the American public that they don't know what's going on. People need to know what it is and how you can get it.

Mr. NIEMIEC. I didn't hear anyone testify that about 40 percent of the HIV infected individuals are co-infected with hepatitis C, about 40 percent. Within our arena of emergency care, in that very chaotic, unsterile, uncontrolled environment where a fire fighter, EMT, EMS person sustains a dirty needle stick, the current stats out there are that individual has anywhere from a zero to 7 percent risk of now contracting hepatitis C, and bear in mind that currently there is no post-exposure prophylaxis for HCV. If I have a dirty needle stick, there are medications out there called the HIV cocktail. And as long as I get the cocktail on board within a certain amount of time, it is not 100 percent efficacious but it's going to reduce my chances of contracting HIV. I have seen nothing as it

relates to a fire fighter, or EMS personnel sustaining a dirty needle stick. There are no recommendations from CDC. If I have a dirty needle stick and if I reside in the State that is fortunate to have implied consent; in other words, I have access to that source patient's blood, I may not know whether or not that patient is infected with hepatitis C. And if I do find out that the individual is serial positive for hep C, there is nothing to do about it but sit and wait. So a lot needs to be done.

Dr. RUDMAN. I think this goes to the educational problems. Most doctors don't know this, but if you have acute hepatitis C, that is new onset hepatitis C, you could treat it with 6 months of interferon alone and current studies indicate that up to 97 percent of the cases will be cured. This comes from Stephen Mann's work out in Germany where 43 out of 44 patients were cured, and we are presently doing that with our acute cases. With the needle stick injury, that may be one of the only situations where you are going to identify an acute hepatitis C case. So if you watch carefully and signs of hepatitis occur and they don't resolve by themselves, then there should be a post-exposure treatment program in place.

Ms. JESSE. If I could just urge you to get behind us passionate advocates, try to get the public aware of this disease to make them aware that it is everybody's disease that can affect you and your friends and people like me and try to break the stigma. And another thing that I constantly work with in my organization is to try to make people aware that there are possibly 5 million people infected in the United States and more than half of them are aware of this. And so help us get risk factors distributed so people can start self-identifying, because if you are infected, you need to press on with this. So do what you can to help us with education and help us get the funding to move on with this very important work.

Chairman TOM DAVIS. Let me ask just a couple of questions. If you don't stop it, though, and it keeps spreading, it becomes much more difficult further down the road. Erika, when you discuss hepatitis C with the average person, what's the reaction you get?

Ms. STEIN. A lot of them don't know what it is. When we introduced it to our class, kids had said they had their vaccine for it. There is no vaccine for it. And it is very common you come across people who have no idea what it is or they can't decipher between hepatitis A, B and C and they have no idea how serious it is and how easily it can be contracted.

Chairman TOM DAVIS. And you would be the last person to stand up here and make this the Erika Stein Show. You have a team behind, you. Your classmates at Robinson have been so active in this. And they have been all over Capitol Hill and everything else, and it makes a difference. Legislation moves very slowly sometimes. I have been working on some bills since I got here 10 years ago, but we don't give up. I think this next session we have a shot of doing some. But time runs out on this one, because we hear more people getting infected.

Dr. Rudman, do you feel people who come to you that if you can get ahold of them and have the resources, that you can get a pretty high cure rate out of it?

Dr. RUDMAN. That is interesting and perhaps sad because the people I see are really sick. And when you look at some of the clean

studies that are done, 16 or 13 percent of the people have severe liver disease when they are entered into random trials. I'm running 48 percent. So our people are a lot sicker, and yet our cure rates, even with all of that fibrosis, are as high as what they get in those clean studies. So if you have a team that motivates patients and cares about them, even these tough patients, you can get them cured. And we are able, thanks to Sharon, to get free drugs for these people. But you have to have all the other support available to give them the drugs. And that's what we were able to do in our community.

Chairman TOM DAVIS. We ought to let more people know about this and replicate it.

Dr. RUDMAN. We designed it to be a model. That is one of the reasons we are here, to get the word out that this can be treated at the local level and communities. And we certainly do need more Federal support and funding.

Chairman TOM DAVIS. NIH has stayed here and I know they are interested in responding. They want to help. Our job is to make sure they have some resources along the way.

Captain Niemiec, you mentioned that 10 people in Fairfax County Fire and Rescue have hepatitis C and other departments across the country have similar numbers. Is this on the rise?

Mr. NIEMIEC. It is unfortunate, chairman, that law enforcement and fire service arenas are not doing any testing, aren't doing anything. A lot of that is because of education, awareness, funding, but moreover, if that fire fighter, if that police officer is now hepatitis C infected, who takes care of him or her? Whose problem? This is one of the things I have heard echoed over and over and over again. We don't want to screen, we don't want to test, because if that fire fighter or that police officer comes up hep C positive, whose problem does he or she become?

Chairman TOM DAVIS. Do you think that is because this is job related for the most part?

Mr. NIEMIEC. That's correct.

Chairman TOM DAVIS. You may want to run down to the legislature, like you do with heart and lung, to make sure it is taken care of.

Mr. NIEMIEC. We are very unique. Latter part of 1999 through 2000, we did a comprehensive screening process with 1,200-plus of our fire fighters. And of those fire fighters, we had 10 who came up hepatitis C positive. Every year we are doing our work required under OSHA, blood-borne pathogen training. It is disquieting and most chilling that a lot of departments out there, a lot of the first responders, are not receiving this training, nor are they getting any type of screening. And we know that they are at risk every single day he or she puts on that uniform and goes out to the streets.

Chairman TOM DAVIS. You give me a lot of ideas just hearing about the seriousness of this. And as we start monitoring this nationally, this has been fairly recently monitored, and we can check the rise, but hopefully we can take some actions that can curb that.

I thank all of you for being here. You add a lot. This has been televised today on C–SPAN. But more importantly, our committee will followup with the appropriate reports. We have to work with other committees of jurisdiction on funding and the like. I know

Mr. Towns isn't discouraged. He is going to keep trying and we will be looking for new ways and hopefully we made a small difference here today. Thank you for taking time to be here, and for all of the Robinson kids. This is one of series of different causes that they have adopted through time, and they weren't here for Ricky Ray and several of the other issues that took several years, but I appreciate their can-do spirit and it's contagious. So we appreciate it, and thank you for your continued advocacy. Hearing is adjourned.

[Whereupon, at 4:20 p.m., the committee was adjourned.]

[The prepared statements of Hon. Mark E. Souder, Hon. Elijah E. Cummings, Hon. Ileana Ros-Lehtinen, Hon. Heather Wilson, and Hon. Sheila Jackson Lee, and additional information submitted for the hearing record follow:]

Statement of Congressman Mark E. Souder
Committee on Government Reform Hearing
"Stalking A Furtive Killer:
A Review of the Federal Government's Efforts to Combat Hepatitis C"

Tuesday, December 14, 2004

Mr. Chairman, thank you for holding this important hearing.

As Chairman of this Committee's Subcommittee on Criminal Justice, Drug Policy and Human Resources, I am very interested in federal efforts to prevent and treat infection with Hepatitis C virus (HCV) and to address the root causes of this disease.

Nearly 4 million people in the United States are, or have been, infected with HCV. HCV infection is associated with injection drug abuse, cocaine or marijuana use, and high-risk sexual behaviors (The New England Journal of Medicine, 1999; 341: 556-562).

According to the federal Centers for Disease Control and Prevention (CDC), "HCV infection is rapidly acquired following the initiation of injection drug use and occurs from the sharing of needles, syringes, or other equipment associated with drug use. Of persons injecting drugs for at least 5 years, 60 percent to 80 percent are infected with HCV" (CDC website, "Hepatitis C Virus Infection in the United States," Posted 11/1/2004).

In 1998, CDC issued "Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease." Among the recommendations, CDC stated, "to reduce the risk for HCV infection among injecting-drug users, local communities can consider implementing syringe and needle

exchange programs" (Morbidity and Mortality Weekly Report, 10/16/1998).

Yet a study of a drug cohort in Seattle-King County, Washington published February 1, 1999 in the *American Journal of Epidemiology*—several months after the CDC recommendations were made-- concluded, "there was no indication of a protective effect of syringe exchange against HBV [hepatitis B virus] or HCV [hepatitis C virus] infection. Indeed, highest incidence of infection occurred among current users of the exchange, even after adjustment for confounding variables."

The researchers found that injection drug users (IDUs) "who had never used the syringe exchange had a lower incidence of HCV than those who did use the exchange (15 percent vs. 21- 26 percent)."

"It is conceivable that participation in the exchange may have truly increased the risk of HBV or HCV among certain users by bringing them into regular contact with compulsive drug users and those with a pattern of routine sharing of injection equipment," the authors concluded, while noting "drug treatment programs that lead to cessation or reduction in drug injection may lower the risk of both HCV and HBV in current drug injectors" (American Journal of Epidemiology, 2/1/1999; 203-213).

Similar outcomes have been observed in other areas with needle exchange programs (NEPs).

Vancouver, Canada has the largest and one of the oldest free-standing legal syringe distribution programs in North America. The city introduced an NEP in 1988. The following year, the city established a street nurse program that distributes needles to addicts. The city has distributed over one million needles annually over the past decade, reaching nearly 3 million in 2002. Other

local organizations also distribute needles. The Vancouver Area Network of Drug Users, for example, runs a program that dispenses 1,200 needles a day. In addition to these needle exchange and distribution programs, pharmacies have been permitted to sell syringes over the counter to addicts without a doctor's prescription since 1995. Syringes are exempt from drug paraphernalia laws in Canada. Unarguably, nowhere is North America are clean needles more accessible.

Despite this widespread, long term availability of clean needles, injection drug use is responsible for half of the new HIV infections recorded and 80 percent of newly identified hepatitis C cases in Vancouver.

When the Vancouver NEP was established in the late 1980s, the estimated HIV prevalence in Vancouver was 1 to 2 percent among the city's population of 6,000 to 10,000 IDUs. Today, it is estimated that 40 percent of the drug using population in Vancouver have HIV, giving Vancouver the distinction of having the highest infection rate of any city in the developed world.

HCV has, likewise, risen dramatically in the city. Since 1994, close to 2,000 cases have been reported annually to the Vancouver/Richmond Regional Health Board (VRHB) district. Roughly 70 percent of these are attributed to IDU. A 1997 study found that of Vancouver's IDUs, 88 percent were infected with HCV. Today, it is estimated that more than 90 percent are infected with HCV.

According to the 2003 "Vancouver's Drug Use Epidemiology" report, HCV and HIV rates among the City's IDUs have reach "saturation," meaning few if any of who are not already infected are left to become newly infected (Vancouver Drug Use Epidemiology, 7/2003).

Baltimore, Maryland administers the largest NEP operated by a local health department in the U.S. Since August 1994, the Baltimore City Needle Exchange Program has distributed over 6.6 million syringes to more than 14,000 addicts. Yet nearly one-third of the addicts enrolled in city programs are infected with HIV and 90 percent have hepatitis C. Researchers at John Hopkins University School of Public Health found that the drug users in Baltimore have twice the rate of both HIV and hepatitis B infection as IDUs in the other U.S. cities examined.

Needle exchange was first introduced in the United Kingdom in 1985 in response to the AIDS epidemic. Most areas within the U.K. have pharmacy-based needle-exchange services. Mobile, agency-based and automated needle exchange programs also exist. Five million needles are distributed annually in London alone. According to a study published November 13, 2004 in the online edition of the *British Medical Journal*, HIV and HCV rates are increasing among IDUs in the U.K. Nearly half (44 percent) of IDUs under the age of 30 are already infected with HCV and 4.2 percent are infected with HIV-- and these rates are increasing (British Medical Journal, 11/13/2004).

Because scientific data and anecdotal evidence indicate needle exchange has failed to prevent, and may even facilitate, the spread of HCV, prevention of the disease, therefore, must focus on preventing the behaviors that lead to infection. This means greater emphasis on prevention of drug abuse and substance abuse treatment.

But in many of the areas suffering from HCV epidemics, substance abuse treatment has been neglected while needle exchange and other unproven "harm reduction" approaches have been aggressively promoted.

In Vancouver, for example, needles and illegal drugs are widely available and accessible, but drug addiction treatment is not. According to the Vancouver Injection Drug User Survey, "in Vancouver, NEP was introduced early, but access to drug and alcohol treatment, methadone maintenance and counseling services remains inadequate. As early as 1990, the lack of appropriate services for addictions treatment in British Columbia, especially for cocaine users, was identified as a major barrier encountered by Vancouver's NEP attenders" and "this situation continues at present."

Needle distribution programs either do not refer addicts to treatment, have no room to treat addicts or addicts simply do not seek treatment. In fact, only 18 percent of NEP participants *ever* received methadone maintenance for their addiction with even fewer reporting current treatment.

While treatment referrals are not common or not even available, NEPs do serve as a link between drug addicts and dealers. Vancouver police shut down a sidewalk needle exchange when undercover surveillance revealed that it was linked to drug use. Inspector John McKay and his officers witnessed a female volunteer smoking crack at the table, volunteers warning others when uniformed police were in the area and another volunteer "steering" an undercover agent to a drug dealer. Vancouver police Inspector Ken Frail noted "this is addicts giving needles to addicts. I question, myself, how that's going to create a useful intervention. I don't see how we're going to break that cycle by giving needles without some kind of medical referral. I'm looking at all of this, where they have stoned people giving out needles."

The lack of treatment and prevention programs in the city has been widely noted. Between November 2000 and March 2001 the public was consulted on the city's draft Framework for Action. Several hundred feedback forms were submitted by the public, six

public forums were held throughout the city and over 30 meetings with community organizations, resident groups, community policing centers and community service agencies were convened. Some of the key themes coming out of the consultation were:

- Problems or frustrations currently in dealing with drug and alcohol addiction; lack of treatment resources, inadequate treatment, waiting lists, fragmentation, lack of coordination to address what people see as a serious problem.
- The urgent need for treatment and a variety of supports for individuals before, during and after treatment, the need for long term residential treatment, treatment on demand and expanded detox.
- The need for more prevention programs, public awareness campaigns and education at early stages of development.
- The need to protect youth, increased rehabilitation programs for youth, treatment beds for youth, long term treatment, housing and detox.
- Concerns were also expressed about harm reduction, especially safe injection sites.

Since 1994, the Baltimore City NEP has distributed over 6.6 million syringes to more than 14,000 addicts. While NEP proponents claim needle distribution provides addicts a bridge to treatment, only a small fraction of those in the program have actually received treatment. Approximately 2,300 people, or only about 16 percent, of those participating in the NEP, have been placed into treatment according Health Commissioner Dr. Peter L. Beilenson.

With 60,000 addicted to heroin in the City, there were only a total of 3,638 slots for methadone treatment—the most common heroin treatment—available citywide in 2000, according to the

Maryland Alcohol and Drug Abuse Administration. Meanwhile, 10,000 addicts-- nearly three times as many as enrolled in methadone treatment-- were participating in the needle exchange. The number of addicts in Baltimore receiving treatment for all drugs in 2002 was 22,274.

In 1999, the city appropriated $321,000 for the needle exchange program as compared to only $250,000 for the drug treatment program. David Vlahov, a professor of epidemiology at the Hopkins School of Public Health, who has tracked 3,000 Baltimore drug addicts for 11 years, said only 15 percent of the city's IV drug users are in treatment.

Don Caldarazzo, a Baltimore addict, was caught with drugs and sentenced to a heroin treatment program. But the halfway house he was sent to was overcrowded and offered little in the way of treatment, he said. He left without permission, and discovered that other programs have long waiting lists. "You have to keep calling them and bugging them," he said outside a needle exchange. "They tend to never call you back," he told *The Baltimore Sun*.

CDC, other federal agencies and localities must make substance abuse treatment and prevention the highest priority of HCV prevention efforts. There is a fundamental problem when those suffering from drug addiction have greater access to illicit substances and drug paraphernalia—often with government assistance—than treatment.

In addition to reprioritizing our approach to drug abuse and HCV prevention, greater efforts must be made to improve HCV detetection and treatment.

CDC recommends those in high risk groups be tested for HVC. Reliable tests now exist for this purpose, although

widespread testing does not currently take place in the general population.

While no vaccine exists, HCV can be treated successfully and even cured, especially when discovered during the initial, acute stage of the illness.

Therapy, which is a combination of alpha-interpheron and ribaviron, does, however, have significant shortcomings. The course of treatment lasts between 6 and 12 months, can have serious side effects, is expensive, and is not an option for those with most other mental or physical illnesses. The success rate of these medicines is listed at 50 percent. Unfortunately, some experts believe this figure is far too optimistic.

Treatment is also far less effective among some minority populations than it is among whites. According to a study published by *The New England Journal of Medicine*, researchers from Duke University Medical Center found 52 percent of whites showed no evidence of the hepatitis virus in their blood six months after treatment with the combination of peginterferon alfa-2b and ribavirin. The response rate was just 19 percent among the 100 African-American volunteers in the study. The reason the treatment is less effective in blacks is unknown and more research is necessary, said Andrew Muir, the study's chief author.

Federal efforts must also focus on addressing the complexities of HIV/HCV co-infection. About 25 percent of the estimated 900,000 persons living with HIV disease in the United States are also infected with HCV. HCV infection progresses more rapidly to liver damage in HIV-infected persons. Some studies have suggested that infection with certain HCV genotypes is also associated with more rapid progression to AIDS or death. End stage liver disease has become a leading cause of death among individuals with HIV/HCV co-infection. HCV infection may

compromise an individuals ability to tolerate and fully benefit from highly active antiretroviral therapy (HAART) used to treat HIV infection.

While HCV infection has been viewed as an opportunistic infection in HIV-infected persons and was included in the 1999 USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus, treatment for co-infection is still not available under the federal Ryan White CARE Act, the primary source of domestic AIDS specific care.

As HAART and prophylaxis of opportunistic infections increase the life span of persons living with HIV, HCV-related liver disease has become a major cause of hospital admissions and deaths among HIV-infected persons. Congress should consider allowing treatment and care for those with HIV/HCV co-infection to be provided by the Ryan White CARE Act. This would require greater fiscal prioritization of CARE Act services to ensure that life saving treatment is not shortchanged at the expense of less essential support services or excessive conferencing by bureaucrats.

CDC and the Health Resources and Services Administration (HRSA) d have a role in educating the public and health care providers about the unique medical conditions and needs of those with HCV, including those co-infected with HIV/AIDS.

I thank the Chairman for holding this important hearing and look forward to learning of federal efforts to combat HCV.

Statement of Congressman Elijah E. Cummings
House Government Reform
Full Committee Hearing
On
"Stalking a Furtive Killer: A Review of the Federal Government's Effort to Combat Hepatitis C"
December 14, 2004 at 2:00 p.m.

Thank you, Mr. Chairman for holding this hearing to address the federal government's effort to fight hepatitis C, which will serve as a review of what measure have been successful and what measures can be implemented to continue combating hepatitis C.

As you are aware, many constituents in our districts are battling hepatitis C (HCV). In 1998 the Subcommittee on Human Resources of the House Government Reform Committee held a hearing discussing the public health threat posed by hepatitis C, which was entitled "Hepatitis C—the Silent Epidemic." At that hearing several points of action were recommended by former Surgeon General, C. Everett Koop. Today, we are here to review whether the recommended points of action have been successful, as well as what more can be done to combat this silent killer.

Mr. Chairman, as you are aware, hepatitis C is currently the most common blood-borne viral infection. According to the Centers for Disease Control (CDC) an estimated 35,000 people become infected with HCV every year, with the highest incident rates among African American and Hispanic males between 20-39. As a result, approximately 3.9 million Americans (nearly 2 percent of the population) are currently infected with HCV. Nearly 2.7 million of these people are chronically infected and are receiving no treatment—often because they are unaware they are infected. HCV is often the contributing factor to chronic liver disease, with HCV-associated liver disease now the leading factor for liver transplantations in the United States. Yet, despite these overwhelming statistics, most Americans—including many who have become infected—still know little about this deadly disease.

In fact, prevention efforts targeting efforts to stop transmission of the disease have faced considerable obstacles. Mr. Chairman,

several factors have hindered preventive efforts such as there is no current vaccine. As I referenced previously, HCV infection is typically asymptomatic, meaning the virus can go undetected for decades. Though patients with HCV are usually treated successfully, especially when the disease is detected in its early stages, the current therapy has many shortcomings. Furthermore, significant portions of the HCV population, roughly 10 percent, have no recognized source of infection. CDC recommends that testing of those in high risk groups—including intravenous drug users, veterans, and those who received either blood transfusions or organ transplants prior to the implementation of effective screening methods in July 1992.

Mr. Chairman, though reliable tests do exist, further efforts are needed to prevent the spread of HCV and to create more successful treatment to fight hepatitis C. As you may be aware, many of the current treatments that are now available are very expensive. Some are ineffective for certain minorities, and treatment is not an option

for those suffering from mental or physical illnesses. In fact, "the success rate of these medicines is listed at 50 percent."

It is my hope that during this hearing, Mr. Chairman, we can assess what actions have been successful and what can be improved to ensure the success of prevention efforts of HCV. I look forward to hearing from today's witnesses, and I hope that we can address further measures to fight this silent killer.

Thank you Mr. Chairman for holding this hearing.

Congresswoman Ileana Ros-Lehtinen
Government Reform Committee
Hepatitis C Hearing Statement for the Record
December 14, 2004

Mr. Chairman, as a cosponsor of H.R. 3539, Hepatitis C Epidemic Control and Prevention Act, I am pleased that the Committee has decided to explore the important issues surrounding the federal government's efforts with regard to hepatitis C (HCV). With nearly 3.9 million American currently infected and an additional 25,000 patients diagnosed each year, hepatitis C remains one of the largest health crises facing the nation.

However, despite those staggering numbers, the fact remains that most people infected with HCV do not even realize they are infected, preventing these individuals from obtaining potentially life-saving medical treatments and, perhaps even worse, enabling them to unknowingly spread the disease to others.

With no vaccine currently available to prevent HCV, the only means we have of controlling and preventing the disease is through education, training and testing. Without these critical prevention measures, HCV infection rates will continue to rise and thousands of Americans will die each year from HCV complications, including cirrhosis, liver failure, and liver cancer.

Currently, there are treatments available that are effective in a large percentage of patients. However, many individuals who could benefit from these treatments are unable to because they may be unaware of their HCV status or because of provider and treatment reimbursement issues.

Enactment of H.R. 3539 would help control this growing epidemic. As you know, the Hepatitis C Epidemic Control and Prevention Act directs the Department of Health and Human Services to develop and implement a plan for the prevention, control, and management of HCV, which includes strategies for education and training, surveillance and early detection, and research.

I am sure that today's hearing will provide us with greater insight as to how Congress can best assist in the government's effort to control and combat this devastating disease.

Statement of Congresswoman Heather Wilson
First District, New Mexico

Mr. Chairman, thank you for holding this hearing today on Hepatitis C. I appreciate your willingness to allow me to submit a statement on this issue, an issue which is of utmost importance in my state of New Mexico.

At least 32,000 New Mexicans have been infected with the Hepatitis C Virus. Hepatitis C attacks and weakens the liver, and this damage is accelerated by a factor of nine with the abuse of alcohol. New Mexico has the highest rate of deaths due to chronic liver disease and cirrhosis in the United States, and the rate is 25% higher than the next highest state. Hepatitis C does not discriminate. This disease has affected people from all walks of life, including transfusion recipients, hemophiliacs, first responders, and veterans. And while the State of New Mexico has implemented an aggressive and effective needle exchange program, injection drug use remains the number one cause of Hepatitis C transmission in New Mexico.

Tricia Monaghan lives in Albuquerque and is an attorney currently practicing law part time. She has two daughters. After a head-on automobile collision in 1989, Tricia acquired Hepatitis C from a blood transfusion. It was not until 2002—13 years later—that Tricia's symptoms developed and she found out she had been carrying Hepatitis C during that time. Because of her symptoms and the side effects of treatment, Tricia has only been able to work part-time and usually feels too sick or tired to socialize or perform the activities of daily living for her family such as cooking and cleaning. While her liver enzyme levels are returning to normal through extensive treatment and her prospects for a

full recovery appear bright, earlier detection of Hepatitis C could have ameliorated Tricia's symptoms and prevented the potential inadvertent transmission to others.

Hepatitis C is a national epidemic that should be addressed with a comprehensive strategy. New Mexico is ahead of other states. We have a Hepatitis C Coordinator, Karen Gonzales, a Hepatitis C Alliance—composed of key stakeholders from around the state—and a Hepatitis C clinic at the University of New Mexico Health Sciences Center. The Alliance, in conjunction with the State Department of Health, developed a comprehensive strategic plan this year to reduce Hepatitis C in New Mexico. The state needs additional resources to carry out its Hepatitis C strategic plan. Many states still have not developed a strategic plan and most Hepatitis C Coordinators lack the resources necessary to carry out their duties.

Last December I joined my colleague Ed Towns of New York in introducing the Hepatitis C Epidemic Control and Prevention Act. Senators Hutchison and Kennedy have introduced an identical version in the Senate. This legislation would direct the Department of Health and Human Services to develop and implement a comprehensive plan for the prevention, control, and treatment of Hepatitis C. It would help provide states with the resources necessary to hire a Hepatitis C Coordinator and carry out state plans to reduce Hepatitis C infection. The legislation contains provisions to 1) educate the general public about the disease, 2) encourage early detection, 3) support state, local, and tribal testing programs, 4) provide counseling, including medical referral, 5) provide vaccinations for Hepatitis A and B to Hepatitis C positive individuals and those at risk for Hepatitis C, 6) support research and a clinical research network, and 7) establish a Liver

Disease Research Advisory Board at the National Institutes of Health. Furthermore, it authorizes $90 million in funding in the first year, and additional funding as necessary in the next four years, for these efforts.

This legislation, H.R. 3539 in the 108th Congress, garnered the support of 44 of my colleagues as cosponsors. I intend to reintroduce this legislation in the 109th Congress and look forward to working with my colleagues in building the support necessary to get this bill passed. It's an effort I believe is important for saving lives.

Thank you again, Mr. Chairman, for holding this hearing.

Statement of
Congresswoman Sheila Jackson Lee
December 14, 2004
Hearing on
A Review of the Government's Efforts to Combat Hepatitis C

Committee on Government Reform

Chairman Davis, Ranking Member Waxman,

Let me thank you for convening this important hearing on the Federal Government's activities to combat Hepatitis C. Our nation is facing an epidemic of Hepatitis C Virus (HCV) infection. HCV is the most common blood-borne infection in the United States. Although many of them do not know it, nearly four million Americans are currently infected and 35,000 new infections occur each year. This insidious virus takes thousands of lives annually – primarily through cirrhosis and liver cancer. HCV costs millions of dollars in healthcare and lost wages each year, but it receives inadequate attention from the public, the medical field, and the federal government.

There are three issues about Hepatitis C that I would like to mention. The first has to do with public awareness. Infection with the Hepatitis C virus generally carries no symptoms -- particularly for the first years or even decades following exposure. Because of this, many patients can be suffering from irreversible degeneration of their liver -- often leading ultimately to cirrhosis or liver cancer. Approximately three quarters of persons with an acute Hepatitis C infection will eventually develop chronic infection, and nearly two thirds of those will develop chronic Hepatitis. Better awareness and outreach programs will help to make patients and health care providers more cognizant about seeking early diagnosis, particularly for high risk groups. Along with my proposal to amend the Labor HHS appropriations bill to fund Hepatitis C research, today's hearing helps to raise the awareness of Hepatitis C.

Second, we need more research. Vaccinations are now available to protect patients against Hepatitis A and B. Additional research is needed to identify effective vaccines for Hepatitis C. New, more effective treatments with fewer side effects also need to be identified. Current treatments for Hepatitis C are generally only effective about 50% of the time, they are expensive, and have significant physical and psychological side effects that are so severe that early stage patients sometimes choose to forgo the treatment. In addition, Hepatitis C patients have a high incidence of co-infection with HIV and with hemophilia. Some of the new treatments for HIV, including highly active antiretroviral therapies (HAART) have proven to be effective. While data on patients co-infected with HIV and Hepatitis C do show good results with HAART, research is also needed to understand the longer term effects of these treatments on liver function.

Third, we need to make sure that underserved and high risk patient groups are provided with the appropriate levels of treatment. For example, researchers at the Thomas Jefferson University analyzed medical records and pharmacy claims for a Medicare Managed Care Organization (MCO) in Philadelphia to determine what therapies patients suffering from HCV received. Although a 'combination therapy' of ribavirin and interfereon is the treatment of choice for HCV, that study found that a disproportionately low number of African American patients (8.4%) received this combination therapy, followed by Latinos (14.3%), and Caucasians (22.7%). While that study did not identify the reason for this disparity, which could include contraindications for this group, inequitable prescribing habits of physicians, cultural barriers to consent to treatment, or non-compliance with obtaining medication, the study does indicate that more attention is needed in this area. A different study reported in the Lancet indicated that rates of HCV infection correlate inversely with socioeconomic status and seropositivity rates are significantly higher among African Americans and Hispanics in the US.

Hepatitis C is a communicable disease, and I believe it is important for the nation to get this disease under control. I hope that you will join me in continuing to address this important health care issue.

FROM :GET TESTED FOR HEP C FAX NO. :2538400202 Dec. 17 2004 01:24PM P1

National
Hepatitis
C
Institute
A non-profit organization
www.nationalhepatitiscinstitute.org

1513 18th St. NW
Puyallup, WA 98371
1-253-840-0202
1-866-902-HEPC
Candelarianhci@hotmail.com

Date: December 16, 2004

Fax number:

RE: "Stalking A Furtive Killer: A Review of the Federal Governments Efforts to Combat Hepatitis C"
Hearing was December 14, 2004 @ 2:00

Please find accompanying information we would like to have included in the record for the above referenced hearing.

Thank you so much,

Kitty Candelaria
Executive Director

National
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1513 18th St. NW
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Representative Henry Waxman
Government Reform Committee
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515

RE: "Stalking A Furtive Killer: A Review of the Federal Governments Efforts To Combat Hepatitis C"

I would like to applaud your efforts to address the Hepatitis C infection in our country. After watching the hearing on **cspan** it became apparent that the hard-core issues concerning the Hepatitis C epidemic would not be dealt with at this hearing.

We are a national advocacy organization and a member of the "The National Hepatitis C Institute and Movement for Awareness" which includes 50 plus Hepatitis C advocacy organizations scattered throughout the United States. We represent well over 10,000 infected individuals. *We are on the front lines.*

The National Hepatitis C Institute has worked hard in Washington State to address the needs of the infected population. My story is a lot like Ms Steins only my husband, David, died from the virus. Our daughters were 10 and 12 at the time of his death. His death was the catalyst for legislation in Washington State mandating the development of the "Washington State Hepatitis C Strategic Plan" in 2003. I am a stakeholder on a number of committees in the State dealing with the issues of Hepatitis C. We have been fortunate to have legislators that believe in the importance of this epidemic and who are working tirelessly to address the issues of the infected population making Washington State a national leader in Hepatitis C issues. Legislation will be presented this next session that would begin to address the modes of transmission without clear direction from the CDC. We no longer rely on the CDC for leadership in this area. We are now using medical studies throughout the world, news media reports and common sense.

Hepatitis C is the smallest molecular structure of a virus we have ever seen. It replicates quickly but because of its size requires trillions of replications before our current tests can detect it in the blood. Our tests do not zero out. What that means is that our tests can only pick up 50 plus particles of replicating virus in a blood sample. Anything below that remains undetectable. We know that Hepatitis C has been found in the lymph nodes of

infected persons after they have completed treatment and reached an SVR (Sustained Virological Response). To tell a patient they are "cured" of Hepatitis C is a gross injustice to the infected population. The word "cure" has been redefined for marketing purposes. It now means "undetectable viremia after 6 months post treatment". The message either stated or implied by the provider to the patient is that the virus has been "eliminated" from their blood so "you can go back to old behaviors", "you no longer need to monitor your condition because the virus is gone" and "you can no longer pass the virus to someone else". Without government intervention the pharmaceutical companies have been able to launch an aggressive and expensive educational campaign to providers with pharmaceutically funded statistics and financial incentives to sell treatment even when unwarranted. The infected population is being re-victimized with deadly consequences. Many of those believing they were "cured" have gone on only to be re-diagnosed with active infection and advanced disease. Sadly, providers and pharmaceutical companies know to well government action is slow and weak leaving them no deterrent.

A diagnosis of Hepatitis C is not a death sentence! Hepatitis C can be managed like any chronic illness i.e. diabetes, heart disease and even some cancers. With help from the University of Washington Medical Centers - Transplant Services, we have been able to educate patients on how to manage their disease and how to gather their health care team.

It begins with establishing the "team". This team consists of a good General Practitioner (GP) to monitor their total health condition. It then includes a Gastroenterologist to monitor the damage done to the liver by the virus and the monitoring of treatment if the patient opts for it. Because Hepatitis C is a *systemic virus* it causes damage to other organs and body functions, sadly not highlighted in your hearing. Therefore, a patient could add a Rheumatologist to deal with the arthritic pains associated with Hepatitis C infection or an Endocrinologist to deal with thyroid disease or diabetes so prevalent in the infected population and maybe a Dermatologist to deal with the skin lesions and rashes also common with Hepatitis C. The list goes on but must include a Dentist, Optometrist and Pharmacist. For those with advanced disease this team is imperative to prepare the patient to qualify for the transplant list.

At the same time, we offer support groups to help those in all stages of Hepatitis C with education and peer information. We stress the importance of changing behaviors that exacerbate the damage caused by the infection i.e. smoking, drug use, drinking, over the counter medicines should be cleared by their GP or pharmacist to insure the medicine is not liver damaging, lower stress levels elevated by the virus, the importance of a holistic life style. This message seems to get lost in the rush to promote treatment.

Sadly, with the lack of funding, an educational campaign targeting the general population, a good, responsible and *accountable* federal strategic plan, we are finding people after symptoms develop leaving them fewer options for their health care needs and far to often the only option is a transplant. Transplants are not a "cure" either. 100% of those transplanted will re-infect the new organ. Transplants are a bridge for time in hopes that a real cure will be found. The life expectancy of a Hepatitis C transplant

recipient is 10 years. Two thirds of those who apply to be placed on the list are denied because they didn't qualify during the review process.

Attached please find a copy of our Medicaid expenses for the care of Hepatitis C patients in Washington State over the last biennium. We are seeing these numbers double each biennium. At this rate the state will not be able to medically care for the small population receiving care now. To prevent even one person from transplant is a savings of $250,000 and an additional $30,000 paid in the 1st year following transplant for immune suppression drugs. In the State of Washington we did 106 transplants this year, so far, and 70% were Hepatitis C cases. Medicaid/Medicare picked up over half of those.

The Governments lack of response to the Hepatitis C epidemic has fueled the public's perception that Hepatitis C is an IV drug users illness when in fact the largest population infected and seeking care are those who received blood or blood products before 1992. The FDA's defiant response to the "look back" mandated by your committee in 1998, their ten year delay in any real response to the American Red Cross's safety violations and the *recently* released Federal Standards for Tissue Banks are sad reminders of the slow responses and deadly consequences of the government agencies empowered to protect the health and well being of the American public. We are losing confidence!

We do not completely understand the epidemiology or the natural history of the infection but we do know enough to begin to slow down the spread and educate the public.

The substance abuse population is at high risk for all diseases, so it would make sense that Hepatitis C would show up in that population. There are other populations yet to be discussed that have higher infection rates such as the foreign born population estimated to be 30 million and come from countries the WHO (World Health Organization) recognizes as having a higher infection rate then the United States.

With the popularity of tattooing/body piercing and the lack of education, we are seeing kids tattooing/body piercing each other on school property, tattooing and body piercing parties, and because of the lack of regulations or enforcement tattooing/body piercing facilities are tattooing minors. Tattooing/body piercing facilities are for the most part "self regulating". These are "artist" not virologist. These are cash businesses and there are seldom records to substantiate a claim of infection if in fact there is an agency to file a claim with. These facilities pose a potentially grave public health threat.

Where there is a lack of government leadership we must use common sense. The virus can live outside the body for 7 to 30 days and can be reconstituted from dry blood making this virus far more stealth then HIV/AIDS. If the equipment isn't sterilized with an autoclave (heat, pressure and time is the only way to kill the virus) it can be passed on. The CDC states "any percutaneous exposure" can pass on this virus. This would include something as simple as getting acrylic nails. If an un-sterilized instrument punctures the skin it can pass on the virus just like unclean needles do for IV drug abusers.

I would have to also ask where is the education to children in our schools. It is through the public schools that we can reach out to the foreign born through their children and to educate children on risk factors that would include tattooing and body piercing. The National Hepatitis C Institute has developed an educational program for Hepatitis C, which includes all of the Hepatitis's and has been taught in many schools in Washington State.

We must look at the Jet Injection system as a mode of transmission in the Veteran community. The VA has not done a public educational campaign to educate the veterans that do not seek services at the VA centers, on their risk for Hepatitis C.

If you would like for me elaborate on any of these issues or supply you with information on these issues I would be happy to assist you.

Again, I applaud your efforts to address this very important public health threat and look forward to being involved in the process in the 109th congressional session.

Kitty Candelaria
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December 15, 2004

Representative Tom Davis
Chair of Government Reform Committee
United States House of Representatives
2157 Rayburn House Office Building
Washington D.C. 70515

Dear Rep. Davis,

Greetings from Washington State. My name is Jim Kastama, State Senator from the 25th District. It has been brought to my attention that your committee is discussing Hepatitis C health concerns. I worked with my colleagues in the State Legislature to pass landmark legislation increasing awareness of the growing Hepatitis C epidemic.

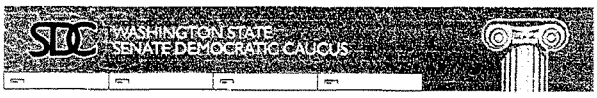
Kitty Candelaria spearheaded grassroots efforts to bring this issue to the forefront and helped moved the public awareness campaign forward. Disseminating information on HCV is at the heart of stemming human suffering. Ms. Candelaria has worked tirelessly to bring the issues of this critical health concern forward.

Please contact me if I can be of assistance in your perusal of this critical issue. I may be contacted at (253) 840-4701. Thank you for your work on behalf of the citizens of the United States.

Sincerely,

Jim Kastama

Committees: Government Operations, Ranking Member • Highways & Transportation
Joint Select Committee on Veteran's and Military Affairs • Economic Development Finance Authority



"This legislation puts Washington among less than a handful of states that have developed a state plan to prepare for Hepatitis C."

Sen. Jim Kastama

Hepatitis C: The worst virus you've never heard of

by Sen. Jim Kastama

When Kitty Candelaria's husband David was diagnosed with the Hepatitis C virus in November 1996, she didn't know about the shame and misinformation attached to it.

It began when a doctor – who assumed David had acquired the blood-borne virus by injecting intravenous drugs – tried repeatedly to make him admit just that. From that point on, David was so worried about being falsely labeled an I.V. drug user that he refused to tell anyone what was wrong with him.

The virus slowly ravaged his liver. Blood draws left puncture wounds that wouldn't heal, making David look like the I.V. drug user he feared people assumed he was. He finally quit work and told his shocked co-workers a month before dying on March 24, 2001, at the age of 46.

His last days were spent lying in the hospital, with Kitty by his side, waiting for a liver transplant that never came.

After David's death, Kitty still had many unanswered questions. Was she infected? Could their two daughters be infected? Why doesn't the public know about this killer virus?

Leaving the hospital that morning, Kitty Candelaria vowed to help break the silence. She soon started the National Hepatitis C Institute out of her Puyallup home. The institute's volunteers are working with established organizations to mount a

national awareness and prevention campaign.

Between 8,000 and 10,000 people die of Hepatitis C annually in the United States, according to the Centers for Disease Control and Prevention. That rate is predicted to double or triple during the next two decades.

In Washington, nearly 11,000 cases have been reported to the state Health Department. Because only about 10 percent of cases are actually reported, national prevalence data indicate that as many as 106,000 could be infected statewide.

Most people walk around with Hepatitis C for decades and never know it because it often causes no symptoms when first transmitted. Had the Candelarias known years ago that David – a Vietnam veteran – was at risk, Kitty says a test could have been done and perhaps saved his life. Veterans, health care workers, I.V. drug users and the prison population are at the highest risk because they come into contact with potentially infected blood or body fluids.

When Hepatitis C is finally diagnosed, often the damage is done. In the meantime, those who are infected continue to infect others unwittingly. The virus is estimated to spread 10 times faster than HIV/AIDS, so it's not a question of "if" we have an outbreak, but "when."

There is no vaccine and no cure. Treatment can cost at least $23,000 a year and is not universally effective. Our focus, then, should be on testing and education.

I worked to pass Senate Bill 5039 during the 2003 legislative session. The new law directs the state Department of Health to lead an effort to create a statewide plan for preventing and managing the disease by Jan. 1, 2004.

This legislation puts Washington among less than a handful of states that have developed a state plan to prepare for Hepatitis C.

California, Texas, and Hawaii also implemented plans during the past three years.

Under the legislation, the state plan should recommend ways to:

- educate the public and the medical community;
- prevent and manage Hepatitis C among the highest-risk groups;
- have the capacity to perform voluntary testing; and
- identify the sources and availability of funds.

Our state isn't required to devote money to developing its Hepatitis C plan. Only funds from the federal government and private sources can be used. Unfortunately, money is the reason our state's preparation efforts have stalled.

Most federal funding for blood-borne illness have been earmarked for preventing and treating HIV/AIDS. There is very little outside money available for Hepatitis C.

Hepatitis C is a different disease than AIDS. Although both viruses are blood borne and can be spread by behaviors such as I.V. drug use, Hepatitis C extends into the general population far more regularly then HIV/AIDS.

Since Hepatitis C transmission can occur in as little as 1/10th of a drop of blood, even the most seemingly incidental practices can potentially transmit the virus to anyone. If we allow it to worsen, an epidemic of Hepatitis C would be far worse than AIDS.

We are all at risk for Hepatitis C, so we should look forward to the state's awareness plan being completed on schedule. It's the only way to assure no more Kitty Candelarias are forced to watch helplessly while their husbands die in their arms.

State Sen. Jim Kastama, D-Puyallup, represents the cities of Puyallup, Milton, portions of Fife and Edgewood, and the communities of Midland and Summit/South Hill. For more information about the National Hepatitis C Institute, call (253) 840-0202 or visit the Web site at www.nationalhepatitisinstitute.org.

To Sen. Kastama's page

Treatment for Hepatitis C

Treatment Goals - First, to reach a *Sustained Virologic Response* (SVR). Second, if a SVR can not be reached, then treatment should; decrease hepatic inflammation and necrosis – improving histology and halt progression to cirrhosis, reduce risk for hepatocellular carcinoma, improve health –related quality of life and control extrahepatic manifestations.

Terminology patients should be aware of –
ETR – end of treatment response
EVR – early virologic response - ≥ 2 log drop or loss of RNA at 12 weeks of treatment
SVR – sustained virologic response – measured 6-months after completion of treatment
Relapser – recurrence of RNA after completion of treatment
Non-responder – HCV RNA never drops while on treatment
Partial Responder – HCV RNA drops by ≥ 2 logs but never disappears

Current Treatments Available:

- Interferon

Infergen	InterMune	Consensus-interferon
Roferon-A	Roche	Interferon-a2b
Intron-A	Schering	Interferon-a2b
Peg-Intron	Schering	Pegylated Interferon-a2b
Pegasys	Roche	Pegylated Interferon-a2b

- Ribavirin

Rebetol	Schering	Ribavirin
Copegus	Roche	Ribavirin

Treatment is Widely Accepted for:

- Those over the age of 18
- Those with abnormal ALT values
- Those with a liver biopsy that shows chronic hepatitis C and significant fibrosis
- Those with compensated liver disease:
  - Bilirubin <1.5
  - INR < 1.5
  - Albumin > 3.4
  - Platelet > 75,000
  - No Encephalopathy
  - No Ascites

- Acceptable hematologic indices:
  - Hemoglobin > 13 in men and 12 in women
  - Neutrophils > 1.5
  - Creatinine < 1.5
- Treated previously for HCV infection
- Well-controlled depression
- Willing to be treated & conform to treatment

Treatment can be individualized for:

- Acute hepatitis C
- Co-infected with HIV
- Under 18 years old
- Chronic renal disease (on or not on hemodialysis)
- Decompensated cirrhosis
- Liver transplant recipient
- Persistently normal ALT values
- Liver biopsy showing mild disease progression
- Current users of drugs or alcohol but willing to participate in abstinence programs
- Failed prior treatment:
  - Interferon alone
  - Peg-interferon alone
  - Interferon/Ribavirin

Treatment is not recommended for:

- Major uncontrolled depressive illness:
  - Including depression, bipolar, schizophrenia, PTSD (Post Traumatic Stress Disorder)
- Renal, heart, or lung transplant recipient
- Autoimmune hepatitis:
  - Or other conditions exacerbated by interferon
- Untreated hypothyroidism
- Pregnant or unwilling to comply with contraception
- Under 3 years of age
- Known hypersensitivity to the drugs
- Severe concurrent disease:
  - Hypertension
  - Coronary artery disease
  - COPD (Chronic Obstructive Pulmonary Disease [catch all phrase i.e. smoking, asthma, emphysema, etc.])
  - Heart failure
  - Poorly controlled DM (Diabetes Mellitus)

Side Effects of Treatment:

Flu-like symptoms:
Asthenia
Fatigue
Fever/rigors
Headache
Arthralgias
Musculoskeletal pain
Myalgias
Dehydration

Respiratory:
Cough
Dyspnea

Ophthalmologic:
Retinal disease

Neuropsychiatric:
Impaired concentration
Anosmia
Depression
Anxiety/ irritability
Emotional lability
Insomnia
Neuropathy (rare)
Seizures (rare)

Gastrointestinal:
Nausea +/- vomiting
Diarrhea
Abdominal Pain
Anorexia
Aphthous Ulcers
Dyspepsia

Dermatologic:
Rash
Alopecia
Pruritis
Dry Skin
Injection-Site Reaction

Weight Loss

Hematologic:
Leukopenia
Thrombocytopenia
Hemolytic Anemia

Autoimmune Thyroid Disease:
4-5% may be permanent

Teratogenicity

Depression – Caused by Interferon, which brings down a persons tryptophan and serotonin causing depression.

- Men are 4.5 times more likely to develop depression
- Pretreatment with antidepressants does benefit

- All newer antidepressants are safe – *avoid* **nefazadone** *(1/300,000 get acute liver failure)*

How Side Effects Are Dealt With While On Treatment:

Anemia:
- Ribavirin dose reduction/discontinuation
- Epoetin – 40,000 U sq weekly

Neutropenia:
- Interferon dose reduction/discontinuation
- G-CSF –
  - 300 mcg sq BIW
  - Titrate to maintain ANC>750

Alopecia:
- Avoid coloring/perms/braiding/ponytails
- Shampoo less frequently

Ophthalmologic:
- Stop treatment, Ophtho. consultation

Thyroid:
- Refer to endocrinologist

Fevers:
- Acetaminophen or NSAIDS (non-steroidal anti-inflammatory drugs)

Arthralgias/Myalgias:
- Low to no impact exercise
- Massage therapy
- Warm bath/shower
- NSAIDS or muscle relaxants (rarely)

Diarrhea:
- Fiber therapy
- Antidiarrheals

Anorexia:
- Small frequent meals and snacks
- Megestrol acetate (800 mg qD liquid; or 40 mg PO QID)

- Dronabinol (2.5-50 mg BID before lunch & dinner)
- Metoclopramide (10 mg qAC & qHS)
- Supplements and exercise

Aphthous Ulcers:
- Mouthwash
  - Lidocaine/diphenhydramine
  - Triamcinolone ointment

Dehydration:
- Optimal intake
  - Fluid ounces = ½ patient body weight in pounds
  - 150 lb = 75 ounces
- Avoid Caffeine

Dyspepsia:
- Antacids, H2RA, or PPIs

Nausea/Vomiting:
- Take ribavirin with food
- Antiemetics/ SSRIs may help/ benzos may help
- Dronabinol
- Small meals
- Acupressure bands

Headache:
- Medications used for migraine/cluster headaches
- Acetaminophen or NSAIDS (pre-and 4-hr post injection)
- Regular sleeping and eating times
- Relaxation techniques and exercise

Skin Effects:
- Frequent injection-site changes
- Antihistamines, topical antipruritics
- Cool baths
- Moisturzers and skin lotions

Insomnia:
- Take Interferon (IFN) in AM and 2nd Ribaviron (RBV) dose before dinner
- Good sleep hygiene and relaxation techniques
- Hypnotics
  - Zolpidem 5-10 mg qHS
- Antideressants
  - Trazodone 25-50 mg/d
  - SSRI's
- Avoid caffeine

- B vitamins, inositol (enhances REM sleep)

Anxiety/Irritability:
- Exercise, relaxation techniques
- Avoid caffeine and stimulation (i.e. crowds)
- Counseling/support programs
- Antidepressants/anxiolytics
    - Bupropion, venlafaxine, paroxetine, nortriptyline

Depression:
- Support programs
- Interferon dose reduction/discontinuation
- Designate "buddy" to support patient
- If depression is sever STOP IFN, psychiatric involvement
- Treat depression early and aggressively

Fatigue:
- Check other causes (TSH, electrolytes, etc)
- PM administration of IFN
- Exercise and fluids
- Antidepressants:

	Brand Names
▪ Bupropion 75-300 mg/d	(Wellbutrin)
▪ Methylphenidate 5-20 mg/d	(Ritilan)
▪ Modafinil 100-400 mg/d	(Provigil)

Antidepressants Currently Used For HCV Patients:

Antidepressant	**Comments**
Fluoxetine (Prozac)	Stimulating; give in AM; good for people who Obsess (mind doesn't "shut off")
Sertraline (Zoloft	Stimulating; give in AM; good for no energy an low affect
Paroxetine (Paxil)	Sedating; give in evening (in AM for anxious patients); stimulates appetite; good for rage
Citalopram (Celexa)	Fewer AE's and drug interactions than other SSRI's; effective in elderly
Venlafaxine (Effexor)	Good for rage; low doses for anxiety; high dose for energy
Bupropion (Wellbutrin)	Sedating; no sexual side effects

Nortriptyline (Pamelor)	Severe anxiety and irritability (10mg TID) depression 75-150 mg daily
Clonazepam	1-2 mg qHS for restless leg syndrome or Insomnia

WARNINGS & PRECAUTIONS RE: THERAPY

Interferon	Ribavirin
Severe psychiatric events	Hemolytic Anemia (10%)
Exacerbation of autoimmune disease	Cardiac events associated with anemia
Thyroid Abnormalities	Pregnancy category X – (not to be used by men
Granulocytopenia	whose partners are pregnant)
Thrombocytopenia	
CV events – hypertension, tachycardia, MI	
Flu-like symptoms	

Pregnancy category C – Women must not be pregnant or become pregnant

The Future of Treatments:

- **Modified Interferons and delivery systems**
  - Albuferon – albumin-interferon-*a*
  - Peg-IFN*a*-con-1
  - Omega IFN
  - ANA245- oral agent to stimulate production of IFN
- **New deliver systems**
  - Disposable infusion pumps
  - Oral delivery systems
  - Liposome-based systems
  - Controlled-release
- **Ribavirin Analogs**
  - Levovirin
    - L-enantiomer of ribavirin
    - Different metabolic pathway; no hemolytic anemia
  - Viramidine (ICN-3142)
    - Prodrug of D-ribavirin
    - Uses different transporter; decreased anemia
- **IMPDH Inhibitors – rate-limited enzyme in purine synthesis**
  - Merimepodib (VX-497) – not effective alone
- **Viral Life-Cycle Targets**
  - Antisense oligonucleotides (ISIS-14803 [HepaSense])
    - Bind RNA, prevent translation
  - Ribozymes

- Cleave pre-genomic RNA (Heptazyme; RPI.13919)

➢ Small Interfering RNA (siRNAs)
- Stop replication of HCV replicons

➢ Protease Inhibitors – candidate molecules developed
- BILN-2061
- SCH6
- VX-950

➢ Helicase Inhibitors
- NTP1 or NTP2
- JTK-003

➢ Polymerase Inhibitors
- BC2125
- BC2329

❖ **Antifibrotics**
- Interferon-γ1b – inhibit stellate cell actvation
- TNA-a – blocks immune-mediated cell injury
- TGF-B Antagonists – inhibit fibrogenesis

❖ **Immune Modulators**
- Zadaxin – Thyumosin *a*-1
- Ceplene – Histamine dihydrochloride
- IL-2/ IL-12 / GM-CSF – little role
- Vaccines – development many years away

This information is being supplied for informational purposes only. Please consult a physician for medical advice.

.bstract

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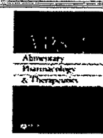

. comparison of hepatitis C treatment and outcomes t academic, private and Veterans' Affairs treatment entres

M. Jensen*, S. J. Cotler*, H. Lam†, G. Harb‡ & A. Shillington§

Summary

Background: Currently, there is a lack of published data examining hepatitis C treatment practices in different care settings.

Aim: To provide data describing treatment practices for patients with hepatitis C virus infection in actual clinical practice, and to examine clinical outcomes in patients treated with interferon alpha-2b/ribavirin combination therapy in academically affiliated centres, private treatment centres and Veterans' Affairs treatment centres.

Methods: This multi-centre, retrospective, cohort study of 231 patients examined hepatitis C virus treatment practices in patients receiving interferon alpha-2b from January 1997 to May 2001 and explored outcomes in academically affiliated, private and Veterans' Affairs centres.

Results: Differences in treatment practice and use of diagnostic procedures were found. Genotype testing was under-utilized in non-academic sites (academic centres, 79.2%; private centres, 33.7%; Veterans' Affairs centres, 35.9%; $P < 0.001$). Liver biopsies were performed less often in private sites (academic centres, 95.8%; private centres, 80.0%; Veterans' Affairs centres, 92.2%; $P < 0.01$). End-of-treatment viral response (academic centres, 40.0%; private centres, 31.3%; Veterans' Affairs centres, 17.2%; $P < 0.05$) was lower than that found in published trial data. Multivariate analysis revealed genotype 1 as the single significant predictor of treatment failure ($P < 0.01$).

Conclusions: Outside of the academic setting, there is significantly less diagnostic work-up performed prior to the initiation of hepatitis C virus therapy. This suggests a need for a standardization of care across treatment settings.

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As Doctors Write Prescriptions, Drug Companies Write Checks

By GARDINER HARRIS

The check for $10,000 arrived in the mail unsolicited. The doctor who received it from the drug maker Schering-Plough said it was made out to him personally in exchange for an attached "consulting" agreement that required nothing other than his commitment to prescribe the company's medicines. Two other physicians said in separate interviews that they, too, received checks unbidden from Schering-Plough, one of the world's biggest drug companies.

"I threw mine away," said the first doctor, who spoke on the condition of anonymity because of concern about being drawn into a federal inquiry into the matter.

Those checks and others, some of them said to be for six-figure sums, are under investigation by federal prosecutors in Boston as part of a broad government crackdown on the drug industry's marketing tactics. Just about every big global drug company — including Johnson & Johnson, Wyeth and Bristol-Myers Squibb — has disclosed in securities filings that it has received a federal subpoena, and most are juggling subpoenas stemming from several investigations.

The details of the Schering-Plough tactics, gleaned from interviews with 20 doctors, as well as industry executives and people close to the investigation, shed light on the shadowy system of financial lures that pharmaceutical companies have used to persuade physicians to favor their drugs.

Schering-Plough's tactics, these people said, included paying doctors large sums to prescribe its drug for hepatitis C and to take part in company-sponsored clinical trials that were little more than thinly disguised marketing efforts that required little effort on the doctors' part. Doctors who demonstrated disloyalty by testing other company's drugs, or even talking favorably about them, risked being barred from the Schering-Plough money stream.

Schering-Plough says that the activities under investigation occurred before its new chief executive, Fred Hassan, arrived in April 2003, and that it has overhauled its marketing to eliminate inducements.

At the heart of the various investigations into drug industry marketing is the question of whether drug companies are persuading doctors — often through payoffs — to prescribe drugs that patients do not need or should not use or for which there may be cheaper alternatives. Investigators are also seeking to determine whether the companies are manipulating prices to cheat the federal Medicaid and Medicare health programs. Most of the big drug companies, meanwhile, are also grappling with a welter of suits filed by state attorneys general, industry whistle-blowers and patient-rights groups over similar accusations.

In many ways, the investigations are a response to the evolution of the pharmaceutical business, which has grown in the last quarter-century from a small group of companies peddling a few antibiotics and antianxiety remedies to a $400 billion behemoth that is among the most profitable industries on earth.

Offering treatments for almost any affliction and facing competition in which each percentage point of market share can represent tens of millions of dollars, most drug makers now spend twice as much marketing medicines as they do researching them. Their sales teams have changed from a scattering of

semiretired pharmacists to armies of young women and men who shower physicians with attention, food and - until the drug industry recently agreed to end the practice - expensive gifts, just to get two to three minutes to pitch their wares. A code of conduct adopted in 1990 by the American Medical Association suggests that doctors should not accept any gift worth more than $100, but the guidelines are widely ignored.

A quarter-century ago, the Food and Drug Administration was the lone cop on the drug industry beat. But the F.D.A.'s enforcement powers over drug marketing have been severely curbed since 1976 by a series of court rulings based mainly on the companies' free-speech rights. That left a vacuum that many companies decided to exploit, said William Vodra, a former F.D.A. lawyer.

"A lot of people decided there was no check on what they were allowed to do," Mr. Vodra said. Using fraud, kickback and antitrust statutes, federal prosecutors, state attorneys general and plaintiffs lawyers stepped into the void , asserting that the companies' sales pitches have cost the government billions of dollars in payments for drug benefits.

This legal scrutiny can be expected to intensify. Once the new Medicare drug benefit takes full effect in 2006, the government will pay for almost half of all medicines sold in the nation. So the marketing programs will cost the government even more money and, if they are uncovered and determined to be illegal, will probably result in even larger fines.

Last month, Pfizer agreed to pay $430 million and pleaded guilty to criminal charges involving the marketing of the pain drug Nuerontin by the company's Warner-Lambert unit. AstraZeneca paid $355 million last year and TAP Pharmaceuticals paid $875 million in 2001; each pleaded guilty to criminal charges of fraud for inducing physicians to bill the government for some drugs that the company gave the doctors free.

Over the last two years, Schering-Plough, which had sales of $8.33 billion last year, has set aside a total of $500 million to cover its legal problems - mainly for expected fines from the Boston investigation and from a separate inquiry by federal prosecutors in Philadelphia who are investigating whether Schering-Plough overcharged Medicaid.

Besides looking into whether Schering-Plough paid doctors large sums to prescribe the company's drug for hepatitis C, prosecutors are investigating whether many company-sponsored clinical trials for the drug were simply another way to funnel money to doctors.

Dr. Chris Pappas, director of clinical research for St. Luke's Texas Liver Institute in Houston, said that Schering-Plough "flooded the market with pseudo-trials."

Dr. Pappas and eight other liver specialists who were interviewed say the system worked like this: Schering-Plough paid physicians $1,000 to $1,500 per patient for prescribing Intron A, the company's hepatitis C treatment. In conventional clinical trials, participants are given drugs free, but the doctors said that in these cases the patients or insurers paid for their medication. Because patients usually undergo Intron A treatment for nearly a year and the therapy costs thousands of dollars, Schering-Plough's payments to physicians left plenty of room for the company to profit handsomely, the doctors said.

In return for the fees, physicians were supposed to collect data on their patients' progress and pass it along to Schering-Plough, the doctors said. But many physicians were not diligent about their recordkeeping, and the company did little to insist on accurate data, according to Dr. Pappas and the

others.

One of the nation's most prominent liver disease specialists, who spoke on condition of anonymity for fear of angering big drug makers, called the trials "purely marketing gimmicks."

"Science and marketing should not be mixed like that," the doctor said.

Schering-Plough did more than encourage physicians to place patients on Intron A, many of the physicians said. They said the company would remove any doctor from its clinical program - and shut off the money spigot - if he or she wrote prescriptions for competing drugs, participated in clinical trials of alternatives to Intron A or even spoke favorably about treatments besides Intron A.

The main competitor to Intron A, which Schering-Plough now sells as Peg-Intron, is Roche's comparably priced drug Pegasys.

Dr. Donald Jensen, the hepatology director at Rush University Medical Center in Chicago, said he wanted to perform clinical trials using drugs from both Schering-Plough and Roche. "I was told by Schering-Plough that I couldn't do both - that I had to sign an exclusive agreement with them," Dr. Jensen said. "That was the juncture when Schering and I parted ways."

Six specialists in liver disease said Schering-Plough also paid what it called consulting fees to doctors to keep them loyal to the company's products. The letter accompanying a check for $10,000 explained that the money was for consulting services that were detailed on an accompanying "Schedule A," said a doctor who insisted on anonymity. But when the doctor turned to the attached sheet, he said, "Schedule A" were the only words printed on an otherwise blank sheet of paper.

Dr. Pappas, who in the past has consulted for Schering-Plough and worked for Roche, said that stories about the enormous sums that Schering-Plough paid its consultants were common among liver specialists. "These were very high-value consulting agreements with selected opinion leaders that looked like payments of money with no clear agreements on what was supposed to be executed," Dr. Pappas said.

In an interview, Mr. Hassan and other top executives declined to discuss past marketing practices. Richard Kogan, the company's previous chairman and chief executive, declined to be interviewed.

Schering-Plough's current management says that much has changed at the company since Mr. Hassan took over. The company no longer allows sales representatives or marketing executives to have any say over its clinical trials, physician education or medical consulting, they said. And in all clinical trials begun in the last year, they said, drugs have been provided free to the enrolled patients, rather than being billed to them or their insurers.

"The temptation to give clinical grants to high prescribers and consulting agreements to high prescribers is why we pulled those decisions out of the hands of the sales representatives," said Brent Saunders, who was named senior vice president for compliance and business practices last year. "Sales representatives had an input into that process before, which I think is still fairly normal in the industry."

In the separate Philadelphia investigation, Schering-Plough is expected to plead guilty soon to charges that it failed to provide Medicaid with its lowest drug prices, as is required by law, and to pay a fine. Investigators are examining whether Schering-Plough, to gain sales with some private insurers, offered premiums, such as free patient consulting arrangements, with its drugs. Prosecutors are arguing that such

incentives had a market value and meant that Schering-Plough was offering drugs to private payers at prices well below those offered to Medicaid. Many other drug companies are the targets of similar inquiries.

The Boston inquiry into suspected kickbacks and improper marketing by Schering-Plough could take months more to resolve, people close to the investigation say. Schering-Plough may also be charged with obstruction of justice and document destruction as part of the Boston inquiry, according to the company's filings with securities regulators.

Industry experts say the federal inquiries into Schering-Plough and the other drug giants have led some companies to adopt significant changes in the way they peddle drugs to doctors. Other companies have been slower to react. "These investigations came out of left field, and no one saw them coming," said Peter Barton Hutt, a former F.D.A. general counsel who now advises drug companies. "The industry has since had to reshape entirely what they are doing, but it was too late to redo what they'd been doing for years."

Tony Farino, leader of the pharmaceutical consulting service at PricewaterhouseCoopers, said that as a result of the investigations many companies in the drug industry were hiring executives to police marketing and sales practices.

"Reputational risk is something they're all trying to manage," Mr. Farino said, "because the damages from failure can be significant."

Military withdraws use of Jet injection system.txt

01 051704Z Dec 97 PP PP UUUU AA ZYUW
FROM
QUAD SERVICE MMQC FT DETRICK MD//USAMMA/AFMLO/NMLC//

TO
AIG 7485
AIG 7486
AIG 7487
AIG 7488
AIG 7783
AIG 9344
AIG 9345

UNCLAS

SUBJ: MMQC-97-1169
AUTOMATIC JET HYPODERMIC INJECTION UNITS/WITHDRAWAL (DPSC 970147)

THIS IS A FOUR-PART MSG
PART ONE IS FOR ALL ADDRESSEES

01. A PRODUCT WITHDRAWAL IS IN EFFECT. REASON: CONCERN OF POTENTIAL TRANSMISSION OF BLOOD BORNE DISEASES. DISPOSITION: IF WHLSE/DIST CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE, INSPECT STK F/MATL. IF FOUND SUSPEND AND DO NOT USE. FURTHER DISPOSITION WILL FOLLOW AS SOON AS IT BECOMES AVAILABLE.

NSN: 6515-00-656-1021 UI: EA
NOM: HYPODERMIC INJECTION APPARATUS: JET AUTOMATIC 115V 50/60 HZ AC
MFR: ALL
LOT/SERIAL NUMBER(S):
ALL

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-00-910-0097 UI: EA
NOM: HYPODERMIC INJECTION APPARATUS JET AUTOMATIC: FOOT OPERATED
MFR: ALL
LOT/SERIAL NUMBER(S):
ALL

03. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-01-070-2665 UI: EA
NOM: HYPODERMIC INJECTION APPARATUS JET AUTO VET FT OR MANUAL OPER:
MFR: ALL
LOT/SERIAL NUMBER(S):
ALL

04. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-01-126-4330 UI: EA
NOM: HYPODERMIC INJECTION APPARATUS: JET AUTOMATIC 115V 50/60 HZ AC
MFR: ALL
LOT/SERIAL NUMBER(S):
ALL

05. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-01-204-1868 UI: EA

NOM: HYPODERMIC INJECTION APPARATUS: JET AUTOMATIC 115V 50/60 HZ AC
MFR: ALL
LOT/SERIAL NUMBER(S):
ALL

06. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-01-362-9912 UI: EA
NOM: HYPODERMIC INJECTION APPARATUS: JET AUTOMATIC 115V 50/60 HZ AC
MFR: ALL
LOT/SERIAL NUMBER(S):
ALL

07. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-NS1 UI: EA
NOM: HYPODERMIC INJECTION APPARATUS: JET AUTOMATIC
MFR: ALL
LOT/SERIAL NUMBER(S):
ALL

08. AIR FORCE: SEE AFMAN 23-110, VOL 5, CHAP 19, PARA 19.7.3 FOR REQUIRED ACTIONS. FOR MAJCOMS & NGB--THIS MSG HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITES IAW AFMAN 23-110, VOL 5, CHAP 19.

09. PASS MSG TO MEDICAL LOG OFCRS, CMD CHANNELS, CLINICAL PERSONNEL, MED STAFF SECTIONS, SUPPLY OFCRS, AND SUPPORTED ACTYS/CTRS.

10. SVC SPECIFIC POCS ARE AS FOLS (FAX NOS. ARE AVAILABLE 24 HRS);
ARMY: JOYCE BROWN, 301-619-4300/2045, DSN: 343, FAX 2938,
E-MAIL: JOYCE_BROWN@FTDETRCK-CCMAIL.ARMY.MIL
AIR FORCE: BONNIE PHILLIPS, 301-619-4170, DSN: 343, FAX 2557,
E-MAIL: PHILLIB@FTDETRCK-CCMAIL.ARMY.MIL
NAVY: ETTA INGRAM, 301-619-3085, DSN: 343, FAX 3087,
E-MAIL: EINGRAM@NML10.MED.NAVY.MIL

PART TWO IS FOR ARMY ONLY.

U.S. ARMY HEALTH CLINIC, FOR MCPHERSON, GA
U.S. ARMY MEDICAL DEPT, FT LEONARD WOOD, MO
MONCRIEF ARMY HOSPITAL, FT JACKSON, SC
NOBEL ARMY HOSPITAL, FT MCCLELLAN, AL
ARMY MEDICAL DEPOT, TAIWAN
MEDICAL SUPPLY OFFICE, FT BENNING GA
DEFENSE DISTRIBUTION DEPT, SUSQUEHANNA, MECHANICSBURG, PA

PART THREE IS FOR AIR FORCE ONLY.

59TH MED WING, LACKLAND AFB, TX
MEDICAL CTR, KELLY AFB, TX
MEDICAL SUPPLY OFCR, EDWARDS AFB, CA

PART FOUR IS FOR NAVY ONLY.

NAVAL HOSPITAL, BEAUFORT, SC
NAVAL MED CTR, PORTSMOUTH, VA
NAVAL MED CTR, SAN DIEGO, CA

Military withdraws use of Jet injection system.txt

NAVAL STATION, JACKSONVILLE, FL
NAVAL HOSPITAL, PENSACOLA, FL
NAVAL HOSPITAL, CHERRY POINT, NC
NAVAL HOSPITAL, CAMP PENDLETON, CA
NAVAL HOSPITAL, GREAT LAKES, IL
NAVAL MEDICAL CLINIC, KINGS BAY, GA
NAVAL HOSPITAL, CORPUS CHRISTI, TX
NAVAL HOSPITAL, MILLINGTON, TN
NAVAL ENVIRONMENTAL & PREVENTIVE MEDICINE, NORFOLK, VA
NAVAL HOSPITAL, TWENTYNINE PALMS, CA
USNS "COMFORT", BALTIMORE, MD
USS FORT MCHENRY-LSD 43
U.S. COAST GUARD, CAPE MAY, NJ
USCG ACADEMY CLINIC, NEW LONDON, CT
U.S. MARINE CORP, PARRIS ISLAND, SC
U.S. MARINE CORP, QUANTICO, VA

Jury sides with hepatitis C victim

By Guillermo Contreras
San Antonio Express-News

Web Posted : 12/04/2003 12:00 AM

A Bexar County jury awarded a woman $[illegible] Wednesday after finding she likely contracted hepatitis C from a San Antonio-area business that performs permanent cosmetic applications.

While medical studies have linked the often-fatal virus to tattoo parlors and related permanent cosmetic businesses, the lawsuit is believed to be the first time nationally that the issue has gone to trial, allowing a jury to make the link, state and national health experts said.

"We have no confirmed records of hepatitis C being transmitted at a licensed studio, so we're certainly interested in this case," said John Gower, director of programs for drugs and cosmetics at the Texas Department of Health in Austin.

The jury found John Shumate, owner of Permanent Cosmetics by John Shumate at 6111 Broadway, and his daughter Julie negligent for infecting Deborah Anderson, who received a series of permanent coloring touch-ups to her lips at the studio, mostly in 1999.

Anderson, 52, learned she had hepatitis C in February 2000 when a blood bank rejected her donation, according to her lawyers.

During an earlier donation, she did not have the virus.

She complained to the state Department of Health, and an inspection of the business found several violations, including dirty floors in the tattooing area, employees not washing their hands between applications, and incorrect or insufficient labeling of sterilized equipment.

"The jury has sent out a message to the public about the seriousness of the health issues involved with tattooing," said LoAn Vo, one of Anderson's lawyers.

Neither Shumate nor his attorney, John Wennermark, returned calls seeking comment.

Roger Sanchez, an epidemiologist with the San Antonio Metropolitan Health District, said getting hepatitis C from a business is rare.

He added that "it's difficult to prove, but it's not impossible."

The case bolsters a study done 10 years ago by researchers at the University of Texas Southwestern Medical Center in Dallas that found most hepatitis C cases in Texas 30 percent were transmitted through commercial tattooing.

Dr. Robert Haley, an epidemiologist who formerly worked for the Centers for Disease Control and Prevention, said the state uses a different standard in determining infections. A person may not know for years after his initial infection that he is carrying hepatitis C, and he can't isolate the tattooing as the likely cause, he said.

"This was the perfect case because you have a lady with no other risk factors," said Haley, who testified for the plaintiff and was the author of the study. "She has a very low-risk lifestyle ... so she has no (other) reason to get hepatitis C."

At trial, Anderson's lawyers introduced evidence of violations at Shumate's studio. A state investigator noticed topical drugs to numb pain that required a prescription or licensed medical practitioner to apply them. Shumate does not have a medical license, according to the state report.

The inspector also observed three tattoo artists providing services for three hours, but none washed his or her hands between tattoo applications on separate clients, the investigator's report said.

The report also noted Shumate complained about the inspection process.

"Mr. Shumate stated that this is just another way that big government is trying to put him out of business," the report said. "He stated that there are some things that the government has no business regulating."

WASHINGTON STATE DEPARTMENT OF SOCIAL AND HEALTH SERVICES

UTILIZATION FOR CLIENTS DIAGNOSED WITH HEPATITIS C BY PROVIDER TYPE

CALENDAR YEAR 2002 AND 2003

PROVIDER		TOTAL FOR 2 YEARS				
TYPE	DESCRIPTION	CLAIMS	UNITS	BILLED $	ALLOWED $	REIMB $
	UNDUPLICATED CLIENTS	8,882				
15	INDIAN HEALTH CENTER	3,828	4,231	$707,518.82	$703,139.86	$702,560.86
18	EMERGENCY ROOM PHYSICIAN	33,537	33,668	$5,738,387.63	$1,461,943.82	$1,448,423.18
19	PSYCHIATRIST	12,428	13,437	$1,373,959.85	$504,657.30	$502,660.97
20	PHYSICIAN	332,861	418,710	$39,988,879.51	$12,047,013.56	$11,949,224.36
22	AMBULATORY SURGERY CENTER	1,557	1,652	$1,500,124.94	$442,004.20	$433,514.96
23	CASE MANAGER	1,971	1,970	$283,692.36	$272,953.03	$272,953.03
24	HEALTH DEPARTMENT	3,556	3,596	$66,265.66	$53,095.31	$52,528.39
25	RADIOLOGY	1,401	1,455	$491,020.72	$124,527.28	$123,527.88
26	PHARMACIST	777,051	1,651,453	$79,216,218.71	$59,524,719.60	$59,105,534.80
27	DENTIST	58,188	60,391	$5,165,023.61	$2,599,634.11	$2,597,786.45
28	OPTOMETRIST	11,350	11,416	$693,333.33	$439,419.41	$439,106.84
29	OPTICIAN	10,436	10,791	$146,677.78	$141,106.56	$141,288.30
30	CHIROPRACTOR	40	54	$4,366.25	$969.56	$969.56
31	PSYCHOLOGIST	74	114	$15,562.75	$3,502.27	$3,502.27
32	PODIATRIST	4,018	5,481	$473,124.35	$166,472.70	$162,097.79
34	PHYSICAL THERAPIST	15,996	22,348	$804,840.81	$321,337.10	$317,000.43
35	MATERNITY SUPPORT	1,484	1,683	$87,990.33	$82,143.80	$81,942.45
36	NEUROMUSCULAR CENTERS	23	45	$2,912.30	$1,339.59	$1,339.59
37	SPEECH PATHOLOGY	177	184	$12,503.29	$4,519.19	$4,391.80
38	PROSTHETIST/ORTHOTIST	1,222	2,072	$525,420.02	$349,583.06	$349,155.81
39	DME SUPPLIERS	11,394	1,027,595	$1,770,100.32	$1,189,632.56	$1,208,909.09
40	OTHER PROVIDERS	4,201	24,864	$483,936.66	$287,838.79	$281,973.32
41	BLOOD BANK	161	432,754	$991,138.87	$702,096.39	$698,517.80
43	LAB FACILITY	130,653	136,634	$5,810,800.70	$1,722,710.10	$1,711,164.35

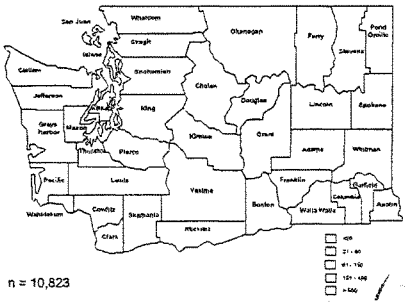
44	HOME HEALTH AGENCY	3,027	3,953	$536,956.62	$321,734.45		$321,213.51
46	HOSPITAL BASED NURSING HOME	27	302	$64,248.08	$64,248.08		$63,773.70
48	ANESTHESIOLOGIST	5,861	359,937	$2,958,269.84	$698,415.24		$692,371.91
49	NURSE ANESTHESIOLOGIST	375	30,162	$195,176.65	$44,870.47		$44,514.14
51	AMBULANCE	17,015	75,793	$4,489,278.29	$1,029,488.95		$1,017,227.65
53	AIR AMBULANCE	169	6,680	$593,165.43	$110,454.90		$110,454.90
55	ITA TRANSPORTATION	7	339	$1,013.60	$1,013.60		$1,013.60
58	SCHOOL MEDICAL SERVICES	103	508	$4,028.30	$4,028.30		$4,028.30
59	HOSPITAL TYPE II	380,376	2,331,288	$141,779,694.01	$25,093,337.63		$58,261,676.38
61	HOSPITAL FULL CARE	1,156	10,417	$766,750.57	$390,513.45		$386,441.29
62	HOSPITAL OUTPATIENT	1,915	17,491	$1,451,470.90	$1,120,773.64		$873,313.44
63	HOSPICE	568	5,168	$706,841.62	$647,552.43		$636,157.33
64	HOSPITAL PSYCHIATRIC	2,904	51,754	$4,119,950.37	$1,998,835.79		$2,075,148.86
65	HOSPITAL PSYCHIATRIC, FREE STANDING	558	10,216	$1,882,750.88	$715,866.44		$711,972.85
66	EPSDT CLINIC HEALTHY KIDS	2	2	$193.70	$105.42		$105.42
71	FAMILY PLANNING CLINIC	1,876	3,492	$63,249.98	$38,064.43		$37,963.06
73	VOLUNTARY COMMUNITY MENTAL HEALTH	1,931	2,776	$146,497.65	$23,547.50		$23,488.74
75	SUBSTANCE ABUSE	72,212	441,048	$4,538,103.68	$4,219,096.44		$4,218,485.20
78	OXYGEN CONTRACT	1,071	4,168	$245,855.88	$87,669.68		$88,213.74
79	OXYGEN NON-CONTRACT	3,628	9,592	$1,002,750.50	$588,490.36		$593,747.53
80	NURSING HOME	1,883	39,240	$5,434,834.22	$5,420,355.00		$5,209,944.79
82	INHALATION THERAPY	154	172	$17,716.24	$14,187.93		$14,279.73
84	HEARING AIDS	65	66	$32,136.73	$21,305.49		$20,845.62
87	DAY HEALTH CARE	3,363	3,835	$178,360.54	$176,452.06		$176,452.06
88	RURAL HEALTH CARE	10,381	10,391	$704,464.22	$680,916.27		$674,322.34
90	HMO/MANAGED CARE PLAN	7,746	7,746	$1,974,679.58	$1,973,058.11		$1,972,518.04
93	ADVANCED RN PRACTITIONER	4,862	4,988	$994,552.77	$160,447.90		$160,113.92
94	MIDWIFE	9	9	$1,310.00	$732.57		$732.57
95	MIDWIFE CLINIC	83	83	$97,880.93	$7,067.78		$7,067.78
TOTALS		1,940,334	7,298,124	$320,736,281.38	$128,798,989.35		$160,987,662.69

Dec 2000 - 9/03

Hepatitis C reported in Washington State
n = 10,823

• Probable cases	5,581	(52%)
• Confirmed	5,242	(48%)
• RIBA	1,125	
• RNA qual or quant	1,865	
• Pierce County	2,252	

HCV by County in Washington State



n = 10,823

NVHR Testimony for Rep. Tom Davis' Hearing on HCV*

The National Viral Hepatitis Roundtable (NVHR) is a diverse public-private partnership composed of over 110 organizations representing the needs of those at risk for viral hepatitis, that is hepatitis A, B and C, as well as those who have already contracted the disease. The goal of the NVHR is to eliminate viral hepatitis in the United States. To that end, the NVHR is currently developing a comprehensive plan to accomplish its mission, including the need for hepatitis screening and prevention, education, care and treatment, and research. It is our intention to improve the health care and quality of life needs of the entire nation. The NVHR National Hepatitis Elimination Plan will be completed and shared with the Congress in mid-2005. Implementation of the strategy will free America of the burdens imposed by the health and economic consequences of these diseases.

Data from the Centers for Disease Control and Prevention (CDC) indicates that 4-5 million Americans are infected with the hepatitis C virus (HCV), of which at least 2.7 million are chronically infected. Another 25,000 become newly infected annually. Chronic HCV is responsible for 40-60% of liver disease in the U.S. and accounts for the majority of liver transplants. Additionally, 8,000-10,000 Americans die each year from HCV-related liver disease.

The NVHR recognizes that the public health infrastructure in the United States is in a strategically optimal position to implement an effective Hepatitis Prevention and Control Program, not just on hepatitis C, but on hepatitis A and hepatitis B as well. The infrastructure established to address HIV/AIDS, sexually-transmitted disease (STD), tuberculosis (TB) prevention, drug treatment, correctional health, and childhood immunization is uniquely positioned to implement a nationwide program of counseling, testing, medical referral, vaccination, professional education and public information. Not long ago, CDC estimated that the cost of launching such an integrated program, including hepatitis A and hepatitis B vaccination for infected adults would cost approximately $50 million. Certainly the estimates have increased since those early projections. But, over the past two years, the federal funding from the CDC to state health departments for HCV programs has been reduced by nearly $2 million. In fact, last year CDC issued a request for proposals to fund Viral Hepatitis Integration Projects (VHIP) and after receiving many applications and identifying 10 finalists, could only fund two of the proposals. The only ingredient lacking now is funding.

The NVHR endorses federal initiatives to institute a National Hepatitis C Prevention and Control Program, and recommends that any such efforts also include programs for hepatitis B and hepatitis A prevention and control as well. In fact, the NVHR recommends that any action by Congress to address viral hepatitis, address all forms of viral hepatitis, and recommends that

Congress specifically initiate a plan for the elimination of the two vaccine-preventable forms of viral hepatitis (hepatitis A and B) within the next ten years while assuring that all treatments for HBV and HCV be available to those many patients who are currently undiagnosed and undertreated. While there is no vaccine available for HCV, we have very effective vaccines for HAV and HBV that give us potent ammunition in our overall goal to eliminate viral hepatitis in the United States. Prevention, control, and treatment goals are feasible and can be accomplished with the existing public health and clinical care infrastructure of the nation. The NVHR also recommends that any program include patient education about healthy lifestyles and appropriate lifestyle modifications to reduce the spread and consequence of these diseases.

In addition to the existing infrastructure, there is a need to strengthen links between community based programs, advocacy groups, and national, state, and local governments. In your district, Mr. Davis, there is an exciting community-based project developing which involves several NVHR members. It is a faith-based effort spearheaded by the Hepatitis B Initiative and assisted by the Korean Central Presbyterian Church in Vienna that involves a number of Korean churches throughout northern Virginia. One of the organizers of this multi-church project is Ms. Leslie Hsu, the co-founder of the Hepatitis B Initiative and a member of the NVHR Board of Directors. As you know, Asian Americans are at particular risk of hepatitis B and this effort will be designed to immunize, detect, and, as needed, refer for treatment as a means of addressing this disease. In addition to Ms. Hsu, other NVHR board members involved are Ms. Molli Conti of the Hepatitis B Foundation and Ms. Thelma King Thiel of Hepatitis Foundation International. It is a true partnership effort that can make a difference in the lives of many and the type of community initiative we need to encourage and support.

In conclusion, the NVHR endorses federal efforts to implement a National Hepatitis C Prevention and Control Program. We look forward to working with you to eliminate this, and other forms of viral hepatitis in the United States.

Richard T. Conlon
Administrator
National Viral Hepatitis Roundtable

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* This testimony has been reviewed by the NVHR Board of Directors and approved by the Executive Committee. Consistent with NVHR policy, federal agency representatives to the NVHR abstained from all discussion and votes on this testimony.

人民网 English UPDATED: 17:34, June 26, 2004
People's Daily Online

41 million Chinese believed to have hepatitis C virus: report

An estimated 41 million people in China have contracted the hepatitis C virus, which could become a fatal "quiet epidemic," according to Professor Xu Daozheng, a liver disease expert with Ditan Hospital in Beijing.

The Chinese Ministry of Health said in a report, issued in February, the number of hepatitis C patient was growing. A national epidemiological survey covering the 1992-1995 period found 3.2 percent of the country's population, or 38 million people, had hepatitis C virus.

Prof. Xu said his estimate is quite conservative, and suggested the disease should be included in normal medical checks, like hepatitis B, because it has become a serious public health issue in China.

At present, a patient with hepatitis C may look normal and feel just as good as a healthy person, and the disease will not be detected until it is too late, the professor warned.

Unlike other types of hepatitis B, 75 percent of people with hepatitis C show no signs of symptoms in the early stage, said Xu.

About 15 percent of the people with hepatitis C will develop cirrhosis and 5 percent would develop cancer if the disease is detected in a later stage, the expert explained.

There is still no vaccine against hepatitis C in China, and the China Medical Association has called for screening the disease in normal blood tests, especially among high-risk groups.

China has about 20 million people with chronic viral liver diseases out of its 1.3 billion population, and half of the 280,000 patients of liver disease died of liver cancer.

Source:Xinhua

1: Am J Infect Control 1998 Aug;26(4):442-445 Related Articles, Books, Li

Potential for cross-contamination from use of a needleless inject

Weintraub AM, Ponce de Leon MP.

Office of Clinic Management and Patient Services, University of Pennsylvan School of Dental Medicine, Philadelphia 19104-6003, USA.

BACKGROUND: Medical devices that are used on patients in fields contain potentially infectious body fluids can become contaminated and transmit infe agents to other sites on the patient or to other patients if the devices are not properly cleaned and decontaminated after use on each patient treatment site. such device is the needleless or jet injector, which is widely used in medicine dentistry to deliver local anesthetic in procedures such as bone marrow aspira lumbar punctures, and cutaneous and intraoral injections. This study was conducted to determine whether cross-contamination can occur on in vitro re a needleless injector and whether a manufacturer's recommended method of injector decontamination (ie, immersion sterilization) is effective in the preve of cross-contamination. METHODS: The study was performed with new autoclaved injectors, fluorescein dye, and Streptococcus crista (the bacteria commonly found in saliva) in the field of use to determine whether these dev can become contaminated during use and carry over the contamination to oth sites during immediate reuse. RESULTS: Fluorescein dye and bacteria tests the needleless injectors showed that contamination or carryover does occur. I appeared to reduced to a minimum when a autoclaved, sterile rubber cap use the head of the device during injection was replaced between each use, altho replacement of the rubber cap alone did not prevent carryover. Immersion of head of the injector in a 2% glutaraldehyde solution for 30 minutes followed sterile water rinse and the replacement of the rubber cap with a sterile cap be uses was shown to curtail bacterial growth and prevent cross-contamination immediate reuse of the device. CONCLUSION: This study demonstrated tha needleless injectors become contaminated during in vitro use and direct cont with contaminated surfaces and that needless injectors carry over the contamination to subsequent sites of release. The replacement of the injector' rubber cap with a new one after initial discharge or the removal of an expose rubber cap and immersion of the head of the injector in 2% glutaraldehyde followed by a rinse of the head in sterile water, as recommended by one injec manufacturer, can minimize or eliminate the carryover.

Statement
of
The American Liver Foundation
Dr. James Boyer
Chairman of The Board

To
The House Government Reform Committee
The Honorable Thomas M. Davis III
Chairman

On
Efforts To Combat Hepatitis C

December 14, 2004

Mr. Chairman, my name is James Boyer, and I am Chairman of the Board of the American Liver Foundation (ALF). I serve as the Ensign Professor of Medicine, Departments of Internal Medicine and Digestive Diseases, and am the Director of the Liver Center at Yale University School of Medicine. I also had the honor two years ago to serve as the Chairman of the NIH Hepatitis C Consensus Conference.

Mr. Chairman, the American Liver Foundation (ALF) is a national voluntary health organization dedicated to the prevention, treatment and cure for hepatitis and other liver diseases through research and education. ALF has a nationwide network of chapters that provides information to hundreds of thousands of patients and families through its Web site and Helpline every year. Ninety percent (90%) of the inquiries we receive are about hepatitis with more than seventy five percent (75%) of those calls requesting information about hepatitis C. This distribution of calls reflects the significant health threat posed by hepatitis and, therefore, the public's interest in an aggressive research response to the problem of hepatitis and other liver diseases.

On behalf of the American Liver Foundation, I would like to express our appreciation to you for convening today's hearing on efforts to combat hepatitis C. Hepatitis C, as you know, is caused by the hepatitis C virus (HCV) and is now the most common chronic blood-borne viral infection in the United States, affecting approximately four million people. Data from the Centers for Disease Control and Prevention (CDC) indicates that between 4 and 5 million Americans (approximately 2% of the population) are infected with HCV, of which at least 2.7 million are chronically infected. Another approximately 30,000 become newly infected annually. Chronic HCV is responsible for 40-60% of liver disease in the U.S and accounts for the majority of liver transplants. Additionally, 8,000-10,000 Americans die each year from HCV-related liver disease.

Efforts to fight hepatitis C have been hindered by several significant factors. There is not a vaccine for HCV, and while treatments are available, they are only successful in approximately 50% of the cases, and are significantly less effective among African American populations. Treatments are also very expensive and have significant side effects. Furthermore, HCV does not present itself in symptoms for many years, often not until serious liver damage has occurred

and other health related illnesses are found. This fact stresses the importance of testing and screening programs for at risk populations. Hepatitis is most efficiently transmitted by exposures that involve direct blood-to-blood contact. Risk groups include: those who received a blood transfusion prior to 1992, blood clotting agents prior to 1987, persons with a history of intravenous drug use, health care workers and others in employments settings with possible exposure to blood products or needle stick accidents, and children born to HCV infected mothers.

It has been the view of the ALF and the American Association of the Study of Liver Diseases (AASLD) that the most effective means of combating hepatitis C is to increase and sharpen the focus of liver disease research. In order to advance this interest, ALF has championed the Liver Disease Research Enhancement Act. We feel passage of this legislation is vital in order to establish the national research leadership and to create a dynamic and targeted research program.

The Liver Disease Research Enhancement Act would create a Center within NIDDK that will be focused solely on liver and liver-related diseases research. This bill will create a Liver Disease Research Advisory Board which will review and update the NIH Liver Disease Research Action Plan every two years. The plan will guide future NIH funding decisions and help the liver diseases research community prioritize research efforts. In addition the bill provides new authorities necessary to help insure that the scientific opportunities identified by the Liver Disease Research Action Plan are adequately funded.

There are two important blueprints for additional research that I would like to bring to the Committee's attention: first is the unfinished research agenda created by the NIH sponsored June, 2002 Hepatitis C Consensus Conference. The major research recommendations made by the Consensus Conference were as follows:

- Educate the American public on the transmission of HCV in order to better identify affected individuals and to institute preventive measures.

- Develop reliable, reproducible, and efficient culture systems for propagating HCV and expand basic research in the pathogenic mechanisms underlying hepatic fibrosis.

- Promote the standardization and wide availability of diagnostic tests for HCV infection and its complications, leading to early diagnosis and the implementation of appropriate treatment practices.

- Promote the establishment of screening tests for all groups at high risk of HCV infection, including IDUs and incarcerated individuals.

- Expand the delineation of disease manifestations, noninvasive tests, and the role of the liver biopsy, so that the application of current treatment practices may be refined.

- Establish a Hepatitis Clinical Research Network for the purpose of conducting research related to the natural history, prevention, and treatment of hepatitis C.

- Organize RCTs to extend treatment to special populations not represented in current clinical trials and to determine the applicability of accepted antiviral drug combinations to populations such as children and adolescents, and patients with acute hepatitis. Effective approaches are needed for drug users receiving drug treatment, alcohol abusers, prisoners, patients with stabilized depression, those with co-infection with HIV, patients with decompensated cirrhosis, and HCV infections in transplant recipients. Such efforts should lead to decreased morbidity and mortality from the disease, as well as a decrease in the reservoir of disease.

- Institute measures to reduce transmission of HCV among IDUs, including providing access to sterile syringes through needle exchange, physician prescription, and pharmacy sales; and expanding the Nation's capacity to provide treatment for substance abuse. Physicians and pharmacists should be educated to recognize that providing IDUs with access to sterile syringes and education in safe injection practices may be lifesaving.

- Evaluate strategies to interrupt mother-to-infant transmission of HCV.

- Compare new therapies to current treatments in nonresponders, to include not just antiviral agents but also combinations of antifibrotic drugs, immunomodulatory agents, and alternative therapies.

- Encourage a comprehensive approach to promote the collaboration among health professionals concerned with management of addiction, primary care physicians, and specialists involved in various aspects of HCVÐto deal with the complex societal, medical, and psychiatric issues of IDUs afflicted by the disease.

- Seek appropriate support from governmental agencies and the private sector to address urgent research questions concerning the epidemiology and treatment of this disease.

Much more needs to be done to fund additional research and to meet the goals outlined by the Consensus Conference.

The second major blueprint to guide the research agenda is the Liver Disease Research Action Plan nearing completion at NIH, which was started in response to the Congressional interest. The Action Plan consists of 16 chapters on specific topic areas of liver disease research, as well as introductory and summary chapters. One chapter is specifically focused on hepatitis C. Each chapter was written by staff of the Liver Disease Research Branch at NIDDK based on advice and input from a 5- to 8-person Working Group of research investigators, academicians, physicians, and concerned laypersons, as well as a representative from the Liver Disease Subcommittee. Each chapter includes an introductory and background section, a summary of recent advances, a central section describing important research goals in the future, and a final section describing steps to achieve the goals. Each chapter is followed by a 3-by-3 matrix containing 9 to 16 concisely worded research goals. The goals are categorized in the matrix as either low-, medium-, or high-risk and as short-, medium-, or long-term. The Action Plan also includes introductory chapters that provide an overview of the burden of liver disease in the United States and rationale for developing an Action Plan.

As we look forward to the convening of the new Congress, we urge that efforts be redoubled to pass the Liver Disease Research Enhancement Act, and to fully fund the research recommendations presented by the Consensus Conference on Hepatitis C and the Liver Disease Research Action Plan.

Thank you for giving the ALF this opportunity to testify.

The National Hepatitis C Institute & Movement for Awareness

The Hepatitis C Awareness and Prevention Campaign
Date: Nov. 29, 2004

Dear members of Congress:

On behalf of the undersigned advocate and organizations we are asking that our statement be included in the Government Reform Full committee hearing, "A Review of the federal Government's Efforts to Combat Hepatitis C".

Government, at all levels in the United States, is doing far too little to combat HEPATITIS C. In order to design an appropriate strategy for stopping the spread of Hepatitis C (HCV), Congress will need accurate and reliable information about this insidious virus and its impact on American society.

HEPATITIS C is a blood borne virus and based on the 2000 cences, infects over 5.8 million Americans. Each week 300 American citizens die from the virus and complications caused by this virus. That number is expected to double if not triple by 2010.

HEPATITIS C is the number one epidemic in the world. The virus is the leading cause of liver transplants in the United States and infects over 200 million people worldwide. To give perspective to the size of this epidemic, for every person with AIDS, there are 5 others with HEPATITIS C. About 300,000 AIDS patients are also co-infected with HEPATITIS C

The HEPATITIS C epidemic is discovering "what was", the consequences of a tragedy that occurred within the nation's blood supply. The blood was not cleaned despite hundreds of warning from Scientists to do so. In 1988, 242,000 HEPATITIS C infections were reported annually. These high figures were reported throughout the 1970-80s. Since 1989, when heating or washing of blood products became mandatory, the annual number of new infections declined more than 80 percent within ten years.

Based on National Institutes of Health (NIH) statistics, 30 percent of middle age adults with infections over 20 years are expected to develop end stage liver disease (appx.1.8 million). When end stage failure occurs, the patient's only hope is a liver transplant. According to the United Network for Organ Sharing, the organ donation and transplantation division state, only 5,000 livers are available each year, leaving the majority on that list with no options for life. There is no cure and no vaccine. The few available treatments that exist do not work for most people. Standard treatment is lengthy, expensive, and debilitating. Early detection, through testing is essential, so

patients can take dietary and other preventive measures known to extend lives and increase the quality of life.
Due to lack in Federal response, HEPATITIS C patients are stigmatized and repeatedly missed by public health efforts. The virus is one of the top five diseases missed by medical professionals diagnosing patients. Populations testing positive, such as low income residents, Military Veterans, the incarcerated, mental health facilities, immigrants, and minorities, are disproportionately hit by this virus with little effort to find out why.
The National Hepatitis C Institute and Movement for Awareness centers responsibility for lack of awareness on the prevention policy laid forth by the CDC in the "Hepatitis C Strategy Plan for Treatment and Prevention". The plan fails to address all methods, past and present, for transmitting the virus. It is little benefit to those infected prior to when universal precautions were put in place (1996) and certainly will not stop the spread of HCV.
One of the major obstacles HEPATITIS C advocates face; although not a sexually transmitted disease, the CDC has placed HEPATITIS C beneath the Sexually Transmitted Disease branch for prevention. HEPATITIS C funding and prevention measures are then placed under the HIV/AIDS division of that branch for control. Unfortunately, recent studies show methods for preventing HIV do not work for HEPATITIS C. The prevention measures in the CDC plan addresses very few people infected prior to cleaning up the blood supply and putting safe practices for medical personnel, patients, and procedures into place.

The Hepatitis C epidemic desperately needs to be addressed, but proposed legislation, S. 1143 and H.R. 3539, The Hepatitis C Epidemic Control and Prevention Act, will not serve this purpose as long as the Centers for disease Control continue . Aside from underreporting current numbers of infected patients, the legislation is far too narrow in its scope and raising serious concern over financial accountability, lacking strategic input from front-line advocates and Hepatitis C grassroots organizations.

Conservative estimates place the costs of lost productivity and medical care arising from chronic infection at over fifteen billion dollars annually. Such costs are expected to increase in the absence of expanded prevention and treatment efforts afford in this bill.

Addressing this epidemic will take courage to look closely at the issues responsible for the epidemic and garmenting the American Public, Hepatitis C will not infect 1 in 5 citizens in the near future, as predicted by the Hepatitis C Global Foundation.

Sincerely,

<List in formation>

Rep. Shelia Jackson-Lee- TX
Latino Org for Liver Awareness
Firebase Networks
Veterans Seeking A Cure

HepCnet Support
ABigSam&Lyric HepC Support
Liver Failure Support Forum
Look Upon the Horizon Hep-C Support Group
Siren to Wail
HepCingles Support Group
NewHepSingles Support Group
The Hepatitis Doctor
Seekers Support Group
Hep C Hide Out Support Group
Hep C Palace Support Group
Vietnam Veterans of America
Chronic House of Illness Support Group
Janis & Friends Hepatitis C Support
National Hepatitis C Institute
Texas Hep Pack
The Right to Know Foundation
Hepatitis C and Emotional Healing Support Group
Hep Place
Heppers Seeking Alternatives Support Group
Canadian Hepatitis C Network
HepRandi Support for Hepatitis
HepHeimers Support Group
hep-c Solano County/h.e.a.l.s. Support Group
Silver Fox's Lair;
Hepatitis C & Nutritional Health Support GroupTransplant Support Forum
Sherry's & Tweety's Hep C Hideout Support Group
Hepatitis Morning coffee-Evening Snacks Support Group
Hepatitis C & Emotional Healing Support Group
The Sleeping Dragon Support Group
Focus-Hepatitis C International;
Hepatitis C & Children Delphi Forum;
hephelper.com;
Hepatitis C Outreach Project;
Pam's Yahoo HepCingles;
Meadowlands HCV Support Group, New Jersey
Living With Liver Disease Support Group
SpringIntoAction
Dragon Fighters of Washington County
Hepatitis C Support Group of the Lehigh Valley
Mercer County Hepatitis Support Group
HCV Support Group of Elmwood Park, Illinois

Veterans and Hepatitis C
HCVets Forum
Hepatitis C Warriors
Albuquerque Hepatitis C Support Group
75th Ranger Regiment Association
Hepatitiscandme
Texas Liver Coalition
HepC in AZ Support Group
Hepatitis Clearing And Clear Support Group
Hepatitis C Support Group of the Lehigh Valley
Hepatitis C Awareness Campaign Support Group
Hep C PathLights Support Group
Hep C Hope, Inc. Support Group
Help & Hope For Hepatitis Support Group
SSG's Support Group
HepPlace Support Group
173rd Airborne bde Chapter IV/VVA #266;
DC's Heppers Domain Delphi Forum;
Hep C and Me Delphi Forum;
United Organ Transplant Association;
HEP-C/CaringCorner Delphi Forum;
Closet Heppers
Hepatitis C-Objectives
Mercer County Hepatitis C Support Group
Hepatitis C Support Forum;
The Hepatitis Encyclopedia of Links;
Hadit.com Veterans website;

Peg's Hep C Help
The Presumed Consent Foundation, Inc.

-----Original Message-----
From: HMAwareness@aol.com [mailto:HMAwareness@aol.com]
Sent: Monday, December 20, 2004 8:23 AM
To: Womack, Bill
Subject: Government Reform Hearing on Hepatitis C

Dear Bill, Please add these statements to the Reform Hearing on HCV.

Thank you,

Tricia Lupole
National Director
Hepatitis C Movement for Awareness
540 248 7324

Vietnam Veterans of America

8605 Cameron Street, Suite 400 • Silver Spring, MD 20910 • Telephone (301) 585-4000
Main Fax (301) 585-0519 • Advocacy (301) 585-3180 • Communications (301) 585-5245 • Finance (301) 585-5542
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A Not-For-Profit Veterans Service Organization Chartered by the United States Congress

Statement of

VIETNAM VETERANS of AMERICA

Submitted for the Record by

Thomas H. Corey
National President

Before the

United States House of Representatives
Committee on Government Reform

Regarding

Hepatitis C

December 14, 2004

Mr. Chairman and other distinguished members of the Committee, on behalf of Vietnam Veterans of America (VVA) and our National President, Thomas H. Corey, we are pleased to have this opportunity to present our views with respect to hepatitis C, a potentially fatal malady that afflicts too many Vietnam-era veterans. VVA is most appreciative of the opportunity to provide a statement for the record in this matter, as well as for your leadership in seeking to improve Department of Veterans Affairs (VA) programs for those affected by this disease.

Years ago, a Vietnam veteran named Paul Reutersham, who was dying of Agent Orange-related cancer, said: "I died in Vietnam and didn't even know it." How many others who served our nation honorably and faithfully are now afflicted with another potentially fatal disease, hepatitis C? How many have already died?

Some claim this is a silent epidemic that cries out for attention and action. Others have argued that hepatitis C is overrated as an epidemic. Some believe that the jet air gun injections given to troops throughout the 1960s during basic training are one of the culprits that transmitted the virus. Others believe that blood on the field of battle could have been the method of transmission of this bloodborne pathogen. Others cite dirty needles used by veterans to inject drugs. The cause ought not be our concern now; it's the result that we, as a society, have to deal with.

To better understand the insidious nature of hepatitis C, we would like to go beyond the numbers and try to give a face to this disease. Because veterans are not numbers.

We know many veterans who have this virus lurking in their bodies. For one of them – we'll call him Denny – this virus has taken over his life. The pain that he lives with every day saps his strength and sometimes his spirit. The pain is not from his entry and exit wounds – his body is riddled with 17 separate bullet holes – but from the effects on his liver of this insidious virus.

Denny volunteered to be drafted. He was trained as an artilleryman. He arrived in Vietnam in September 1968. He soon was chosen to be part of a four-man team that would chopper out to the bush near the DMZ, set up on the high ground, and observe enemy activity along the Ho Chi Minh Trail. They would call in a fire mission before being extracted by chopper – and before the NVA could pinpoint their location.

On May 12, 1969, while he was back at his base camp, NVA regulars attacked in force, overrunning the camp. Denny was at the side of a bunker. As one sapper came around the corner, he opened up. So did the sapper. Denny killed the sapper. The explosive charge the sapper was carrying detonated, lifting Denny into the air and blowing him several meters from where he'd been standing. Only the quick action of his buddy, and the skill of a chopper pilot who medevac'ed him, saved his life.

Denny spent the next 18 months in military hospitals. Where he contracted the virus that wracks him now is unclear. Was it in Vietnam? Was it during one of the dozen or so surgeries he underwent? What is clear is the effects of this virus: Denny has cirrhosis.

Denny gained almost 100 pounds. He suffers intense pain around his liver, in his back, in his feet, despite the morphine and other medications he takes. For more than nine years he's battled the eruptions of this disease. He's had to quit work, living on Social Security payments and service-connected disability compensation. After a series of tests, he is now a candidate for a liver transplant.

And so he waits, with hope and not a little bit of fear, for the operation that can save his life.

How many Dennys are there? We don't know. Many can live long and productive lives despite this virus in their system. We do know that the VA, thanks in no small measure to the efforts of Dr. Lawrence Deyton, has over the past five years made tremendous strides in fighting this scourge. The VA has become more proactive in testing veterans who enter the system, and treating those for whom treatment can be helpful. In this respect, the VA may be light years ahead of the rest of the medical establishment in this country.

In testimony here today, you will doubtless hear bundles of numbers – of veterans known to be afflicted with this disease, of veterans tested and treated by the VA. Because the vast majority of Vietnam veterans – of all veterans – do not use the VA for their medical care, and because there seems to be very little public outreach to this at-risk population, we believe the numbers lowball the prevalence of this potentially fatal disease, that many more in-country Vietnam veterans have this disease and don't even know it.

We have the moral and ethical responsibility to test and then treat those afflicted with this disease ***before*** they end up as potential candidates for a life-saving liver transplant. The efforts of this committee towards that end are to be applauded.

Questions for the Record
from the
Honorable Tom Davis, Chairman
Committee on Government Reform
House of Representatives
December 14, 2004, Hearing on the
Federal Government's Efforts to
Manage Hepatitis C

1. In your testimony you mention that over 90% of at-risk veterans were screened in 2004. This is up from the 2001 level of 50% mentioned in the December 2003 GAO report. How were you able to accomplish this large increase? Is there a consistent level of testing across all Veterans Affairs (VA) networks?

Response: The large improvements in hepatitis C screening and testing were accomplished through a coordinated effort involving the establishment of performance standards, a system of accountability for performance improvements, the creation and dissemination of tools to assist in reaching performance targets, and continued education and awareness activities. Two hepatitis C screening and testing measures were incorporated in performance contracts for VHA network and facility managers in 2002. Each year, minimal levels of "fully successful" and "exceptional" performance were established based on incremental improvement over the previous years' performance. Managers were provided credible and timely data on performance through VA's External Peer Review Process (EPRP), and were evaluated on these and other performance measures in their annual performance reviews. To assist with reaching targets, a national clinical reminder was added to the electronic medical record system, prompting providers to complete risk assessment for patients who had not been screened, tested, or diagnosed. Educational materials aimed at patients as well as clinical care providers were distributed to raise awareness or and knowledge about the importance of hepatitis C to veterans.

These efforts led to the significant increases observed in hepatitis C screening and testing. Based on the 2004 EPRP survey, over 98 percent of veterans were screened for risk factors and over 90 percent of those at risk were tested or diagnosed. For risk factor screening, individual network performance ranged from 95 to 99 percent and for testing of those at risk from 90 to 98 percent.

2. Is VA's Hepatitis C Case Registry shared with CDC as part of federal surveillance efforts?

Response: VA sends clinical data on daily basis to the Centers for Disease Control and Prevention (CDC) as a part of CDC's biosurveillance activities. The data sent are health care data on every veteran seen in VA clinics and in VA

hospitals, inclusive of but not limited to hepatitis C clinical data. CDC's infectious disease surveillance activities related to hepatitis C are executed through individual studies such as the National Health and Nutrition Examination Survey (NHANES) and by reporting of disease activity submitted to CDC by individual state and local health departments. State and local reporting requirements for hepatitis C differ by jurisdiction. VA providers are encouraged to cooperate with state or local health department requests for reporting of infectious diseases including hepatitis C. VA's Hepatitis C Case Registry (HCCR) allows local VA providers to identify patients with hepatitis C cases who may present to VA for health care. This eases VA reporting to state or local health departments. VA does not directly share data contained in the National Hepatitis C Case Registry (HCCR) with CDC nor has CDC requested it. Any direct sharing of HCCR data between VA and CDC would need to be structured in accordance with VA and HIPAA regulations protecting veterans' privacy and confidentiality of medical records.

3. How does VA coordinate its research portfolio with that of NIDDK and the other institutes that conduct liver research? How do you avoid duplication in research projects, and how is VA-sponsored research translated into clinical application for veterans?

Response: VA's Office of Research and Development (ORD) regularly communicates with the National Institutes of Health (NIH) and with the individual institutes such as the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) to coordinate research portfolios and avoid duplication in research projects. VA's Chief Research and Development Officer (CRADO) and ORD Service Directors meet periodically with the Director of NIH to discuss coordination of research efforts, most recently on October 8, 2004. In addition, ORD leadership meets quarterly with NIH liaisons, Drs. Richard Hodes, Director of National Institute of Mental Health (NIMH), and Judy Salerno, Deputy Director of National Institute on Aging (NIA). An ex-officio VA representative on the NIDDK Council facilitates exchange of program information between NIDDK and VA. In addition, VA has access to the National Institutes of Health (NIH) funded studies through the NIH on-line database, Computer Retrieval of Information on Scientific Projects (CRISP). When making project funding decisions, VA closely monitors investigators' projects funded by other federal agencies, as well as pending projects, for scientific overlap. VA also works closely with program officers at NIH on coordinated and jointly funded research projects.

VA-sponsored hepatitis C research is translated into clinical practice through the VA National Hepatitis C Program. The Program is conducted by VA facilities across the country and takes a comprehensive approach towards hepatitis C that includes universal screening for risk of infection, testing and counseling those at risk, educating patients and families, proactive research to improve clinical care, and data-based quality improvement. The VA Hepatitis C Resource Centers are

an integral part of the VA National Hepatitis C Program and facilitates translational research. The network consists of four Centers located at Minneapolis VA medical center, San Francisco VA medical center, VA Connecticut Health Care System, and the Puget Sound Health Care System. In addition, since hepatitis C is a leading cause of liver cancer, in 2004 the VA National Hepatitis C Program co-sponsored with NIDDK a scientific meeting on screening, diagnosis and treatment of liver cancer. In addition, the VA National Hepatitis C Program sponsored a follow-up meeting for VA researcher experts in liver disease, liver cancer and liver transplantation with representatives of multiple NIH institutes including NIDDK and NCI in order to catalyze increased NIH funding of VA researchers in these areas. In FY 2002, VA also sponsored a widely-attended meeting of VA hepatitis C experts with representatives of various NIH institutes (NIDDK, NIAID, NCI, NIAAA, NIDA, etc), the Centers for Disease Control and Prevention, Department of Defense and various pharmaceutical and biotechnology companies also in order to catalyze increased external funding for VA hepatitis research.

4. Mental illness usually disqualifies a patient from undergoing current available drug therapies. Yet VA has been able to administer these treatments to mentally ill patients after coordinating care with mental health professionals. What exactly must be accomplished for this to happen, and would it be feasible to replicate these efforts in the civilian medical community?

Response: There is a high prevalence of substance abuse and mental health disorders among those living with chronic hepatitis C infection. Unfortunately, the concern that these co-morbid conditions might make anti-viral therapy for hepatitis C less effective or more dangerous has meant that many hepatitis C patients have not received potentially curative treatment. To overcome these problems, coordinated efforts among mental health professionals, liver specialists, addiction services providers, and other members of the health care team is essential. Fragmented health care does not meet the needs of patients with multiple, chronic conditions. In the case of hepatitis C, several specific steps have demonstrated the potential to improve care in the VA health care system.

The use of standardized and validated symptom-rating scales for depression and other conditions allows liver specialists to do a better job of identifying which patients may benefit from antidepressant therapy or referral to a mental health specialist, and which patients can be safely treated despite a past history of depression. Education of mental health and addiction specialists into the natural history and treatment of hepatitis C enables them to provide more informed and useful consultation and co-management of patients. The use of standardized algorithms or care plans for assessment and management of mental health and substance use disorders increases the confidence and skill of hepatitis care providers and decreases variation in care. In some VA facilities, a mental health specialist (psychiatric nurse specialist, social worker, psychologist, or psychiatrist) is actually located in the hepatitis clinic to see patients and to assist

in their management without an additional appointment. In others, expedited referral processes are in place. Although VA, as an integrated health care system, has a unique opportunity to evaluate and implement improvements in care coordination, many of these innovations are readily exportable to other health care systems. VA has published results of some early experience in this area in the Federal Practitioner (July, 2004; volume 21, number 7, pages 90-101) and will shortly make available on its hepatitis C web site a manual on management of psychiatric and substance use disorders among hepatitis C patients (www.hepatitis.va.gov).

Responses to Questions for the Record
Hepatitis C Virus Congressional Hearing Held December 14, 2003
National Institutes of Health

Question 1

Mr. Davis: What research efforts does NIH share with the Department of Veterans Affairs?

Dr. Hoofnagle: A productive working relationship has been established between the NIDDK and the Veterans Health Administration (VHA), which is part of the Department of Veterans Affairs. A number of VHA-based investigators working in the area of liver disease and viral hepatitis in particular are supported by NIH research grants. In addition, the VHA co-sponsored a recent NIH conference on hepatocellular carcinoma (liver cancer), and also several scientific meetings between VHA investigators, VHA hepatitis C program staff, and representatives of various NIH institutes, including the NIDDK and the National Cancer Institute. The NIDDK and VHA are exploring a range of mechanisms to find the best approach to future collaboration between the two agencies. As we continue to examine these options, the NIH will be guided primarily by the quality of the scientific work proposed, the experience and expertise of the investigators involved, and the likelihood that the research will lead to new knowledge that will improve hepatitis care. An important resource that outlines future directions for research on liver disease, including hepatitis C, is the recently completed *Trans-NIH Action Plan for Liver Disease Research*. The objective of the *Action Plan* is to advance research on liver disease with the aim of decreasing the burden of liver disease in the United States. The Plan includes opportunities for collaborations with other Federal Agencies, including the VHA, as well as private foundations and industry. The *Action Plan* can be accessed on the internet at (http://www.niddk.nih.gov/fund/divisions/ddn/ldrb/ldrb_action_plan.htm).

Question 2

Mr. Davis: Why is it that minority populations often do not respond to current treatments?

Dr. Hoofnagle: Early studies of interferon alfa therapy of hepatitis C suggested that African American patients were less likely than Caucasians to have a sustained virological response to treatment. An initial problem was that very few African American patients were enrolled in industry-sponsored trials of interferon therapy, so it was difficult to analyze possible reasons for the racial differences in responses or to say with any assurance that these differences were real. In December 1999, the NIDDK sponsored a scientific workshop, entitled "Hepatitis C in African Americans," that highlighted these issues and brought together all information on racial differences in response rates to interferon-based therapy of hepatitis C. Subsequent to this meeting, several studies were initiated comparing response rates of African Americans and Caucasians to interferon therapy. The largest such study was reported last year in the

New England Journal of Medicine, and showed that the combination of peginterferon and ribavirin given for 48 weeks—which is the currently recommended optimal therapy—resulted in sustained clearance of the hepatitis C virus in 52 percent of Caucasian but only 19 percent of African American patients.

The reasons for these differences in response rate were not identified in these clinical studies. For this reason, the NIDDK, in collaboration with the National Center for Minority Health and Health Disparities, initiated a prospective, large-scale study of response to antiviral therapy. The study, known as "Virahep-C," has enrolled 400 patients with chronic hepatitis C—half African Americans and half Caucasians. All patients were given the most up-to-date therapy. Importantly, the Virahep-C trial included careful analysis of the clinical, biological, viral, immunological, and genetic factors of the patients, and is focusing the analysis upon the underlying mechanisms for the relative lack of efficacy of interferon alfa. The results of this study are due to be released within the next one to two years. Preliminary analyses suggest that the actions of interferon are blunted in some patients, and this relative resistance to interferon action is more common among African Americans than among Caucasians. Identifying the cause of this relative lack of response is extremely important, as it may allow for design of new therapies. Indeed, preliminary results indicate that ribavirin acts not in isolation as an antiviral agent, but rather to increase interferon antiviral activities inside of cells. Thus, design of a more effective—and better tolerated—ribavirin may materially enhance response rates to current therapies.

This research goal is highlighted in the recently released *Trans-NIH Action Plan for Liver Disease Research* (page 69, goal A1: "Define basis for interferon resistance to HCV in humans"). This research goal is the focus of several ongoing research project grants supported by NIDDK and NIAID in addition to Virahep-C.

Response rates of peginterferon and ribavirin among other minority groups have not been well defined. It appears that Asian patients are more likely to respond to treatment than Caucasians. Persons of Hispanic or Latino ethnicity have rates of response to interferon-based therapies that are similar to non-Hispanics, but particularly low rates have been reported recently among Mexican Americans. There is no information on response rates among American Indians.

Question 3

Mr. Davis: We have heard how difficult current hepatitis C treatments can be on the patient. Is it necessary for a patient to complete the entire course of treatment in order to determine whether or not it will be effective? If not, how long does it take to know whether or not it is having any effect?

Dr. Hoofnagle: The currently recommended regimen of therapy for hepatitis C is a 48-week course of the combination of peginterferon and ribavirin for patients with the genotype 1 strain of HCV (the most common in the United States) and a 24-week course of peginterferon and a slightly reduced dose of ribavirin for those with genotypes 2 or 3

strains of HCV. Combination therapy has many side effects and between 10 and 20 percent of persons cannot complete a full course of treatment. The major side effects are fatigue, muscle aches, sleep disturbance, depression, anxiety, and irritability. An important focus of clinical studies has been to identify which patients will respond to treatment and which will not at an early point during therapy, so as to be able to stop therapy in "non-responders" and spare them the side effects and expense of continued therapy. It appears that the most accurate early markers for a response are changes in levels of hepatitis C virus (HCV) RNA in blood during treatment. Various time points and cut-off values for viral levels have been used: the most reliable one is testing for HCV RNA levels before and at 12 weeks of treatment. If there has been less than a hundred-fold drop in HCV RNA by 12 weeks, the likelihood of a sustained response is 1 percent or less. This is the basis for the "early stopping rule" of therapy that is commonly used and was recommended by the 2002 NIH Consensus Development Conference on "Management of Hepatitis C."

Current research efforts are attempting to improve the predictive value of HCV RNA testing. In the NIDDK sponsored "Virahep-C" study HCV RNA levels are taken on multiple occasions during the first weeks of treatment with the plan to evaluate whether earlier testing may have better sensitivity and specificity than the current 12-week stopping rule.

Question 4

Mr. Davis: In recent years, there has been a considerable decline in the incidence of newly acquired hepatitis C infections in the United States. The Consensus Development Conference 2002 report attributes the decline "largely due to a decrease in cases among IDUs for reasons that are unclear and, to a lesser extent, to testing of blood donors for HCV." Since that report was written, have we discovered anything that helps explain this decline?

Dr. Hoofnagle: The incidence of newly acquired hepatitis C in the United States declined by more than 80 percent between 1989 and 1995, but has remained fairly constant since that time. One cause of the decline was the virtual disappearance of post-transfusion hepatitis C, the result of the introduction of routine screening of blood donors for antibody to HCV starting in 1990. However, by 1990, blood transfusions were the cause of only 5 percent of cases of hepatitis C, so that most of the 80 percent decline in new cases can not be attributed to blood donor screening. In contrast, about half of cases of hepatitis C in 1990 were identified among injection drug users and by 1995, the number of such cases had declined by 88 percent. There are likely multiple reasons for this trend, including adoption of safer injection practices as a result of educational efforts to prevent HIV and other blood-borne infections; a trend among illicit drug users toward use of non-injectable drugs; and the saturation of the current injection drug using population with HCV infection. It is this latter explanation that likely played the greatest role in the overall decline in new cases of hepatitis C. Most (80-90 percent) drug users who have been injecting for more than a few years have already been infected and have chronic hepatitis C. Although the incidence of new infections remains high among new

drug injectors, these new users account for a relatively small reservoir of susceptible users compared with those already infected.

It is important to stress than the incidence of new cases of hepatitis C is now fairly constant and new efforts are needed to more completely control or eradicate hepatitis C in the United States. Public health measures are vitally important but are only partially effective. Ultimately, a specific means of prevention (or easy detection and treatment) will be necessary. These factors form the basis for the major research focus on developing a hepatitis C vaccine. Currently, a large component of the research portfolio on hepatitis C funded by the NIH is directed towards understanding immunity to hepatitis C and developing a practical HCV vaccine. This goal was also highlighted in the *Trans-NIH Action Plan for Liver Disease Research* (page 69, goal C3: "Develop HCV Vaccine").

CDC HEPATITIS C FUNDING

CDC funds both states and individual cities/counties. Funds are listed by total amount to each state.

State	**FY 2004**
ALABAMA	$61,389
ALASKA	$73,913
ARIZONA	$210,763
Maricopa County (non-add)	*$124,154*
ARKANAS	$73,961
CALIFORNIA	$486,985
San Francisco City and County (non-add)	*$233,761*
COLORADO	$375,510
Denver (non-add)	*$219,043*
CONNECTICUT	$541,943
DELAWARE	$7,000
FLORIDA	$230,997
Pinellas County (non-add)	*$138,497*
GEORGIA	$70,607
HAWAII	$85,163
IDAHO	$26,470
ILLINOIS	$203,276
Chicago Dept of Health (non-add)	*$105,169*
INDIANA	$80,033
IOWA	$98,805
KANSAS	$68,578
LOUISIANA	$81,022
MAINE	$89,042
MARYLAND[1]	
MASSACHUSETTS	$76,579
MICHIGAN	$100,726
MINNESOTA	$166,442
MISSISSIPPI	$69,752
MISSOURI	$238,355
Jefferson County (non-add)	*$154,131*
MONTANA	$32,706
NEBRASKA	$73,883
NEVADA	$99,532
NEW HAMPSHIRE	$65,691
NEW JERSEY	$109,308
NEW MEXICO	$57,554
NORTH CAROLINA	$98,967
NORTH DAKOTA	$10,000
New York	$769,843

NYC Dept. of Health (non-add)	*$187,430*
Health Research Inc., NY State DOH (non-add)	*$133,000*
OHIO	$90,400
OKLAHOMA	$79,364
OREGON	$238,856
PENNSLYVANIA	$157,516
Philadelphia (non-add)	*$71,898*
RHODE ISLAND	$86,649
SOUTH CAROLINA	$56,631
TENNESSEE	$59,438
TEXAS	$80,276
UTAH	$67,889
VERMONT	$95,374
VIRGINA	$61,237
WEST VIRGINA	$70,700
WASHINGTON	$440,833
Seattle (non-add)	*$175,000*
Tacoma-Pierce Counties (non-add)	*$172,962*
WISCONSIN	$242,782
WYOMING	$64,549
TOTAL Hepatitis C Funding	**$6,727,289**

1-Maryland Dept. of Health Requested that their Hep C Coordinator in FY 2004 be supported through carryover funds.

Implementation Status of the *National Hepatitis C Prevention Strategy*, January 2005

Prevention Activities	Implementation Status		
	Completed	**Ongoing**	**Pending**
I. Communication about Hepatitis C			
Viral Hepatitis Education Projects (VHEP) - Cooperative Agreements	10 non-governmental or voluntary health organizations were supported to develop and disseminate health educational information	12 organizations are being supported during FY 2004-2006 to develop and disseminate health educational information	▪ Support additional organizations to address issues of minority populations and high risk youth ▪ Expand activities of current partners to better address groups at risk of viral hepatitis
National Viral Hepatitis Information Center	Development and distribution of a broad range of hepatitis C health education and communication materials for health care professionals, the general public and groups at risk of infection	Education and training materials to support hepatitis C prevention activities are available at http://www.cdc.gov/hepatitis	Develop, evaluate the effectiveness, and distribute public service advertising, media outreach and health education materials
Consultants meetings to develop recommendations to prevent viral hepatitis	▪ Hemodialysis patients ▪ Incarcerated persons ▪ Serologic screening for HCV infection		Prevention of viral hepatitis among injection drug users
Hepatitis C Prevention ATool Kit® for Health Care Providers	Distribution to >150,000 primary care physicians in 26 States		Nationwide distribution

Prevention Activities	Implementation Status		
	Completed	**Ongoing**	**Pending**
II. Integration of Hepatitis C/ Viral Hepatitis Prevention into State and Local Public Health Programs			
State Hepatitis C Prevention Plans	23 States have developed plans	5 States are in the process of developing plans	▪ Provide technical assistance to States without plans to develop such plans ▪ Conduct an assessment of the effectiveness of plans
Hepatitis C Coordinators	▪ Hepatitis C Coordinators have been funded in 48 States, 3 large metropolitan health departments, and the Indian Health Service (IHS) ▪ A National Hepatitis Coordinators Conference was held in 2002	A National Viral Hepatitis Prevention Conference is being planned for December, 2005	▪ Establish hepatitis C Coordinators in remaining State and large metropolitan health departments ▪ Sponsor future National Viral Hepatitis Prevention Conferences
Viral Hepatitis Integration Projects (VHIPs)	18 projects were established in the following prevention settings: general health department, STD clinic, HIV/AIDS counseling and test site, corrections, drug treatment	Currently, there are 4 demonstration projects for high risk youth; 3 for IHS; 1 for a prevention effectiveness evaluation	Develop additional demonstration projects in other appropriate prevention settings
State and Local Hepatitis C/Viral Hepatitis Prevention Programs	Development of guidance for identification, counseling and testing of persons at risk for HCV infection, and medical evaluation or referral of those found to be HCV infected	A number of States and local health departments have begun to implement the integration of some components of hepatitis prevention into their existing public health programs	▪ Continue to enhance the components implemented in hepatitis C prevention programs, including HCV counseling, testing, medical referral and immunization

III. Surveillance	Establishment of surveillance to monitor acute and chronic hepatitis C disease trends, including classification of chronic HCV infection as a nationally notifiable disease	¡ Provide technical assistance to States to develop best practices for hepatitis C surveillance ¡ Provide technical assistance to States to establish, maintain, and analyze information on HCV-infected persons ¡ Expand and enhance hepatitis C surveillance systems in sentinel sites ¡ Test NHANES participants to determine age-specific trends in prevalence of HCV infection	¡ Enhance States' capacity to conduct surveillance for acute and chronic hepatitis C. ¡ Develop and evaluate new methods to monitor acute and chronic hepatitis C disease trends
IV. Epidemiologic and Laboratory Investigations	¡ Studies to determine risk factors for HCV transmission ¡ Studies of the incidence and prevalence of HCV infection among persons with high risk behaviors, (IDUs, homeless, incarcerated youth and adults) ¡ Molecular epidemiologic studies to determine the source for transmission of HCV infection in various settings (hemodialysis units and other health related settings)	¡ Prevalence and incidence of infection in incarcerated persons ¡ Risk of infection among steady heterosexual partners of HCV-infected persons ¡ The dynamics of HCV acquisition among injection drug users and the effectiveness of harm reduction strategies in preventing infection ¡ Disease burden, including chronic liver disease and liver cancer mortality ¡ Risk factors for health care related transmission	¡ Evaluate the feasibility and effectiveness of various models for delivering HCV prevention services ¡ Assist in the development of diagnostic tests for HCV infection

Responses to Questions for the Record
Hepatitis C Virus Congressional Hearing Held December 14, 2004
Centers for Disease Control and Prevention

Questions from the hearing for the record:

(1) In response to a Representative Towns question, we need to provide the amount of funds that we provide to states for implementation of the Hepatitis C Virus (HCV) prevention programs. Specifically, he would like to know the amount of money per State's program.

(2) Of the approaches outlined in CDC's National Hepatitis C strategy, what elements have not been funded/implemented?

(Please see additional attachments)

Follow up questions from Representative Tom Davis:

1. **Advocates are critical of current federal efforts to prevent hepatitis C, saying they are simply integrated into pre-existing HIV/AIDS and STD programs. How do you respond?**

Federal efforts to prevent hepatitis C target and reach a variety of people receiving healthcare services in both the private and public sectors as well as persons in the general population. These efforts have included multiple types of educational tools targeting healthcare professionals and the general public regarding how hepatitis C is spread, how to prevent it, who should be tested, and the most current approaches to management and counseling (a recent example is the "Physicians Toolkit" of educational and training materials that was mailed to the offices of 150,000 primary care providers); training materials specifically for healthcare professionals; campaigns to encourage persons who received blood transfusions before donor screening began to get tested for hepatitis C, including assisting blood collection and transfusion services with targeted lookback efforts; and updating and expanding published guidelines used by healthcare professionals and professional and non-governmental voluntary organizations to identify and manage persons with hepatitis C in different types of settings.

These efforts have been part of an overall strategy for the prevention of hepatitis C that began in 1997-1998 when both consensus guidelines for the management of persons with hepatitis C and recommendations for counseling, testing, and other prevention measures were first published. The Centers for Disease Control and Prevention (CDC) has taken a number of steps to facilitate implementation of counseling, testing, and other prevention strategies for the broadest possible audience. It has provided support for hepatitis C Coordinators to 48 states and several large metropolitan areas. It has also supported the development of state hepatitis prevention plans which translate the national strategy into

actions specific to the needs of individual states. Because illicit injection drug use is the most common risk factor for HCV infection in the United States, integration of hepatitis prevention services into settings that serve a large proportion of injection drug users is a particularly efficient means both of identifying HCV-positive persons and of implementing measures to prevent further spread. Those settings include HIV/AIDS, STD, drug treatment, and corrections health programs. The Viral Hepatitis Integration Project (VHIP) demonstration sites that have been supported previously in such settings have developed "best practices" for the integration of hepatitis prevention services that can be adapted by public health programs nationwide. The ultimate goal is for each state, through its Hepatitis C Coordinator, to implement comprehensive hepatitis C prevention activities in both public and private settings.

2. Please describe current hepatitis C surveillance practices.

CDC conducts a number of different types of surveillance for hepatitis C, including national surveillance for acute hepatitis C and chronic HCV infection, sentinel surveillance for acute hepatitis C, prevalence surveys (such as the National Health and Nutrition Examination Surveys), and chronic liver disease surveillance.

Acute hepatitis C and chronic HCV infections are both designated nationally notifiable diseases. Reports of these conditions are collected by state and local health departments and sent by state health departments to CDC's National Notifiable Disease Surveillance System (NNDSS).

a. When did CDC require both acute and chronic cases of hepatitis C to be reported?

Although disease reporting is mandated by legislation or regulation at the state and local levels, state reporting to CDC is voluntary. CDC does not have the authority to require reporting of any condition to it by the states. The Council of State and Territorial Epidemiologists (CSTE), with input from CDC, makes recommendations annually for additions and deletions to the list of nationally notifiable diseases. However, it is up to each state to decide if it wishes to mandate reporting of a nationally notifiable disease. Acute hepatitis C became a notifiable condition in 1982 (as non-A, non-B hepatitis), when laboratory tests to identify other forms of acute viral hepatitis became widely available. Chronic HCV infection became a nationally notifiable disease in 2003.

b. Are there uniform reporting procedures from each state?

There are uniform case definitions for each nationally notifiable condition and standardized procedures for reporting cases to CDC. However, there can be substantial variation among states in how case definitions are applied and the extent to which cases are reported.

c. How does CDC share pertinent information with state health departments?

CDC shares pertinent hepatitis surveillance information with the states in several ways. Hepatitis surveillance information is reviewed by CDC staff each week, resulting in ongoing communication with relevant states to identify outbreaks and clarify points of concern. CDC summarizes each state's hepatitis surveillance data quarterly and provides each state with an electronic quarterly report of its own data. Finally, CDC publishes an annual hepatitis surveillance report.

3. The September 2004 GAO review of state and federal disease surveillance efforts raises some pertinent issues in this debate. For example, how successful has the government been at educating health care providers as to their reporting responsibilities?

CDC has been most successful in educating health care providers through its efforts to build surveillance capacity at the local level.

a. Is there a way to gauge the success of CDC's educational efforts?

The best source of information that CDC currently possesses would be through program monitoring and evaluation data.

b. When a physician diagnoses a case of cirrhosis or liver cancer, for example, do they know to test for hepatitis C? If so, are they reporting it?

In addition to those published by CDC, recommendations for HCV testing and diagnosis have been published by several clinical groups including the National Institutes of Health's Consensus Panel on Management of Hepatitis C, the American Association for the Study of Liver Diseases, and the American Gastroenterology Association. Published surveys of primary care physicians indicate that the vast majority routinely test patients with evidence of liver disease for hepatitis C. Regarding the second question, each state mandates which conditions are notifiable by physicians, laboratories, or both. HCV infection reporting by physicians is mandated in 38 states and by laboratories in 35 states. However, the extent of reporting of HCV infection by physicians can vary substantially even in states that mandate such reporting. Furthermore, the usefulness and validity of the reports will vary considerably depending on whether the state has a system to account for duplicate tests and the resources to obtain additional information on the report.

c. The report also points to slow implementation of the National Electronic Disease Surveillance System (NEDSS). What efforts are underway to improve implementation in the states?

CDC recognizes that NEDSS is a critical surveillance system and has accelerated the implementation. Since the release of the GAO report, CDC has added six additional states. Currently, almost half of the states are on-line and CDC is committed to continuing to press efforts at implementation.

4. Please describe the action CDC has taken to address the high rate of infection among the prison population.

CDC published recommendations for the prevention and control of infections with hepatitis viruses in correctional settings in its *Morbidity and Mortality Weekly Report* (*MMWR*) in January, 2003. At the time of the release of that document, a meeting was held to bring together state and federal prison directors, medical directors, public health officials, and hepatitis experts to discuss management of hepatitis C in prisons. The meeting concluded that the success of HCV efforts would be dependent on the overall availability of resources for substance abuse treatment, HCV testing, hepatitis C treatment, and continuity of care with the community. The proceedings from this meeting will soon be submitted for publication to a peer-reviewed journal.

In July 2003, a small, focused consultation was held to discuss implementation of CDC's recommendations in jails. This meeting was attended by representatives from a selected group of jails and public health officials from the localities in which these jails are located. Jail officials present at this meeting agreed that this aspect of HCV prevention could be begun quite effectively in a jail setting, depending on the overall availability of resources for substance abuse treatment, including community resources after discharge. In addition, jail inmates with longer stays could be tested and treatment initiated if appropriate. Proceedings from this consultation, emphasizing the need for a high level of collaboration between state and city/county health and corrections officials, were distributed to participants and to CDC's hepatitis C coordinators in each state.

For several months in 2002-2003, a CDC medical epidemiologist was assigned to the Federal Bureau of Prisons (BOP) on a temporary duty assignment. During this time, the BOP revised hepatitis C testing and treatment guidelines with her assistance. Similarly, Hepatitis C Coordinators in the states are working to include prisons and jails in coalitions to implement hepatitis C prevention activities.

CDC is continuing to update knowledge on the prevalence of HCV infection by testing serologic specimens collected as part of studies of bloodborne pathogens in correctional populations. CDC is also continuing to track implementation of hepatitis A and hepatitis B vaccination, and hepatitis C testing and treatment, through work with the National Institute of Justice.

a. What specific guidance has been issued to the Federal Bureau of Prisons and the State Departments of Prisons?

As was noted above, CDC published recommendations in the *MMWR* in January 2003. That document (*Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings*) can be found at: www.cdc.gov/mmwr/PDF/rr/rr5201.pdf.

5. While the CDC has a key role to play in stopping the spread of hepatitis C, much of your work is done in conjunction with state health departments. Are there statutory or procedural impediments to thorough and efficient implementation of plans to stop the spread of this disease?

As was noted above in response to question 1, illicit injection drug use is the most common risk factor for HCV infection in the United States. Consequently, integration of hepatitis prevention services into settings that serve a large proportion of current or recent injection drug users is a particularly efficient means both of identifying HCV-positive persons and of implementing measures to prevent further spread. Those settings include HIV/AIDS, STD, drug treatment, and corrections health programs. However, there is great difficulty in integrating hepatitis C and viral hepatitis prevention into such diverse public health programs. Programs often reside organizationally in different parts or outside of a state, territory, or large metropolitan health department and/or are supported through disease-specific categorical funding; both geographic dispersion and categorical program funding can hinder efforts to develop and implement comprehensive prevention strategies for populations at risk for multiple infections as a result of risky behaviors. Even when such barriers can be overcome, technological barriers to integration (e.g., the different timeframes and skill sets necessary to administer rapid [oral] HIV testing and HCV serological testing) remain. Finally, states which have recently experienced difficulty in maintaining their public health infrastructure have been reluctant to add new responsibilities for existing programs. HCV testing programs, which would actively seek to identify and test these individuals at risk, are therefore in place in very few states or localities.

An even larger hurdle involves finding effective approaches for identifying the larger number of persons who are at risk for HCV infection through limited or occasional drug use in the remote past. Many such persons are unlikely to be receiving services in the public sector settings that target persons with current or recent high-risk behaviors. States generally lack effective mechanisms to reach those "hidden" individuals and the private sector primary healthcare providers who do see them. Another impediment to the thorough and effective implementation of hepatitis prevention programs involves the ability of states to establish, maintain, and analyze information on infected persons in order to evaluate the effectiveness of prevention efforts, including efforts to ensure that HCV-infected persons receive counseling to prevent transmission to others and medical management to prevent progression of chronic liver disease. As was noted above in response to question 3b, many states do not have a system to account for duplicate HCV test results by physicians and laboratories.

CDC has been working to assist the states with their hepatitis prevention efforts in a number of ways. Already noted above are its support for the development of state hepatitis prevention plans; funding of Hepatitis C Coordinators to lead integration efforts;

developing "best practices" through the VHIP demonstration sites; and developing training and educational materials for patients and clinicians in both the public and private sectors. In conjunction with representatives from national voluntary health organizations, nongovernmental organizations, professional societies, health insurers, industry, and other governmental agencies, CDC also has established a National Viral Hepatitis Roundtable to coordinate efforts by CDC and its partners to address hepatitis C and other forms of viral hepatitis. CDC has also worked to reduce procedural barriers to full implementation of the *National Hepatitis C Prevention Strategy*. For example, in fiscal year 2004 CDC's program announcements that fund both STD and HIV prevention activities in the states were updated to specifically encourage integration of viral hepatitis prevention activities. CDC has adopted and promoted a 'comprehensive approach' to the prevention of bloodborne disease among IDU (see www.cdc.gov/idu). The 'comprehensive approach' encourages professionals working with injectors to promote 'one-stop-shopping' to address all of the substance abuse, HIV and hepatitis prevention, and other social needs of injectors.

a. What single step could the Congress take to improve this inter-governmental function?

Congress could assure that existing Federal programs and resources are utilized effectively in furtherance of such efforts. One example would be to specifically authorize the use of existing funding mechanisms, pending the availability of resources, to provide hepatitis C prevention services to individuals at high risk of HCV infection who are currently served by programs already receiving such funds.

6. Those who are exposed to blood in employment settings, in particular first responders, are at risk of hepatitis C infection. Has the CDC issued guidance for instances of inadvertent exposure to blood or needle sticks?

Yes, CDC's most recent guidance on how to approach these situations was published in the *MMWR* in June 2001. That document (*Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis*) can be found at: www.cdc.gov/mmwr/PDF/rr/rr5011.pdf

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